The following is for evaluating Medical Equipment and their Alarm Systems to the requirements of the IEC 60601-1 Standards. This does not replace the Standards, so a purchased copy of the IEC and National standards should also be used. This is a free document that may be downloaded at MECA's website: **http://60601-1.com**

MECA ALARM STANDARDS CROSS-REFERENCE

A comparative resource for those who work with Alarm Systems and the corresponding Standards in the field of Medical Electrical Equipment

This is a select Cross-Reference of the major Alarm System portions of the ME Collaterals and Particulars. It is intended as a companion to IEC 60601-1-8 Ed. 2.1, organizing requirements and references for Medical Device Alarm Systems and Alarm Signal Testing. The clauses have been edited to create a condensed multi-standard collection for quick assessments and comparisons between related documents. References to "alarms" have been replaced with "Alarm Systems", "Alarm Conditions", "Alarm Signals" etc...
Common terms such as "False Alarm" or parts of speech, such as "alarming", have not been modified.
In the clauses below, the typical SMALL CAPS formatting is removed from defined terms, so that we can focus on the information that is related to Alarm Systems. I have **bolded** key words, as well as imperatives such as "shall, required, necessary, must or has to" and recommendations such as "should, could, may or might". These modifications are intended to aid those who are encountering new information as well as industry veterans who must assess products relating to a variety of device categories.
The document ends with a multi-standard Alarm-focused Dictionary. Don't let your project suffer due to misunderstood terminology!

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ANSI / AAMI ES60601-1:2005 (IEC 60601-1:2005) / (R) 2012 and A1:2012, C1:2009 / (R) 2012 and A2:2010 / (R) 2012

General requirements for Basic Safety and Essential Performance

4.3 * **Essential Performance** -
During **Risk Analysis**, the Manufacturer **shall** identify the performance of the clinical function(s) of the ME Equipment or ME System, other than that related to Basic Safety, that is necessary to achieve its Intended Use or that could affect the safety of the ME Equipment or ME System.
NOTE 1: The performance of the Risk Control measure **might** well become an aspect of the Essential Performance of the ME Equipment or ME System. For example, the **generation** of the Alarm Signal to indicate the interruption of the Supply Mains **could be** "essential" if an interruption of the Supply Mains could result in an unacceptable Risk if it went unattended.
Example 1: If Essential Performance is lost because of an interruption of the Supply Mains an Alarm System intended to notify the Operator that the Supply Mains has been interrupted would **need** to have a backup power source so that the generation of the Alarm Signal would not depend on the Supply Mains

7.8 * Indicator lights and controls, 7.8.1 **Colors** of **indicator lights** - The colors of indicator lights and their meanings **shall** comply with Table 2.
NOTE: IEC 60601-1-8 contains specific **requirement** for the **color, flashing frequency** and **Duty Cycle** of alarm indicator lights. Dot-matrix and other alphanumeric displays are not considered to be indicator lights

Table 2 – **Colors** of indicator lights and their meaning for ME Equipment:

Color	Meaning
Red	Warning – immediate response by the OPERATOR is required
Yellow	Caution – prompt response by the OPERATOR is required
Green	Ready for use
Any other color	Meaning other than that of red, yellow or green

9.6.2.1 **Audible acoustic energy** In Normal Use - The Patient, Operator and other persons **shall not** be exposed to acoustic energy from ME Equipment, except sound from auditory Alarm Signals, exceeding the levels specified below.
– **80 dB(A)** for a **cumulative exposure** of 24 h over a 24 h period; an offset of 3 dB(A) is to be added to this value when halving the cumulative exposure time over a 24 h period (e.g. 83 dB(A) for 12 h over a 24 h period);
– **140 dB dB(C)** (peak) sound pressure level for **impulsive** or **impact acoustic energy** (noise).
NOTE 1: Interpolation or extrapolation is allowed for exposure times in accordance with the following formula, 80 - 10* $\log_{10}(h/24)$, in dB(A), where h is cumulative exposure time over a 24 h period
NOTE 2: Since Patients might have a higher sensitivity to acoustic energy (noise), a lower level could be more appropriate. Consideration **should** also be given to perception of auditory Alarm Signals. The World Health Organization has recommended a maximum impulse or impact acoustic energy (noise) level for children of 120 dB
NOTE 3: If the A-weighted sound pressure level exceeds 80 dB(A), noise protection measure **should** be considered.
Compliance is checked by measuring the maximum A-weighted sound pressure level at the minimum distances of Patient, Operator and other persons from the source of acoustic energy (noise) in Normal Use, and if necessary, calculating the A-weighted sound pressure level produced by the ME Equipment in accordance with ISO 3746, ISO 9614-1 or IEC 61672-1. The following conditions apply. a) The ME Equipment is operated under worst-case Normal Condition. b) Any protective means provided or called for in Accompanying Documents are to be in place during sound measurement. c) Sound level meters used in

*the measurement conform to IEC 61672-1 and IEC 61672-2. d) The test room is semi-reverberant with a hard reflecting floor. The distance between any wall or other object and the surface of the ME Equipment is not less than 3 m. e) When sound measurements in a test room are not feasible (e.g. for a large Permanently Installed Equipment), measurements **may** be done in situ*

12.3 **Alarm Systems** - If the Manufacturer has implemented an Alarm System, this Alarm System **shall** comply with **IEC 60601-1-8**.
Compliance is checked as specified in IEC 60601-1-8

12.4.4 **Incorrect output** - When applicable, the Manufacturer **shall** address in the **Risk Management** Process the Risks associated with incorrect output.
Example: The Risks associated with incorrect delivery of energy or substances to a Patient can be addressed by providing an Alarm Signal to alert the Operator to any significant departure from the set level of delivery
Compliance is checked by inspection of the Risk Management File

Subclause 7.8 – **Indicator lights** and **controls** - For colors of indicator lights see also IEC 60073 [5]. Color alone **should not** be used to convey important information. A **redundant** means of conveying information such as shape, location, sound or marking is recommended.

Subclause 11.8 – * **Interruption** of the **power supply** /Supply Mains to ME Equipment Interruption of the power supply **could** result in a Hazardous Situation due to loss of functionality. This Hazardous Situation is dealt with in 7.9.2.4. Restoration of the power source can also result in Hazardous Situations.
Example: Examples could include unintended activation of moving parts or resumption of dangerous outputs. These potentially Hazardous Situation and the duration of the power interruption that could result in the Hazardous Situations need to be considered as part of the Risk Management Process. IEC 61000-4-11 [21] defines general and reproducible conditions for the operation of electrical and electronic equipment if they undergo voltage dips, short interruptions and voltage variations. The voltage level and duration of short interruptions are defined in Tables 210 and 211 of IEC 60601-1-2:2001. IEC 60601-1-2 treats these short interruptions as a Normal Condition. For ME Equipment in which the safety of the Patient depends on the continuity of the power, particular standards **should** include requirements regarding power failure Alarm Signals or other precautions

IEC 60601-1-2 Third edition 2007-03 Collateral standard:

Electromagnetic Compatibility – Requirements and tests

Definition 3.11 – **Function**- clinically significant operation that the ME Equipment or ME System is intended to perform in the diagnosis, treatment or monitoring of a Patient or for compensation or alleviation of disease, injury or disability.

Example: The following are examples of the **Functions** of ME Equipment or an ME System. – The Functions of a heart-rate monitor include measurement and display of heart rate, and **may** additionally include audible and visual **Alarm Signals** and display of the ECG waveform

6.2.1.8 - If a **Function** associated with **Essential Performance** (e.g. High Priority and Medium Priority Alarm Conditions) cannot normally be observed or verified during the test, a method **shall** be provided (e.g. display of internal parameters) for determining compliance. The use of special software or hardware **may** be needed.

6.2.1.10 - Under the test conditions specified in 6.2, the ME Equipment or ME System **shall** be able to provide the Basic Safety and **Essential Performance**. The following Degradations, if associated with Basic Safety and Essential Performance, **shall not** be allowed: **–** False Alarms; **–** cessation or interruption of any intended operation, even if accompanied by an Alarm Signal; **–** initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an Alarm Signal; **–** failure of automatic diagnosis or treatment ME Equipment and ME Systems to diagnose or treat, even if accompanied by an Alarm Signal.

Subclause 6.2.7.1 b) – ME Equipment and ME Systems are allowed a deviation. For **Life-Supporting ME Equipment** and ME Systems for which an Alarm System is required, it is likely that the Alarm System will need to be powered by stored energy during power interruptions. A test **should** be performed to verify that **sufficient stored energy** is available to operate this Alarm System for an extended period of time, e.g. 5 min or as **may** be specified in particular standards (IEC 60601-2-X).

Table 11 – IMMUNITY TEST LEVEL for voltage interruption

Voltage test level % U_T	Voltage dip % U_T	Duration s
<5	>95	5
NOTE U_T is the a.c. MAINS VOLTAGE prior to application of the test level.		

IEC 60601-1-6 Edition 3.0 2010-01 General requirements for Basic Safety and Essential Performance – Collateral Standard: **Usability**

6.1 * **Safety** for the Patient, Operator and other persons - A **Usability** Engineering Process **shall** be conducted to provide safety for the Patient, Operator and other persons related to Usability of the Operator-Equipment Interface.
NOTE 3: The following are examples of **Hazards** for the Operator: - **loud noise** emanating from the ME Equipment resulting in hearing impairment

Operator-Equipment Interface - The Operator-Equipment Interface **includes** all means of communication between the ME Equipment to the Operator and the Operator to the ME Equipment. These means include, but are not limited to: **Alarm Signals**

A.2 Rationale for particular clauses and subclauses - Definition 3.4 –The **Operator-Equipment Interface** includes all means of communication between the ME Equipment to the Operator and the Operator to the ME Equipment. These **means** include, but are not limited to: **– Alarm Signals**

Definition 3.6 – **Primary Operating Function** - For the purposes of this collateral standard, a Primary Operating Function is a function that is directly related to the Basic Safety or Essential Performance of the ME Equipment in Normal Use or a function that is frequently used.
Example: Examples of Primary Operating Function that directly relate to Basic Safety or Essential Performance include: – **inactivating** an Alarm Signal (temporarily or indefinitely); – **setting** Alarm Limits

C.2 **Use Errors** – Operator fails to detect a dangerous increase in heart rate because the Alarm Limit is mistakenly set too high and Operator is over-reliant on Alarm System.

C.3 **Abnormal Use** - The following are abbreviated descriptions of events that occurred **despite** proper Accompanying Documents, proper design, and proper Training, and were determined to be beyond any reasonable means of Risk Control by the Manufacturer. **– Operator inactivates** the Alarm System and does not properly monitor the condition of the Patient, preventing detection of the deterioration of the Patient. **–** Ventilator Alarm System is **intentionally disconnected**, preventing detection of hazardous condition.

Table D.1 – Sample of design flaws and associated USE ERRORS

Example of design flaw	Possible resultant USE ERROR
Push-buttons on a control panel are too closely spaced	OPERATOR presses the wrong button
Two icons on a software screen look too similar	OPERATOR misinterprets the icon and selects the wrong function
An OPERATOR-EQUIPMENT INTERFACE requires a complex, lengthy, and arbitrary sequence of button pushes to initiate an infusion	OPERATOR enters incorrect sequence and fails to initiate infusion
Infusion pump displays misleading "Open Door-Reset" message when there is air in the infusion line	OPERATOR repeatedly opens the door and presses the reset key instead of clearing air from the infusion line
OPERATOR-adjusted high and low ALARM LIMITS on a heart-rate monitor are not continuously displayed	OPERATOR fails to detect a dangerous increase in heart rate because ALARM LIMIT is set too high and OPERATOR is over-reliant on ALARM SYSTEM
Typical OPERATOR-applied force exceeds breaking strength of catheter connector	OPERATOR cracks catheter connector when tightening

The following are examples of detailed Operator-Equipment Interface design requirements.– The ME Equipment **shall** be capable of producing an auditory Alarm Signal with a sound pressure level adjustable over the range of **45 dB(A) to 80 dB(A) as measured 1 m** in front of the ME Equipment.

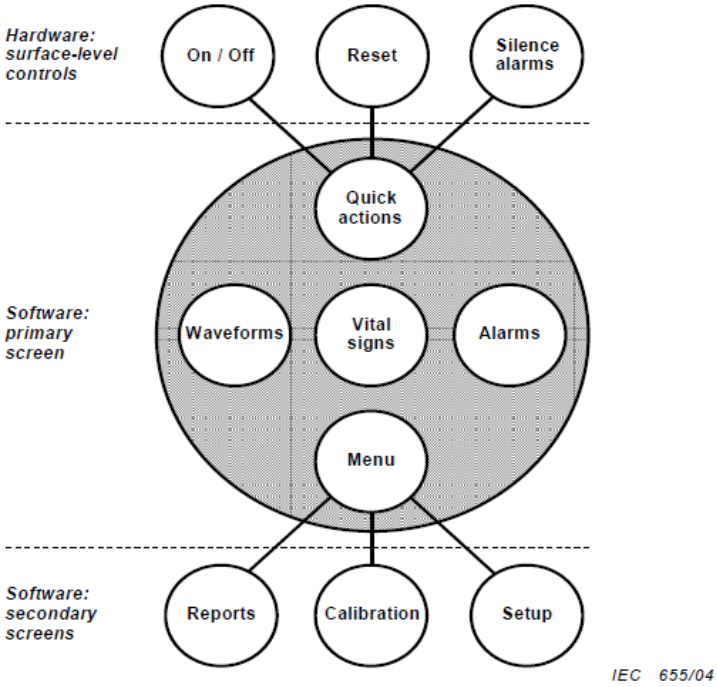


Figure D.2 – Bubble diagram of the conceptual model of a physiological monitor

MECA ALARM STANDARDS CROSS-REFERENCE

IEC 60601-1-11 Edition 1.0 2010-04 Requirements for Medical Electrical Equipment and Medical Electrical Systems used in the **Home Healthcare Environment**

General Note: Edition 2.0 has been submitted for review, but has not been published yet.

7.4.6 Additional requirements for ME Equipment **–** Messages In addition to the requirements of 7.9.2.10 of the general standard, the instructions for use **shall** include a **troubleshooting guide** for use when there are indications of a ME Equipment malfunction during start-up or operation. The troubleshooting guide **shall** disclose the **necessary** steps to be taken in the event of an Alarm Condition.
NOTE: See also IEC 60601-1-8
Compliance is checked by inspection of the instructions for use

7.4.10 Additional requirements for ME Equipment and ME Systems - For ME Equipment or an ME System utilizing a **Distributed Alarm System** - The instructions for use **shall** include the **recommended placement** of the **remote parts** of the **Distributed Alarm System** to ensure that an Operator can be notified at all times by an appropriate element of the Distributed Alarm System within its specified range.

8.4 Additional requirements for **interruption** of the **power supply**/Supply Mains to ME Equipment and ME System - If an Internal Electrical Power Source is not used, the Life-Supporting ME Equipment or ME System **shall** be equipped with an Alarm System that includes at least a **Medium Priority** Alarm Condition that indicates a power supply failure. If an Internal Electrical Power Source is used, the Life-Supporting ME Equipment or ME System **shall** be equipped with an automatic switchover to the Internal Electrical Power Source and an Alarm System that includes at least a **Low Priority** Alarm Condition that indicates the switchover to the Internal Electrical Power Source. If an Internal Electrical Power Source is used, the Life Supporting ME Equipment or ME System **shall** be equipped with an Alarm System that includes at least a Medium Priority Technical Alarm Condition that indicates that the Internal Electrical Power Source is **nearing** insufficient remaining power for ME Equipment or ME System operation. This **Technical** Alarm Condition **shall** provide for a sufficient time or for a sufficient number of procedures for a Lay Operator to act. A Technical Alarm Condition of at least Low Priority **shall** remain active until the Internal Electrical Power Source is returned to a level that is above the Alarm Limit or until it is depleted. It **shall** not be possible to inactivate the visual Alarm Signal of this Technical Alarm Condition.

13 Additional requirements for Alarm Systems of ME Equipment and ME Systems **- IEC 60601-1-8:2006** applies **except** as follows:

13.1 * Additional requirement for **generation** of Alarm Signals - Notwithstanding the requirements of 6.3.1 of IEC 60601-1-8:2006, for the Alarm System of ME Equipment and ME Systems intended for the Home Healthcare Environment, unless they are connected to a Distributed Alarm System that includes the generation of auditory Alarm Signals as specified in IEC 60601-1-8:2006, each **High** Priority and **Medium** Priority Alarm Condition **shall** cause the generation of auditory Alarm Signals as specified in **IEC 60601-1-8:2006.**

13.2 * Additional requirement for Alarm Signal **volume** - Notwithstanding the requirements of 6.3.3.2 of IEC 60601-1-8:2006, for the Alarm System of ME Equipment and ME Systems intended for the Home Healthcare Environment **reducing** the auditory Alarm Signal volume below audible levels **shall**: • activate the indication of **Alarm Off or Audio Off** as specified in IEC 60601-1-8:2006. • for **Life-Supporting** ME Equipment or ME System **not be possible unless** the Alarm System is connected to a Distributed Alarm

System that includes the generation of auditory Alarm Signals as specified in IEC 60601-1-8:2006.
NOTE: Guidance on suitable auditory Alarm Signal volumes is found in the rationale for 6.3.3.2 of IEC 60601-1-8:2006
Compliance is checked by functional testing. Many non-Life-Supporting ME Equipment or ME Systems do not need a Technical Alarm Condition that indicates a loss of battery power, since the lack of any displayed output can be an adequate indication of no operation. However, inaccurate output data frequently could be considered as a loss of Essential Performance and would generally require a Technical Alarm Condition. See 8.4 for additional requirements when the safety of the Patient is dependent on continual operation

Subclause 13.1 – Additional requirements for **generation** of **Alarm Signals** - In the Home Healthcare Environment, **auditory Alarm Signals are at least as important as visual Alarm Signals**. Alarm Conditions that require either immediate or prompt Operator action to protect the safety of the Patient are **required** to have an auditory Alarm Signal. That Alarm Signal is permitted to be present either at the ME Equipment or at a Distributed Alarm System. By permitting a Distributed Alarm System to provide the auditory Alarm Signals, this standard permits designs that allow the Patient area to be quiet, e.g. the baby's room, while the Alarm Signals are present where the Operator is located, e.g. the parent's room.

Subclause 13.2 – Additional requirements for Alarm Signals **volume** - Reducing the auditory Alarm Signal volume **below audible levels** effectively initiates the **Alarm Off** or **Audio Off** Alarm Signal Inactive State. This standard requires such an action to indicate that Alarm Signals are inactivated. Such an action is inappropriate for a Life-Supporting Equipment or ME System unless it is connected to a Distributed Alarm System that is capable generating auditory Alarm Signals.

IEC 60601-1-12 Ed.1.0 2014 Requirements for Medical Electrical Equipment and Medical Electrical systems intended for use in the **Emergency Medical Services Environment**

6.3.5 Additional requirements for ME Equipment messages - In addition to the requirements of 7.9.2.10 of the general standard, the instructions for use **shall** include a **troubleshooting guide** for use when there are indications of a ME Equipment malfunction during start-up or operation. The troubleshooting guide **shall** disclose the **necessary** steps to be taken in the event of each Technical Alarm Condition.
NOTE: See also IEC 60601-1-8.
Compliance is checked by inspection of the instructions for use

8.2 Additional requirements for **interruption** of the **power supply** to ME Equipment and ME System
NOTE 1: For most ME Equipment or ME Systems, **Essential Performance** is providing an intended clinical function within specified limits or alerting the Operator of the loss or degradation of that function with an **Alarm Signal**.
If an Internal Electrical Power Source is **not** provided, ME Equipment or ME Systems with Essential Performance intended to actively keep alive or resuscitate a Patient **shall** be equipped with an Alarm System that includes at least a **Medium Priority** Alarm Condition that indicates a power supply failure.
Example 2: The Supply Mains voltage falls below the minimum value required for normal operation

If an Internal Electrical Power Source is used, the ME Equipment or ME System with Essential Performance intended to actively keep alive or resuscitate a Patient **shall** be equipped with an Alarm System that includes at least a **Medium** Priority **Technical** Alarm Condition that indicates that the Internal Electrical Power Source is **nearing** insufficient remaining power for ME Equipment operation. This Technical Alarm Condition **shall** provide for a sufficient time or for a sufficient number of Procedures for an Operator to act. A Technical Alarm Condition of at least Low Priority **shall** remain active until the Internal Electrical Power Source is returned to a level that is above the Alarm Limit or until it is depleted. It **shall not** be possible to **inactivate** the visual Alarm Signal of this Technical Alarm Condition.
Compliance is checked by inspection, functional testing and inspection of the Risk Management File

Subclause 6.3 – **Instructions for use** - Space is limited in ambulances and frequently the full instructions for use are not stored in the ambulance, but in the facility where the ambulance is stationed. The Manufacturer of ME Equipment intended for the EMS Environment **should** consider creating shortened instructions for use that contains the most essential operating instructions. These **shortened instructions** for use are more likely to follow the equipment into the ambulance. The information in these shortened instructions for use **should** include items such as the start-up Procedure, the most **common operating instruction** and **controls** for any Alarm Systems. Additionally, troubleshooting instructions and, if applicable, altitude compensation tables **should** be included.

IEC 60601-2-2 Edition 5.0 2009-02 Particular Requirements for the Basic Safety and Essential Performance of **High Frequency Surgical Equipment and High Frequency Surgical Accessories**

201.3.211 **Contact Quality Monitor** CQM - Circuit in HF Surgical Equipment or Associated Equipment intended for connection to a Monitoring NE providing an **Alarm Signal** in the event that Neutral Electrode (NE) **contact** with the Patient becomes **insufficient.**
NOTE: A Contact Quality Monitor is functional only when used with a Monitoring NE

201.3.212 Continuity Monitor - Circuit in HF Surgical Equipment or Associated Equipment intended for connection to an NE, except Monitoring NE, providing an **Alarm Signal** in the event of **electrical discontinuity** in the NE cable or its connections

201.7.8.1 * **Colours** of **indicator lights** - Replace Table 2 in the general standard with the following:
Table 201.101 – Colours of indicator lights and their meaning for HF Surgical Equipment

Colour	Meaning
Red	Warning – immediate response by the OPERATOR is required, for example, a fault in the PATIENT circuit
Yellow	CUTTING mode
Blue	COAGULATION mode
Green	Ready for use
Any other colour	Meaning other than that of red, yellow, blue or green

201.7.8.2 * **Colours** of **controls** - Addition: Where operating controls, output terminals, indicator lights, pedals (see 201.12.2) and pushbuttons of Fingerswitches (see 201.12.2) are associated with a particular HF Surgical **Mode**, they **shall** be identified by a consistent, unique colour not in conflict with Table 201.101.
Compliance is checked by inspection

201.7.9.2.2.101 * Additional information in **instructions for use** - e) * A **statement of compatibility** with specific Monitoring NE, a warning that, **unless** a compatible Monitoring NE is used with a Contact Quality Monitor, loss of safe contact between the NE and the Patient will **not** result in an auditory Alarm Signal.
NOTE 1: This requirement **does not** apply for HF Surgical Equipment **only** incorporating **Bipolar** output
NOTE 2: This requirement **does not** apply for HF Surgical Equipment intended for use **without a Neutral Electrode**. (See 201.15.101)

201.8.4.101 * Neutral Electrode monitoring circuit - HF Surgical Equipment having a Rated Output Power of more than 50 W **shall** be provided with a Continuity Monitor and/or a Contact Quality Monitor arranged so as to de-energize the output and to give an **audible** Alarm Signal when a failure of the Neutral Electrode circuit or its connections occurs. The audible Alarm Signal **shall** meet the sound level requirements of 201.12.4.2.101 and **shall not** be externally adjustable.
NOTE: This audible alarm and visible indicator light is **not intended to meet the definition of an Alarm Signal in IEC 60601-1-8**. See also Clause 208 of this standard

The monitoring circuit **shall** be supplied from a power source isolated from the Mains Part and from earth and having a voltage not exceeding 12 V. The limitation of monitoring current for a Contact Quality Monitor is defined in 201.8.7.3. An additional visible warning consisting of a **red** indicator light **shall** be provided (see 201.7.8.1).

*Compliance of a Continuity Monitor is checked by operating the HF Surgical Equipment at maximum output control setting in each operating mode into the circuit shown in Figure 201.103. The switch is closed and opened five times and the HF output **shall** be disabled and the Alarm Signal **shall** sound at each opening of the switch*

*Compliance of a Contact Quality Monitor is checked by switching on the mains of the HF Surgical Equipment and setting its controls for Monopolar operation, except that it **shall not** be activated. Then a compatible Monitoring NE, selected according to the advice per 201.7.9.2.2.101 e), is connected to the NE connections of the Contact Quality Monitor. The NE is then placed, according to marked instructions for use, with full contact on a human subject or a suitable surrogate surface, and the Contact Quality Monitor is set up according to instructions for use. The HF Surgical Equipment is then activated in a Monopolar HF Surgical Mode. No Alarm Signal **shall** sound and HF output **shall** be present. With the HF Surgical Equipment now activated, the contact area between the NE and the human subject or a suitable surrogate surface is gradually reduced until an NE Alarm Signal occurs. The remaining contact area (alarm area), Aa **shall** be recorded for subsequent thermal rise testing per subclause 201.15.101.5, and no HF output **shall** be produced when activation is attempted. This test **shall** be repeated along both axes using at least three samples of each compatible Monitoring NE*

201.12.4.2.101 **Output indicator** - HF Surgical Equipment **shall** be provided with a device which gives an audible signal when any output circuit is energized by the operation of a Switch Sensor or as a result of a Single Fault Condition. The sound output **shall** have its major energy content in the band of frequencies between **100 Hz and 3 kHz**. The sound source **shall** be capable of producing a sound level of at least **65 dB(A)** at a distance of **1 m** from the HF Surgical Equipment according to the one direction specified by the manufacturer. An accessible sound level control **may** be provided, but **shall not** reduce the sound level **below 40 dB(A)**. For simultaneous activation see also 201.12.2 d). In order that the Operator **may** distinguish between the audible Alarm Signal called for in 201.8.4.101 and the signal specified above, either the former **shall** be pulsed or two different frequencies **shall** be employed.

NOTE: This audible signal is **not intended to meet the definition of Alarm Signal in IEC 60601-1-8**. See also Clause 208 of this standard

201.12.4.4.101 * **Maximum allowed output power** in **Single Fault Conditions** - Monopolar HF Surgical Equipment having a Rated Output Power greater than 50 W and all BIPOLAR outputs of HF Equipment **shall** be provided with an Alarm and/or interlock System to indicate and/or prevent a significant **increase** in the output power relative to the output setting.

208 General requirements, tests and guidance for Alarm Systems in medical electrical equipment and medical electrical systems - IEC 60601-1-8:2006 applies except as follows: Amendment: The audible Alarm Signal and the red indicator warning light described in 201.8.4.101 **shall not** be considered an Alarm Signal as defined in this collateral standard. The audible signal described in 201.12.4.2.101 **shall not** be considered an Alarm Signal as defined in this collateral standard.

Subclause 201.7.8.1 – **Colours of indicator lights** - The standardization of the colors of indicator lights is regarded as a safety feature. For many years the **yellow** indicator light has been used to signify that the **Cutting mode** is selected or in use on HF Surgical Equipment. During surgery, a "blend" mode is used mainly for Cutting with varying amounts of Coagulation added. As the main function of "blend" is to cut, it is considered that a yellow light is most appropriate when "blend" is in use.

Subclause 201.7.8.2 – Colours of controls - The same colour coding as specified for indicator lights **should** be used in other places to avoid confusion.

IEC 60601-2-4 Edition 3.0 2010-12 Particular requirements for the Basic Safety and Essential Performance of **Cardiac Defibrillators**

201.12.3.101 * Audible **warnings prior** to **energy delivery** - The Defibrillator **shall** be equipped with an Alarm System that includes a **High Priority** Alarm Condition that indicates when the Defibrillator is preparing to or is about to deliver energy to the Patient. This Alarm Condition **shall** be provided with either **verbal** or **auditory** Alarm Signals. The preparing-to or about-to-deliver-energy-to-the-Patient Alarm Signal **shall not** be capable of being **Audio Paused** or **Audio Off**. The Alarm Condition **shall** be: a) for AEDs with Operator activated discharge control, when the Rhythm Recognition Detector has reached a determination that a shockable rhythm is detected and the discharge control is active; b) for AEDs with automatic discharge control, at least 5 s prior to energy delivery; c) for manual Defibrillators, when the device is ready to be discharged by the Operator.

IEC 60601-2-10 Edition 2.0 2012-06 Particular requirements for the Basic Safety and Essential Performance of Nerve and Muscle stimulators

201.12.4.103 *** Output indicator** - In Normal Condition and Single Fault Condition, ME Equipment **shall** indicate when it can deliver an output of more than 10 mA or 10 V, or can deliver PULSES having an energy exceeding 10 mJ per PULSE, into a load resistance of 1 000 Ω. If the indication is by means of a signal lamp, its colour **shall** be **yellow**. *Compliance is checked by inspection and functional test.*

Subclause 201.12.4.103 – **Output indicator** - An output indication is **required** for this single fault condition because a fault in the Stimulator could unintentionally make energization of the electrodes possible. The requirement may be met by a power on indicator with zero actual output or by an indicator activated by the Stimulator output.

ISO 80601-2-12 First edition 2011-04-15 Particular requirements for Basic Safety and Essential Performance of **Critical Care Ventilators**

201.7.9.2.8.101 * Additional requirements for **start-up** procedure -
NOTE: A start-up Procedure for this standard is a pre-use **functional test** that is used to determine that the Ventilator is ready for use
The instructions for use **shall** disclose a method by which all of the Alarm Signals can be **functionally tested** to determine if they are operating correctly. Portions of this test method **may** be automatically performed by the Ventilator or **may** require Operator action.
Example – A combination of the power-on self-test routines and Operator action.
Check compliance by inspection

201.7.9.3.101 Additional requirements for the **technical description** - The **technical** description **shall** disclose a description of a method for checking the function of the Alarm System for **each** of the Alarm Conditions specified in this standard, if not performed automatically during start-up. The technical description **shall** disclose which checks are performed automatically.
Check compliance by inspection of the technical description

201.11.8.101.1 **Technical** Alarm Condition for **power supply failure** - The Ventilator **shall** be equipped with an Alarm System that includes a **High** Priority **Technical** Alarm Condition to indicate when the power supply falls outside the values **necessary** to maintain normal operation. If the normal operation of the Ventilator is maintained by the switchover to an Internal Electrical Power Source, the supply failure High Priority Technical Alarm Condition **shall not** be activated. Any such switchover to an Internal Electrical Power Source **shall** be indicated by an **Information Signa**l or a **Low** Priority Technical Alarm Condition.
Check compliance with the following test: a) Cause the power supply/Supply Mains to drop below the Rated value until either the supply failure Alarm Condition occurs or normal operation is maintained by a switchover to an Internal Electrical Power Source. b) Verify that a High Priority Technical Alarm Condition occurs at or prior to loss of normal operation, unless normal operation is maintained by a switchover to an Internal Electrical Power Source. c) If normal operation is maintained by a switchover to an Internal Electrical Power Source, verify that the switchover is indicated by an Information Signal or a Low Priority Technical Alarm Condition. d) Return the power supply/Supply Mains to a Rated value. e) Cause the power supply/Supply Mains to rise above the Rated value until either the supply failure Alarm Condition occurs or normal operation is maintained by a switchover to an Internal Electrical Power Source. f) Verify that a High Priority Technical Alarm Condition occurs at or prior to loss of normal operation, unless normal operation is maintained by a switchover to an Internal Electrical Power Source. g) If normal operation is maintained by a switchover to an Internal Electrical Power Source, verify that the switchover is indicated by an Information Signal or a Low Priority Technical Alarm Condition

201.11.8.101.2 **Internal Electrical Power Source** or **external reserve** electrical power source - If the Ventilator has an Internal Electrical Power Source, the Ventilator **shall** be equipped with a means of determining the remaining capacity or operation time provided by this power source. This indication **may** be qualitative. A Ventilator with an Internal Electrical Power Source **shall** be equipped with an Alarm System that includes a **Medium** Priority Technical Alarm Condition to indicate when the Internal Electrical Power Source nears depletion, prior to the loss of all power. As the Internal Electrical Power Source depletes, at least **5 min** prior to depletion, the depleted Internal Electrical Power Source **Technical** Alarm Condition **shall** escalate to **High** Priority. The instructions for use for a Ventilator with an Internal Electrical Power Source or external reserve electrical power source **shall** disclose a) the operational time of the power sources when fully charged. b) the means by which the reserve power source can be tested. c) the behaviour of the Ventilator after a switchover to the Internal Electrical Power Source or external reserve electrical power source. d) the behaviour of the Ventilator while the Internal Electrical Power Source or

external reserve electrical power source are recharging.
Check compliance by functional testing and inspection of the instructions for use

201.12.4.101 **Oxygen monitor** - The O2 Monitoring Equipment **shall**, in addition, be equipped with an Alarm System that includes a **high oxygen level Alarm Condition**.
NOTE: **A low oxygen level Alarm Condition is required by ISO 80601-2-55**
Check compliance by inspection of the instructions for use or application of the tests of ISO 80601-2-55

201.12.4.103.1 **Ventilators intended** to **provide** a **Delivered Volume > 50** ml - The expired volume Monitoring Equipment **shall** be equipped with an Alarm System that includes at least **Medium** Priority Alarm Conditions to indicate when the low-expired volume Alarm Limit and the high-expired volume Alarm Limit are reached. The expired volume Monitoring Equipment **may** be equipped with an Alarm System that starts with **Low** Priority Alarm Conditions to indicate when the expired volume reaches either Alarm Limit and, if this state continues, escalates to **Medium** Priority Alarm Conditions. The expired volume Alarm Limits **may** be pre-adjustable, Responsible Organization -adjustable, Operator-adjustable, Ventilator -adjustable or a combination of Operator-adjustable and Ventilator -adjustable. If the Alarm Limits are adjustable by the Ventilator, a summary description of the algorithm that determines the Alarm Limit values **shall** be disclosed in the **instructions for use**.
NOTE: Depending on the type of ventilation mode being utilized, there can be more than one active Alarm Limit.
Check compliance by functional testing using the test conditions described in Table 201.103 and Table 201.104 and inspection of the instructions for use. Select and set up the worst case VBS configuration indicated in the instructions for use

201.12.4.103.2 **Ventilators intended** to **provide** a **Delivered Volume u 50 ml** - If a Ventilator is intended to provide a Delivered Volume u 50 ml, it **may** be equipped with expired volume Monitoring Equipment. The accuracy of expired volume Monitoring Equipment at an expired volume u 50 ml **shall** be disclosed in the instructions for use. The expired volume Monitoring Equipment **may** be equipped with an Alarm System that includes at least a **Low** Priority Alarm Condition to indicate when the volume reaches the low-expired volume Alarm Limit. If provided, the expired volume Alarm Limit **may** be pre-adjusted, Responsible Organization -adjustable, Operator -adjustable, Ventilator -adjustable or a combination of Operator -adjustable and Ventilator -adjustable. If the Alarm Limit is adjustable by the Ventilator, a summary description of the algorithm that determines the Alarm Limit values **shall** be disclosed in the **instructions for use**.
NOTE: Depending on the type of ventilation mode being utilized, there can be more than one active Alarm Limit.
Check compliance by functional testing using the test conditions described in Table 201.103 and Table 201.104 and inspection of the instructions for use. Select and set up the worst case VBS configuration indicated in the instructions for use

201.12.4.105 **High-pressure Alarm Condition** and **Protection Device** - The Ventilator **shall** be equipped with Monitoring Equipment with an Alarm System that includes a **High** Priority Alarm Condition to indicate when the high-pressure limit for **Airway Pressure** is reached. The Alarm Limit **may** be independently adjustable, connected to an adjustable pressure limitation or **may** be related to the set pressure of the Ventilator. If independently adjustable it **shall not** be possible to set the Alarm Limit to a value less than that of the adjustable pressure limitation. Patient-generated transient pressure increases **should not** cause the high-pressure limit Alarm Condition.
Example: Transient pressure increase caused by the Patient coughing. Each time the high-pressure Alarm Limit for Airway Pressure is reached, the Ventilator **shall** act to reduce the pressure at the Patient-Connection Port to the level of the set PEEP. The interval from the moment that the Airway Pressure equals the high-pressure Alarm Limit to the moment that the pressure starts to decline **shall** not exceed 200 ms. During Single Fault Condition, the Airway Pressure **may** go below the set PEEP level.
Check compliance by functional testing

201.12.4.106 **PEEP** Alarm Conditions - The Ventilator **shall** be equipped with Monitoring Equipment with an Alarm System that includes an Alarm Condition to indicate when the end-expiratory pressure is above the high PEEP Alarm Limit. The Ventilator **may** be equipped with Monitoring Equipment with an Alarm System that includes an Alarm Condition to indicate when the end-expiratory pressure is below the low PEEP Alarm Limit. Both the high- and low-PEEP Alarm Conditions **shall** be of at least **Medium** Priority. The Alarm Condition Delay **shall not** exceed the duration of three breaths.
Check compliance by functional testing with every VBS indicated in the instructions for use
NOTE: To perform this test, modification of the Ventilator can be required to cause failure of the PEEP control

201.12.4.107 * **Obstruction** Alarm Condition - The Ventilator **shall** be equipped with MON Monitoring Equipment with an Alarm System that includes a **Technical** Alarm Condition to indicate when Airway Pressure reaches the Alarm Limit for obstruction.
Examples: Alarm Condition to warn of: - an obstructed inspiratory or expiratory breathing tube - a blocked exhalation valve - a blocked expiratory Breathing System Filter
The obstruction **Technical** Alarm Condition **shall** be High Priority. The maximum Alarm Condition Delay **shall** be no more than two breath cycles or **5 s**, whichever is greater. Whenever the obstruction Alarm Condition occurs, the Ventilator **shall**, within no more than one breath cycle, reduce the Airway Pressure to either atmospheric pressure or the set PEEP level. The Ventilator **should** be equipped with a Protection Device to allow spontaneous breathing when obstruction occurs. If equipped with the Protection Device, the pressure drop measured at the Patient-Connection Port, with all recommended Accessories in place, **shall not** exceed 6,0 hPa (6,0 cmH2O) at a flow rate of: 30 l/min for a Ventilator intended to provide Delivered Volume, V_{del} W 300 ml; 15 l/min for a Ventilator intended to provide Delivered Volume, 300 ml W V_{del} W 50 ml; 2,5 l/min for a Ventilator intended to provide Delivered Volume, V_{del} u 50 ml. The means by which the obstruction Alarm Condition is determined and a means to test it **shall** be described in the **Accompanying Document**.
Check compliance by functional testing with each VBS indicated in the instructions for use, according to the test method described in the Accompanying Document

201.12.4.108 * **Partial-occlusion** Alarm Condition - The Ventilator **should** be equipped with Monitoring Equipment with an Alarm System that includes a **Technical** Alarm Condition to indicate when the expiratory limb is partially occluded. A summary description of the means by which the expiratory-limb-partial-occlusion Alarm Condition is determined **shall** be described in the Accompanying Document.
Check compliance by functional testing with each VBS indicated in the instructions for use, according to the test method described in the Accompanying Document

201.13.102 * **Failure** of **one gas supply** to a **Ventilator** - Following the failure of one gas supply, a Ventilator **shall** automatically use the remaining gas supply, and otherwise maintain Normal Use. This switchover **shall** be accompanied by a gas-supply-failure **Technical** Alarm Condition. This gas-supply-failure Technical Alarm Condition **shall** be at least **Low** Priority. When the loss of the failing gas supply changes the delivered oxygen concentration by more than 3 % volume fraction, the Technical Alarm Condition **should** be at least **Medium** Priority.
Check compliance by functional testing

201.13.103 * **Independence** of **ventilation control function** and related **Risk Control** measures - A Single Fault Condition **shall not** cause the ventilation-control function and the corresponding Protection Device to fail simultaneously. A Single Fault Condition **shall not** cause: the ventilation-control function and the corresponding Monitoring Equipment; or the ventilation-control function and the corresponding **Alarm System**; to fail in such a way that the loss of the ventilation-control function is not detected.
Check compliance by inspection and functional testing

201.15.102 **Delivered oxygen concentration** - A Ventilator **shall** be capable of supplying gas to the Patient containing an O2 concentration over the range from ambient to at least 90 %. When the loss of the failing gas supply changes the delivered oxygen concentration by more than 3 % volume fraction, the **Technical** Alarm Condition **should** be at least **Medium** Priority.
Check compliance by functional testing

201.101.1 * Protection against **reverse gas leakage** - Means **shall** be provided to limit reverse gas leakage flow from gas input ports into the supply system of the same gas to less than 100 ml/min in Normal Condition. Means **shall** be provided to limit cross leakage from gas supplied through one High-Pressure Input Port into the supply system of another different gas to less than 100 ml/h in Normal Condition. If under Single Fault Condition the cross leakage from gas supplied through one High-Pressure Input Port into the supply system of another different gas can exceed 100 ml/h the Ventilator **shall** be equipped with an Alarm System that includes at least a **Medium** Priority **Technical** Alarm Condition to indicate this cross leakage flow. This cross flow **shall** not exceed 100 ml/min.
Check compliance by functional testing

201.106.3 * **Connection** to a **Distributed Alarm System** - A Ventilator **should** be equipped with a Signal Input/Output Part that permits connection to a Distributed Alarm System.

201.108.1 **Expiratory pause** - A Ventilator **may** be equipped with an Operator-controlled **means** to pause the Ventilator in expiration. If a Ventilator is equipped with a means to pause the Ventilator in expiration, c) during the expiratory pause, any apnoea-related ventilatory Alarm Condition that would be caused by this expiratory pause **shall** be **Audio Paused** or **Alarm Paused** for the duration of the expiratory pause. d) in addition to the requirements for **Alarm Signal Inactivation** of 6.8.5 of IEC 60601-1-8:2006, the Ventilator **shall** indicate the presence of the expiratory pause with an **Information Signal** or **Low** Priority Alarm Condition.

201.108.2 **Inspiratory pause** - A Ventilator **may** be equipped with an Operator-controlled means to pause automatic ventilation at end inspiration. b) The high-pressure **Alarm Condition** and Protection Device of 201.12.4.105 **shall** remain active during an inspiratory pause. d) During the inspiratory pause, any apnoea or sustained Airway Pressure Alarm Condition that would be caused by this inspiratory pause **should** be **Audio Paused** or **Alarm Paused** for the duration of the inspiratory pause. e) In addition to the requirements for **Alarm Signal Inactivation** of 6.8.5 of IEC 60601-1-8:2006, the Ventilator **shall** indicate the presence of the inspiratory pause with an **Information Signal** or **Low** Priority Alarm Condition.

206 Medical electrical equipment – Part 1-6: General requirements for Basic Safety and **Essential Performance –** Collateral Standard: Usability IEC 60601-1-6:2010 applies except as follows: For a Ventilator, the following **shall** be considered **Primary Operating Functions**: a) setting the Operator -adjustable controls; **Setting Alarm Limits**; **Inactivating Alarm Signals**; g) performing a basic **pre-use functional check** of the Ventilator including the **Alarm System**.

208.6.3.3.2.101 * Additional requirements for characteristics of **Alarm Condition logging** - The Alarm System of a Ventilator **shall** be equipped with **Alarm Condition logging** according to IEC 60601-1-8:2006, 6.12, for **all High** Priority and **Medium** Priority Alarm Conditions.

208.6.8.3.101 Additional requirements for **global indefinite Alarm Signal Inactivation States** - A Ventilator **shall not** be equipped with a means to initiate a global Alarm Off **while connected to a Patient**.
Check compliance by functional testing

208.6.8.4.101 * Additional requirements for **Termination** of **Alarm Signal Inactivation** - The **duration** of **Audio Paused** for the Alarm Conditions required by this standard **shall not** exceed **120 s** without Operator intervention.
NOTE: This **permits an Operator to deliberately extend the duration of Audio Paused by direct action.**
Check compliance by functional testing

Subclause 201.4.3.101 – Additional requirements for **Essential Performance** - The modern critical care Ventilator with an active exhalation valve has differing modes of ventilation that can consist of multiple breath types. This is **necessary** as Patient response to ventilation is unpredictable. Patient-initiated breaths or breaths where the inspiration is terminated by the Patient can have characteristics that are different than those that have been set by the Operator. Essential Performance as "**ventilation within the Alarm Limits set by the Operator**" is inclusive of those breaths that the Patient modifies outside of the ventilatory parameters set by the Operator, but still within the Alarm Limits which are considered safe by the Operator. It is expected that the Operator will set appropriate Alarm Limits which thereby define the Essential Performance for a particular Patient. All gas-powered ME Equipment **should** be designed so as not to present an unacceptable Risk if its supply pressure rises up to this value but in the case of critical care Ventilators it is considered that, because all the Ventilators in a critical care unit **could be** affected simultaneously, it is **not acceptable** that such Ventilators **should** just generate an **Alarm Signal** and shut down under these overpressure conditions. Direct Patient monitoring, and usage of the appropriate settings for, and prompt attention to, Ventilator **Alarm Conditions are essential** to provide maximum Patient safety.

Subclause 201.7.9.2.8.101 – Additional requirements for **start-up procedure** - In some designs, adequate checking of the Alarm System **can** be performed with a combination of Operator action and the power-on self-test routines that Verify the integrity of the software and the integrity of the computer controlling the Ventilator, as well the **measuring sensors** and the Alarm **Signal generation**.

Subclause 201.12.1 – Accuracy of **controls** and **instruments** - The committee considered that the **accuracy** of set and displayed values is a key component of the **Essential Performance** of a Ventilator (i.e., the delivery of ventilation at the Patient-Connection Port within the **Alarm Limits** set by the Operator or **generation** of an **Alarm Condition**).

Subclause 201.12.4.103 – Measurement of **expired volume** and **low-volume Alarm Conditions** - **It is desirable to have a fast responding measurement of volume and narrow Alarm Limits**. However, as there is often considerable variation in a Patient's ventilatory pressures and volumes, **narrow Alarm Limits inevitably lead to clinically insignificant Alarm Conditions**. As a result, Operator choose to set wide Alarm Limits to reduce the number of insignificant Alarm Conditions despite the fact that this can compromise Patient care when there is a prolonged small change in their ventilation. Therefore, it is **recommended** that a Ventilator be designed to **initially** use a **lower** priority **Alarm Condition**, which **escalates** to a **higher** priority if the **Alarm Limit** violation persists. The initial Alarm Condition priority and the priorities and timing of the escalation **should** be determined by the severity of the potential Harm to the Patient in combination with the length of time that the Operator **has to** prevent the Harm from occurring.

Subclause 201.12.4.107 – **Obstruction** Alarm Condition - Sustained elevated Airway Pressure levels can cause hazardous increases in intra-thoracic pressure. Such pressure increases can result in decreased venous return, reduced cardiac output and a subsequent drop in arterial blood pressure. Obstruction of the expiratory limb is the most common obstruction in a Ventilator. The obstruction of expiratory limb Alarm Condition **should** be designed to detect promptly a reduced expiratory flow due to an increased resistance

in the expiratory limb. The nature or duration of an occlusion in the expiratory limb of the VBS cannot be predicted. Assuming that the occlusion is severe and the safety valve opens quickly, the Patient is not exposed to potentially injurious high pressures, although at the likely expense of the loss of PEEP. Further inspirations, whether or not assisted by the Ventilator, necessitate rebreathing the previously exhaled gas trapped in the inspiratory limb. Given these considerations and their consequences, the associated Alarm Condition is required to be at least Medium Priority. Even if the Ventilator is highly sophisticated, the presence of an occlusion in the expiratory limb of the VBS represents a significant corruption of the Ventilator's ability to provide essential respiratory support to the Patient, which requires prompt action by the Operator. Examples of causes for continuing Airway Pressure include a malfunctioning expiratory valve, kinked tubing and expiratory filter blockage. Nebulised drugs can block expiratory filters within a short time. Other consequences of incomplete expiration (increased peak Airway Pressure or decreased ventilation) can be detected and indicated by other Alarm Conditions required by this standard. Practice shows that clinically used **Alarm Limits** are **not** always sensitive enough to provide early and specific detection of this potentially Hazardous Situation.

Subclause 201.12.4.108 – **Partial-occlusion** Alarm Condition - Total obstruction of the expiratory gas pathway that immediately leads to an increased end-expiratory pressure, is detected and acted on as indicated in 201.12.4.107. In this circumstance, the opening of an inspiratory safety valve is also required. More commonly the underlying causes responsible for total obstruction can also cause a partial obstruction (e.g., minor kinking of the expiratory hose) or a slowly increasing resistance (e.g., due to slow buildup of nebulised aerosols on an expiratory Breathing System Filter, dependent on the filter material and the composition of the nebulised drug). Partial obstruction not only leads to Patient discomfort (expiratory work of breathing, missing triggers), but can develop into total obstruction. It is therefore desirable to detect and alert the Operator to an increased resistance of the expiratory limb as early as possible to give the Operator sufficient time for remedy without interrupting ventilation. This **standard does not specify the degree of obstruction that should be detected or the priority of the partial obstruction Alarm Condition**. The sensitivity of this monitor that can be achieved without generating False Positive Alarm Conditions not only depends on the design of the Ventilator, but also on properties of the individual Patient. The committee therefore came to the conclusion that it is not desirable to be more specific.

Subclause 201.106.3 – **Connection** to **Distributed Alarm System** - Patients who are Ventilator-dependent are usually located in clinical environments that are staffed with Operators in sufficiently close proximity to **hear** Alarm Signals coming from the Patient's room. However, many Patients are in lower acuity rooms without Operators in close proximity to the Patient's room. Patients also can be in enclosed (positive or negative pressure) isolation rooms. In these settings, it can be difficult or impossible for Operators to hear Alarm Signals. As a result, an appropriate response can be delayed with catastrophic results. A Distributed Alarm System facilitates delivery of Alarm Signals to remotely located Operators, thereby permitting a timely response and intervention to support Patient care. The data transmission **should** be capable of being provided with a Network/Data Coupling in accordance with ASTM F2761-09.

Subclause 208.6.3.3.2.101 – Additional requirements for characteristics of **Alarm Condition logging** - Optimal management of a Patient **requires** the ability to review the **history** of important **Alarm Conditions**. This is a **more reasonable** means of Risk Control in the critical care environment for a Life-Supporting ME Equipment OR ME System **than Latching** Alarm Signals. Additional information is also found in IEC 60601-1-8:2006, Annex A, for 6.12 **–** Alarm Condition logging.

Subclause 208.6.8.4.101 – Additional requirements for **termination** of **Alarm Signal Inactivation** - Permitting **very long pauses** of Alarm Signals **can** be **hazardous** for the Patient since the Operator will not be notified of the existence of an Alarm Condition. However, Patient management often requires delicate procedures that can be disrupted by **auditory** Alarm Signals. Therefore, **extending Audio Paused by Operator action is useful** to prevent the Ventilator from disturbing the Operator or others in the vicinity (e.g. surgeon or cardiologist) in the Patient's room. Ventilators **should** be equipped with an **Audio Paused** capability that permits the Operator to pause the Alarm Signals **prior** to the creation of an Alarm Condition. Such a capability permits the Operator to minimize nuisance auditory Alarm Signals in situations that are known to be associated with creation of nuisance Alarm Conditions. A 'planned' disconnect is a common situation where this capability is **needed**. Examples include open suctioning, Breathing System Filter change, or insertion of a medication treatment. A closed suctioning mode **should** also include such a capability.

MECA ALARM STANDARDS CROSS-REFERENCE

ISO 80601-2-13 First edition 2011-08-01 Particular requirements for Basic Safety and Essential Performance of an **Anaesthetic Workstation**

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Oxygen flow under all conditions except the failure of the oxygen supply (pipeline or cylinder) to the ANAESTHETIC WORKSTATION or the generation of a TECHNICAL ALARM CONDITION	201.12.4.107.2 (oxygen supply failure PROTECTION DEVICE) 201.101.2 (interruption of the electrical POWER SUPPLY) 201.101.8 (oxygen flush)
Delivery of a non-hypoxic gas mixture to the PATIENT or generation of a TECHNICAL ALARM CONDITION	201.11.8.102 (ALARM CONDITION for POWER SUPPLY failure) 201.11.8.103 (INTERNAL ELECTRICAL POWER SOURCE) 201.12.4 (protection against hazardous output) 201.101.4.2.3 (reserve flow and cross flow PROTECTION DEVICE) 201.101.7 (gas mixers) 201.101.8 (oxygen flush)
Non-delivery of excessive concentrations of a volatile anaesthetic agent or generation of a TECHNICAL ALARM CONDITION	201.104.2 (delivered vapour concentration) 201.12.4.103.3 (anaesthetic agent MONITORING EQUIPMENT)
AIRWAY PRESSURE monitoring and associated alarm	201.12.4.109 (AIRWAY PRESSURE MONITORING EQUIPMENT)

201.7.9.2.14 Accessories, supplementary equipment, used material - Addition: The **instructions for use** of the Anaesthetic Workstation and its individual components **shall** include the following: aa) information on the **method** of enabling the Anaesthetic Workstation or its individual components, including the Monitoring Equipment, **Alarm Systems** and Protection Devices, required by this International Standard; this information **may** form part of the **pre-use checklist** (see 201.7.9.2.8);

201.9.2.101 **Maintenance points** - Any maintenance points **shall** be located outside Danger Zones and adjustment, maintenance, repair, cleaning and servicing operations **shall** be possible when the Anaesthetic Workstation is not being operated. Where this is not achievable, alternative means of **Risk mitigation**, e.g. **alarming** and information of safety and training are permitted to reduce the Risk to acceptable levels.
Check compliance by inspection of the Risk Management File and Usability Engineering File

201.9.2.104 * Arrangement of **control positions** - For Anaesthetic Workstations which contain one or more Danger Zones – an **audible** or **visual** Alarm Signal **shall** be given long enough before the Anaesthetic Workstation is started to allow **anyone** wholly or partially in a Danger Zone to leave the area.

201.11.8.102 * **Alarm Condition** for **Power Supply failure** - The Anaesthetic Workstation **shall** be equipped with an Alarm System that includes a **Power Supply failure Alarm Signal** that indicates when the Power Supply is outside the range specified by the Manufacturer. The Alarm Signals for the Power Supply failure Alarm Condition **shall** be – generated for at least **7 s** if pneumatically generated, or – at least **5 bursts** and

a **High Priority Alarm Signal** that complies with IEC 60601-1-8, if electronically generated.
Example: The Ritchie Whistle is a pneumatic Alarm Signal generator
NOTE 1: The Power Supply failure Technical Alarm Condition applies to the supply mains, an Internal Electrical Power Source or pneumatic (driving) power supply
NOTE 2: The 7 s duration of the Alarm Signals for the Power Supply failure Alarm Condition is measured exclusive of any Interburst Interval
The A-weighted sound pressure level **shall** be at least **2 dB** above a white background sound level of **55 dB** when tested as described in **ISO 3746**. If the normal operation of the Anaesthetic Workstation or its individual components is maintained by the automatic switchover to an Internal Electrical Power Source or alternate pneumatic Power Supply, the Power Supply failure High Priority Technical Alarm Condition **shall not** occur. Any such switchover to an Internal Electrical Power Source or alternate pneumatic Power Supply **shall** be indicated by an **Information Signal** or a **Low** Priority Technical Alarm Condition.

201.11.8.103 * **Internal Electrical Power Source** - If the Anaesthetic Workstation or its individual components has/have an Internal Electrical Power Source, a) it/they **shall** be equipped with: 2) an Alarm System that is equipped with a **Technical** Alarm Condition of at least **Medium** Priority that indicates when the Internal Electrical Power Source nears depletion; this Alarm Condition **shall** occur prior to the loss of function
Example 4: A Medium Priority Technical Alarm Condition 5 min prior to the loss of all function

201.12.4.104.2 **Alarm Conditions** - The exhaled volume Monitoring Equipment **shall** be equipped with an Alarm System that includes a **Physiological** Alarm Condition of at least **Medium** Priority that indicates when the Patient's exhaled volume falls below an Operator-adjustable **Alarm Limit**. If the Alarm Signal can be delayed, the Alarm Signal Generation **Delay shall not exceed 90 s**. The Alarm Signal Generation Delay **may** be Operator-adjustable.
Check compliance by functional testing

201.12.4.105 * **Anaesthetic Breathing System integrity Alarm Condition** - The Anaesthetic Breathing System integrity Alarm Condition **shall** indicate when the Anaesthetic Breathing System has significant leakage, including disconnection, and **shall** be of at least **Medium** Priority. The Anaesthetic Breathing System integrity Alarm Condition **may** be indicated by other Alarm Conditions including low Airway Pressure, low or zero exhaled carbon dioxide or low exhaled volume.
NOTE: The Alarm System indicates specific Alarm Conditions and does not necessarily differentiate between possible causes.
Check compliance by functional testing

201.12.4.106 * **Anaesthetic Breathing System continuing-positive-pressure Alarm Condition** - The Anaesthetic Breathing System **shall** be equipped with an Alarm System that includes an Alarm Condition that indicates when the Airway Pressure exceeds the continuing positive pressure **Alarm Limit**. If not so equipped, the instructions for use of the Anaesthetic Breathing System **shall** contain a statement to the effect that the Anaesthetic Breathing System **is to be provided** with an Alarm System that includes an Alarm Condition that indicates when the Airway Pressure exceeds the continuing positive pressure **Alarm Limit** before the Anaesthetic Breathing System is put into service. Unless the Alarm System that includes an Alarm Condition that indicates when the Airway Pressure exceeds the continuing positive pressure Alarm Limit is an integral part of the Anaesthetic Breathing System, information on how to connect it **shall** be disclosed in the instructions for use of the Anaesthetic Breathing System. The maximum Alarm Condition Delay **shall** not exceed **17 s** or two breath cycles, whichever is longer. The Anaesthetic Breathing System continuing positive pressure Alarm Condition **shall** be at least Medium Priority. The Anaesthetic Breathing System continuing positive pressure Alarm Limit **may** be Operator-Adjustable.
Check compliance by functional testing and, if applicable, inspection of the instructions for use.

201.12.4.107.1 **Oxygen supply failure** Alarm System - The Anaesthetic Gas Delivery System **shall** be equipped with an Alarm System that includes a **High Priority Technica**l Alarm Condition that indicates when the oxygen supply, whether derived from a Medical Gas Pipeline System or from a cylinder, is about to fall, or has already fallen, below a value **necessary** for normal operation. A pneumatically generated **auditory** Alarm Signal **may** be used. A pneumatically generated **auditory** Alarm Signal **shall** be at least **7 s** in duration, and when tested as described in **ISO 3746**, its A-weighted sound pressure level **shall** be at least **2 dB** above a white background sound level of **55 dB**. A pneumatically generated Alarm Signal **shall** derive its energy from the oxygen supply source.
Example: "Ritchie whistle"
Check compliance by functional testing

201.12.4.109 **Airway Pressure Monitoring Equipment** - The Airway Pressure Monitoring Equipment **shall** include an Alarm System that generates an Alarm Condition of at least **Medium** Priority to indicate when the Airway Pressure exceeds an Operator-Adjustable high pressure **Alarm Limit**. If the Alarm System generates an Alarm Condition upon a failure to reach an Operator-adjustable minimum pressure threshold, that Alarm Condition **shall** be of at least **Medium** Priority.
NOTE: The failure to reach an Operator-adjustable minimum pressure threshold Alarm Condition can act as a "failure to cycle" Alarm Condition
The Airway Pressure Monitoring Equipment **should** include an Alarm System that generates an Alarm Condition of at least **Medium** Priority to indicate when the Airway Pressure falls below an Operator-adjustable **Alarm Limit**.
Check compliance by functional testing and, if applicable, by inspection of the instructions for use

201.13.101 * **Simultaneous failure** - A Single Fault Condition **shall not** cause the simultaneous failure of a control function and **–** its associated Monitoring Equipment or **Alarm System**, or **–** its associated Protection Device.
Check compliance by inspection or functional testing

201.16.101.3 **Connection** to **Distributed Alarm System** - An Anaesthetic Workstation or its individual components **may** be equipped with a Signal Input/Output Part for connection to a Distributed Alarm System.

201.102.1.1.1 Non-metallic components - Non-metallic components of an Anaesthetic Breathing System or its components that are made of antistatic or conductive materials, and the packaging of such components, shall be marked with the Clearly Legible word "antistatic" or "conductive" or the equivalent in a language that is acceptable to the intended Operator. These non-metallic components may additionally bear an indelible **yellow** coloured mark.

201.105.7.1 **Expiratory pause** - An Anaesthetic Ventilator **may** be equipped with an Operator-controlled **means** to pause the Anaesthetic Ventilator in expiration. The following applies to an expiratory pause. c) During the expiratory pause, any apnoea-related ventilatory **Alarm Condition** that would be caused by this expiratory pause **shall** be automatically **Audio Paused** or **Alarm Paused** for the duration of the expiratory pause. d) In addition to the requirements for **Alarm Signal Inactivation** of 6.8.5 of IEC 60601-1-8:2006, the Anaesthetic Ventilator **shall** indicate the presence of the expiratory pause with an **Information Signal** or **Low** Priority Alarm Condition.

201.105.7.2 **Inspiratory pause** - An Anaesthetic Ventilator **may** be equipped with an Operator-controlled means to pause automatic ventilation at end-inspiration. The following applies to an inspiratory pause function. b) The high-pressure **Alarm Condition** of 201.4.109 and the **Protection Device** of 201.105.2 **shall**

remain active during an inspiratory pause. d) During the inspiratory pause, any apnoea or sustained Airway Pressure **Alarm Condition** that would be caused by this inspiratory pause **should** be Audio Paused or **Alarm Paused** for the duration of the inspiratory pause. e) In addition to the requirements for **Alarm Signal Inactivation** of 6.8.5 of IEC 60601-1-8:2006, the Anaesthetic Ventilator **shall** indicate the presence of the inspiratory pause with an **Information Signal** or **Low** Priority Alarm Condition.

201.105.8 * **Sub-atmospheric pressure** - A **High** Priority Alarm Signal **shall** be activated when the Airway Pressure falls **10 hPa** (10 cmH2O) below atmospheric pressure for more than **1 s**.
Check compliance by functional testing

206.6.2.2.2 **Primary Operating Functions** - Addition For the Anaesthetic Workstation and its individual components, if provided, the following **shall** be considered **Primary Operating Functions**: hh) **setting Alarm Limits**; ii) **inactivating Alarm Signals**

208.5.2.2 * **Technical description** - Addition The technical description **shall** include: **–** a **list** of Alarm **Systems** and Alarm **Conditions** to be **tested** by the **user**;

208.6.8.3 * **Global indefinite Alarm Signal Inactivation States** Addition: An Anaesthetic Workstation and its individual components **shall not** be equipped with a means to initiate a **global Alarm Off** while connected to a Patient.

208.6.8.4 * **Termination** of **inactivation** of **Alarm Signals** - Addition: The duration of **Audio Paused** for the **High** Priority Alarm Conditions required by this International Standard **shall not exceed 120 s** without Operator intervention. Other priority Alarm Conditions (Low and Medium Priority Alarm Conditions) **may** have longer Audio Paused durations.

208.6.12 * **Alarm Condition logging** - Amendment: Replace the introductory sentence to the list by the following: The Alarm System of an Anaesthetic Workstation **shall** be equipped with Alarm Condition **logging** for at least **High** Priority and **Medium** Priority Alarm Conditions.
NOTE: This logging **may** be Operator-configurable

Subclause 201.7.9.2.8 **Start-up Procedure** - For many years, pre-use checklists described those checks **necessary** for safe operation. These checks are to be performed by the Operator prior to use either every day or before each case. The less integrated an Anaesthetic Workstation is, the more important a thorough pre-use check becomes to ensure that all **necessary** equipment is present, correctly connected, switched on and fully functional. An **essential** part is **verifying** that Alarm Systems function properly. Most modern Anaesthetic Workstations incorporate PEMS that perform some of the pre-use checks. Almost all Monitoring Equipment test all its Alarm Systems. Here it is important to inform the Operator or Responsible Organization which checks are automatically performed by the Anaesthetic Workstation to enable the Operator to adapt checklists.

Subclause 201.11.8.102 Alarm Condition for **Power Supply failure** - The requirement for the duration of this Alarm Signal is consistent with the pneumatic loss of pressure Alarm Signal (“Ritchie whistle”). See also 201.12.4.107.1.

Subclause 201.12.4.105 **Anaesthetic Breathing System integrity** Alarm Condition - The committee generally agreed that currently there is **no way to indicate reliably** the failure of Anaesthetic Breathing System integrity (for example, partial or even complete disconnection of the Anaesthetic Breathing System). Under certain circumstances, the monitoring of abnormal or low values of carbon dioxide, pressure, exhaled

volume, concentration of vapour or oxygen can individually or in combination indicate or contribute to the detection of loss of Anaesthetic Breathing System integrity. It is for these reasons that a Medium Priority Alarm Condition is required, but that a specific method of determining or labelling of that Alarm Condition is not specified.

Subclause 201.12.4.106 **Anaesthetic Breathing System continuing-positive pressure** Alarm Condition - A minimum of **17 s delay** is a compromise between immediately alarming to annunciate a Hazardous Situation and avoidance of **nuisance** Alarm Signals. The wording "**shall** not exceed … two breaths" allows the Manufacturer to adapt the delay to, for example, synchronized ventilation modes with two breaths per minute. Interruption of ventilation caused, for example, by an occlusion of the expiratory limb, is a major Risk that is mitigated by an Anaesthetic Breathing System continuing-positive-pressure Alarm Condition.

Subclause 201.101.2 **Interruption** of the **electrical Power Supply** - Most mechanical/pneumatic Anaesthetic Gas Delivery Systems are independent from electrical power. These devices do not **need** any special precautions. For an electronically operated Anaesthetic Gas Delivery System an "alternative means of gas delivery" can be, for example: **–** an automatic switch-over to pure oxygen and a **Technical Alarm**, or **–** a Technical Alarm and an alternative, manual gas delivery unit, or **–** a Technical Alarm Condition and an external oxygen cylinder with Pressure Regulator and flow-metering device and labelling advising the Operator to have this ready.

Subclause 208.5.2.2 **Technical description** - **Testing** of Alarm Systems and Alarm Conditions helps to prevent unnoticed failure of important monitoring functions. If not performed automatically by the Anaesthetic Workstation or its individual components, the Responsible Organization **has to** ensure regular testing. Therefore, detailed information about these tests is **necessary**. Such tests will usually be too complex to be performed by the Operator, and **providing the information in the technical description is therefore considered sufficient**.

Subclause 208.6.8.3 **Global indefinite Alarm Signal Inactivation States** - **Incidents repeatedly occur when Alarm Systems are permanently disabled. These incidents can be easily prevented by restricting the functions to Alarm Off for individual parameters only and time-limited global audio pause functions**.

Subclause 208.6.8.4 **Termination** of **inactivation** of **Alarm Signals** - Permitting **very long pauses** of Alarm Signals **can** be hazardous for the Patient since the Operator will **not** be notified of the existence of an Alarm Condition. However, Patient management often requires delicate Procedures that can be disrupted by auditory Alarm Signals. Therefore, **extending Audio Paused by Operator action is useful** to prevent the Anaesthetic Workstations from disturbing the Operator or others in the vicinity (e.g. surgeon).

Subclause 208.6.12 **Alarm Condition logging** - Optimal management of a Patient **requires** the ability to review the history of important Alarm Conditions. This is a more reasonable means of Risk Control in the clinical environment for a Life-Supporting ME Equipment or ME System than **Latching** Alarm Signals. Additional information is also found in IEC 60601-1-8:2006, Annex A, for 6.12.

MECA ALARM STANDARDS CROSS-REFERENCE

IEC 60601-2-16 Edition 4.0 2012-03 Particular Requirements for the Basic Safety and Essential Performance of **Haemodialysis, Haemodiafiltration and Haemofiltration Equipment**

201.7.9.2.2 **Warning** and **safety notices** - Addition: The instructions for use **shall** additionally include the following, if applicable: **–** an explanation of the adequate **Operator action** upon an Alarm Condition and potential Hazards, if the Alarm Condition is repeatedly cleared without solving the underlying problem.

201.7.9.2.5 ME Equipment description Addition: The instructions for use **shall** additionally include the following, if applicable: **–** the **delay time after** which an **audible** Alarm Signal is activated **after interruption of the power supply**

201.7.9.2.6 **Installation** - Addition: The instructions for use **shall** additionally include the following, if applicable: **–** if different schemes for **colour coding** of visual Alarm Signals can be configured, a statement that the Responsible Organization **should** select the colour coding scheme which minimizes the Risk of confusion in their environment

201.7.9.3.1 General - Addition: The technical description **shall** additionally include the following, if applicable: **–** the type, the measurement accuracy and the value(s) or range(s) of the **Alarm Limit(s)** of the Protective System required by 201.12.4.4.101 (Dialysis Fluid composition); **–** the type, the measurement accuracy and the value(s) or range of the Alarm Limit(s) of the Protective System required by 201.12.4.4.102 (Dialysis Fluid and Substitution Fluid temperature); **–** the type, the measurement accuracy and the value(s) or range(s) of the Alarm Limit(s) of the Protective System required by 201.12.4.4.103 (Net Fluid Removal); **–** the type, the measurement accuracy and the value(s) or range(s) of the Alarm Limit(s) of the Protective System required by 201.12.4.4.104.1 (extracorporeal blood loss to the environment); **–** * the type and the measurement accuracy of the Protective System required by 201.12.4.4.104.2 (Blood Leak to the Dialysis Fluid) and the Alarm Limit of the Protective System at the minimum and maximum flow through the Blood Leak detector; **–** the type and the Alarm Limit(s) of the Protective System required by 201.12.4.4.104.3 (extracorporeal blood loss due to coagulation); **–** the audible Alarm Signal **Audio Paused period**; **–** the range of **sound pressure levels** of any adjustable audible Alarm Signal source

201.8.7.4.7 Measurement of the **Patient Leakage Current** - Addition: * aa) The measuring device **shall** be connected where both extracorporeal blood lines are connected to the Patient. For the duration of the test, a test solution with the highest selectable conductivity, referenced to a temperature of 25 °C, and to the highest selectable Dialysis Fluid temperature in the application, **shall** be flowing in the Dialysis Fluid circuit and in the Extracorporeal Circuit. The Haemodialysis Equipment **shall** be operated in typical treatment mode with highest possible blood flow and **no Alarm Signals activated**. For practical reasons the measuring device **may** be connected to the Dialysis Fluid connectors.

201.11.8 ***Interruption** of the **power supply** /Supply Mains to ME Equipment - Addition: a) Haemodialysis Equipment **without** Internal Electrical Power Source: In the event of an interruption of the power supply /Supply Mains to the Haemodialysis Equipment, the following safe conditions **shall** be achieved: **–** activation of an **audible** Alarm Signal, lasting for at least **1 min**; b) Haemodialysis Equipment **with** Internal Electrical Power Source: In the event of an interruption of the power supply /Supply Mains to the Haemodialysis Equipment, the following safe conditions **shall** be achieved: **–** activation of a **visual** Alarm Signal

201.12.4.4.101 *Dialysis **Fluid composition** - a) The Haemodialysis Equipment **shall** include a Protective System, independent of any fluid preparation control system, which prevents Dialysis Fluid reaching the Dialyser that, due to its composition, **may** cause a Hazard. The design of the Protective System to prevent a hazardous composition of the Dialysis Fluid **shall** consider a potential failure in any phase of preparation of the Dialysis Fluid. Operation of the Protective System **shall** achieve the following safe conditions: **–** activation of an **audible** and **visual** Alarm Signal (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101). The audible Alarm Signal **may be** delayed as specified in 208.6.3.3.101 b); b) Conductivity profiles and Physiologic Closed-Loop Controllers: In case of pre-programmed time-dependent variation of the Dialysis Fluid composition or in case of feedback control of the Dialysis Fluid composition by measuring a physiologic relevant parameter of the Patient, the Haemodialysis Equipment **shall** include a Protective System, independent of the control system, which prevents any unintentional changes in the control system that could cause a Hazard. Operation of the Protective System **shall** achieve the following safe conditions: **–** activation of an **audible** and **visual** Alarm Signal (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101); c) If the Haemodialysis Equipment is equipped with a concentration bolus administration feature, the Haemodialysis Equipment **shall** include a Protective System, independent of the control system, which prevents the concentration bolus administration function to cause a Hazard to the Patient. Operation of the Protective System **shall** achieve the following safe conditions: **–** activation of an **audible** and **visual** Alarm Signal (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

*Compliance is checked by functional tests and by the following tests. • Test 1 for determining the Alarm Limits – Set the unit under test to the lowest and the highest Alarm Signal free compositions of the Dialysis Fluid respectively. – Slowly change the Dialysis Fluid composition until the Protective System activates an Alarm Signal. – Take samples at the Dialyser inlet under Normal Condition and immediately after the Alarm Signal. – Determine the difference of the Dialysis Fluid composition of the samples taken in Normal Condition and after Alarm Condition (e.g. by flame photometry). • Test 2 for **in-time Alarm Condition reaction** – Set the unit under test to the highest possible Dialysis Fluid flow – Simulate complete interruption of each Dialysis Fluid Concentrate supply, one at a time. – Take samples at the Dialyser inlet under Normal Condition and immediately after the Alarm Condition. – Determine the difference of the Dialysis Fluid composition of the samples taken under Normal Condition and after Alarm Condition (e.g. by flame photometry). • Test 3 for foreseeable misuse – Exchange Dialysis Fluid Concentrate, if possible. – Determine the Alarm Signal activation*

201.12.4.4.102 *Dialysis **Fluid** and **Substitution Fluid temperature** - d) Operation of the Protective System **shall** achieve the following safe conditions: **–** activation of an **audible** and **visual** Alarm Signal (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101). The audible Alarm Signal **may** be delayed as specified in 208.6.3.3.101 b);

Compliance is checked by functional tests and by the following tests. • Test 1 for Dialysis Fluid ‑ Set the unit under test to the highest Dialysis Fluid flow, if this setting is possible. ‑ Set the highest / lowest Dialysis Fluid temperature. ‑ Wait for stable temperatures at the Dialyser inlet. ‑ Slowly increase / decrease the temperature of Dialysis Fluid until the Protective System activates an Alarm Signal. ‑ Measure the temperature continuously at the Dialyser inlet and determine the maximum / minimum value. •Test 2 for Substitution Fluid – Set the unit under test to the highest Substitution Fluid flow, if this setting is possible. – Set the highest / lowest Dialysis Fluid / Substitution Fluid temperature. – Wait for stable temperatures at the inlet to the Extracorporeal Circuit. – Slowly increase / decrease the temperature of the Dialysis Fluid / Substitution Fluid until the Protective System activates an Alarm Signal. – Measure the temperature of the Substitution Fluid continuously at the inlet to the Extracorporeal Circuit and determine the maximum / minimum value

201.12.4.4.103 *Net **Fluid Removal** - Operation of the Protective System **shall** achieve the following safe conditions: **–** activation of an **audible** and **visual** Alarm Signal (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

Compliance is checked by functional tests and failure simulations, including the following tests. ⍰ Test for deviations of the Net Fluid Removal rate ‑ Set the unit under test to the highest Dialysis Fluid flow. ‑ Set the highest Substitution Fluid flow, if this is adjustable. ‑ Set the Dialysis Fluid temperature to 37 °C, if applicable. ‑ Set the highest and the lowest Ultrafiltration flow rates (one at a time). ‑ Simulate a low and a high failure in each of the pump control systems (one at a time) which influence the Net

Fluid Removal rate until the Protective System activates an Alarm Signal. ‑ Determine the volume difference in relation to the theoretical volume

201.12.4.4.104.1 Extracorporeal blood loss to the environment - If a Protective System is utilizing measurement of the Venous Pressure, the Operator **should** have at least the possibility to adjust **the lower Alarm Limit manually** as closely as possible to the current measurement value.

201.12.4.4.104.2 ***Blood Leak to** the **Dialysis Fluid** - b) Operation of the Protective System **shall** achieve the following safe condition: **– activation of an audible and visual Alarm Signal** (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

*Compliance is checked by functional tests and by the following test. • **Test for determining the Alarm Limits:** – Create maximum flow through the Blood Leak detector (highest Dialysis Fluid flow, highest Ultrafiltration flow, if relevant also highest Substitution Fluid flow). – Add bovine blood (Hct 32%) to the Dialysis Fluid so that the flow through the Blood Leak detector represents the Blood Leak Alarm Limit as specified by the Manufacturer*

201.12.4.4.105 * **Air infusion** - b) Operation of the Protective System **shall** achieve the following safe condition: **–** activation of an **audible** and **visual** Alarm Signal (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

201.12.4.4.106 **Alarm System override modes** - a) All Protective Systems **shall** be operational throughout treatment.

NOTE 1: For exceptions, see item b) below

NOTE 2: Within the meaning of this subclause treatment is considered to have started when the Patient's blood is returned to the Patient through the Extracorporeal Circuit, treatment is considered to be finished when the venous needle is disconnected

b) The Protective System for Dialysis Fluid composition and temperature **shall** be operational before the first contact of Dialysis Fluid with blood in the Dialyser. c) During an Alarm Condition, temporary override modes **may** apply individually to the Protective System utilizing Blood Leak monitoring (see 201.12.4.4.104.2). d) The override time **shall not** exceed 3 min, but under certain clinical conditions it **may** be necessary to deactivate the Blood Leak detector completely or partially for unlimited time. e) Operation of the override mode **shall** maintain a **visual** indication that the Protective System is being overridden. f) Overriding a particular Protective System (see item b) **shall** have **no effect** on any other subsequent **Alarm Conditions**. Subsequent Alarm Conditions **shall** achieve the safe condition specified. A remaining Alarm Condition **shall**, after the elapsed override period, re-achieve the safe condition specified**.**

NOTE 3: Within the meaning of this subclause, override is the means to allow the Haemodialysis Equipment to function under Alarm Conditions if the Operator consciously selects to temporarily disable the Protective System. A delayed start is not regarded as an override of the Haemodialysis Equipment if it does not cause a Hazard.

Compliance is checked by inspection of the Accompanying Documents and by functional tests

208 General requirements, tests and guidance for Alarm Systems in medical electrical equipment and medical electrical systems - IEC 60601-1-8:2006 applies except as follows: 208.4 *General requirements Addition: If the **Intended Use** of the Hemodialysis Equipment includes the intensive care or surgery environment, it is **acceptable** to implement **additional Alarm Systems** deviating from IEC 60601-1-8:2006 in the following subclauses: • 6.1.2 Alarm Condition **priority**; • 6.3.2.2 Characteristics of **visual** Alarm Signals; • 6.3.3.1 Characteristics of **auditory** Alarm Signals. If additional Alarm Systems deviating from IEC 60601-1-8:2006 are implemented, a) the Alarm System according to IEC 60601-1-8:2006 **shall** be the factory **default**; b) only the Responsible Organization **shall** be able to change the Alarm System.

Compliance is checked by functional tests

NOTE 1: Table AA.1 of Annex AA shows possible Alarm Condition priorities according to IEC 60601-1-8:2006 6.1.2 adapted for Haemodialysis Equipment needs

If the Intended Use of the Hemodialysis Equipment **does not** include the intensive care or surgery environment, the following clauses of IEC 60601-1-8:2006 are **not mandatory**: • 6.1.2 Alarm Condition

priority; • 6.3.2.2 Characteristics of visual Alarm Signals; • 6.3.3.1 Characteristics of auditory Alarm Signals.
NOTE 2 7.8.1: Colours of indicator lights of the general standard applies, but the Urgency of the response of the Operator can have other than Patient centric causes.

208.5.2.1 **Instructions for use** - Addition:
NOTE 101: In the **listing** and **description** of **every possible Alarm Condition** only these conditions need to be written with a remaining Hazard beside the safe state of the Haemodialysis Equipment.

208.6.3 **Generation** of **Alarm Signals** -208.6.3.1 *General - Addition: Unless otherwise specified by this particular standard, Alarm Signals **shall** be activated both **visually** and **audibly**. The **visual** Alarm Signal **shall** remain activated for the **entire duration** of the Alarm Condition, whereas it is **allowed** to **pause** the **audible** Alarm Signal for the amount of time specified in 208.6.3.3.101 b).
Compliance is checked by functional tests

208.6.3.3.2 * **Volume** of **auditory Alarm Signals** and **Information Signals** - Addition: In the initial setting by the Manufacturer the Haemodialysis Equipment **shall** generate a sound pressure level of at least **65 dB(A)** at a distance of **1 m**.
Compliance is checked by measuring the A-rated sound pressure level with instruments meeting the requirements for measuring instruments of Class 1 according to IEC 61672-1 and free field conditions as specified in ISO 3744

208.6.3.3.101 *Special characteristics of **auditory** Alarm Signals for Haemodialysis Equipment - Audible Alarm Signals **shall** meet the following requirements: a) If the Haemodialysis Equipment enables the Operator to set the audible Alarm Signal volume to lower values, a **minimum value shall** be **defined**. This minimum value **may** only be changed by the **Responsible Organization**. If the Responsible Organization can reduce the audible Alarm Signal volume to zero, there **shall** be an alternative means to notify the Operator under Single Fault Condition. b) If it is possible to pause the audible Alarm Signal, the Alarm Signal Audio Paused period **shall not exceed 3 min.** Exception: for Alarm Signals as described in 201.12.4.4.101 (Dialysis Fluid composition) or 201.12.4.4.102 (Dialysis Fluid and Substitution Fluid temperature) the Alarm Signal Audio Paused period **shall not** exceed **10 min**. c) If during an Alarm Condition Audio Paused period another Alarm Condition occurs requiring the immediate response by the Operator to prevent any Hazard, then the Audio Paused period **shall** be interrupted.
Compliance is checked by functional tests

Clause 201.12 **Accuracy** of **controls** and **instruments** and protection against hazardous outputs - The preceding second edition of this particular standard (IEC 60601-2-16:1998) usually did not specify any definite values for the **necessary** Alarm Limits of the Protective Systems. It was up to the Manufacturer to define the deviation from the value that presented a Hazard which had to be detected by the Protective System and justified in the Manufacturer's Risk Management Process.

Subclause 201.12.4.4.104.3 - Extracorporeal **blood loss due** to **coagulation** - In this case, an independent Protective System is not required because the degree of harm is limited to the blood loss in the Extracorporeal Circuit. At the time of writing of this standard there are no scientific publications available about coagulation of blood as a function of the stopping time of the extracorporeal blood flow. A **maximum Alarm Signal delay time** of **three minutes** has been proven by experience to be appropriate**.**

Table AA.1 – Possible ALARM CONDITION priorities according to 6.1.2 of IEC 60601-1-8:2006, adapted for haemodialysis equipment needs.

ALARM CONDITION	ALARM CONDITION priority
Different reasons (e.g. pressures, technical faults)	
Reasons, that lead to a stop of the blood system	LOW PRIORITY, yellow
Blood loss due to coagulation in the extracorporeal system	
Blood pump stop alarm (201.12.4.4.104.3), as escalation of above alarm	MEDIUM PRIORITY, yellow flashing
Mains off – battery running system, before battery goes down	
Possible blood loss out of the puncture side or open catheter, following accidental needle or catheter disconnect	
Detectable by low VENOUS PRESSURE	HIGH PRIORITY, red flashing
PHYSIOLOGICAL ALARM CONDITIONS, if not specified in other standards	
Physiological alarms, e.g. non invasive blood pressure limit alarm	HIGH PRIORITY, red flashing Possible: escalation with two different limits.
Treatment deviation, influence on prescription	
E.g. balancing alarms, long lasting bypass of DIALYZING FLUID	LOW PRIORITY, yellow
Technical information	
Technical faults, but blood system is running, e.g. short bypass of dialysate	INFORMATION SIGNAL, e.g. green flashing Alternative is the use of LOW PRIORITY, yellow

An Alarm Signal activated in case of **extracorporeal blood loss** to the environment (see 201.12.4.4.104.1) is one example of a HIGH Priority Alarm Signal that **requires immediate response** by the Operator. If the blood flow is stopped for an **extended period** of time (201.12.4.4.104.3), this is an example for a **Medium** Priority Alarm Signal. In most other Alarm Conditions the Protective System puts the Haemodialysis Equipment in a state, which is safe for the Patient, at least temporarily, and therefore such an Alarm Signal is indicated by a Low Priority Alarm Signal. Other Alarm Signals **should** be determined by the Manufacturer's Risk Management Process.

Subclause 201.12.4.4.106 Alarm System **override modes** - It **should not** be possible to deactivate the Blood Leak detector inadvertently. Possible solutions **might**, for example, be two independent actions on the Operator's part and automatic restart on commencement of the next treatment. Deactivation of the Blood Leak detector **should not** increase the Risk of blood loss to a higher degree than **necessary**. An acceptable method is to design the Blood Leak detector such that it is not only possible to switch it off completely but

also to reduce its sensitivity and that this reduction will be automatically cancelled again on commencement of the next treatment.

Subclause 208.4 General requirements - IEC 60601-1-8 is written from the view of intensive care or surgery environments and adds in the clause 6.1.2 Alarm Condition priority a very Patient centric view of potential results of failure to respond to the cause of Alarm Condition. Haemodialysis Equipment is mainly used in a chronic ambulant approach. The **Patients normally do not have life threatening status**, **Alarm Conditions mostly arise from technical causes** and the therapy has in most cases of problems the chance to go to a safe state, which only loses time for Patient and Operators, but which is one of the most important issues in a timely exact planned schedule of subsequent following shifts. The environment in a normal chronic Haemodialysis clinic is dominated by the Haemodialysis Equipment, in many cases from one Manufacturer. Normally other ME Equipment will not be used continuously beside the Haemodialysis Equipment in the Patient Environment. In this ambulatory environment the Alarm Condition categories need completely different priorities than in an environment where the Patients have life threatening status and the therapy is life supporting. In the ambulatory environment subclause 6.1.2 Alarm Condition priority with Table 1 would not mirror the needed priorities. Even in the critical care environments the Haemodialysis Equipment is not life-supporting and most Alarm Condition situations would not be a Hazard for Patient and Operator and the Alarm Condition priority will be low. In some cases Operators from chronic haemodialysis support and operate the Haemodialysis Equipment in the intensive care environment. For Haemodialysis Equipment not used in intensive care environments the actual used **–** over years of operation optimized **– Alarm Systems should not be worsened by the need of applying IEC 60601-1-8:2006. Because of this reasons this standard only requires the complete implementation of IEC 60601-1-8:2006 for Haemodialysis Equipment with Intended Use in the intensive care environment**. For this environment Table AA.1 shows how possible Alarm Condition priorities according to IEC 60601-1-8:2006 could be adapted for Haemodialysis Equipment needs. If the Haemodialysis Equipment is intended to be used in both environments the Alarm System according to IEC 60601-1-8:2006 **has to** be implemented and selectable by the Responsible Organization, but Alarm Systems with deviation from subclauses 6.1.2 Alarm Condition priority, 6.3.2.2 Characteristics of visual Alarm Signals, 6.3.3.1 Characteristics of auditory Alarm Signals are allowed for additional implementation. This particular standard does not mandatorily require for Haemodialysis Equipment with a screen that the visual Alarm Signal **has to** be indicated by an indicator light that is independent of the screen, since there **may** be applications where it is appropriate if the Alarm Signal is indicated on the screen. In large-size dialysis units, however, it is probably more appropriate to provide an indicator light that can be seen from a far distance and is installed at an up-raised position, so that the Haemodialysis Equipment activating the Alarm Signal can be readily located. An Alarm Signal activated in case of extracorporeal blood loss to the environment (see 201.12.4.4.104.1) is one example of a High Priority Alarm Signal that requires immediate response by the Operator. If the blood flow is stopped for an extended period of time (201.12.4.4.104.3), this is an example for a Medium Priority Alarm Signal. In most other Alarm Conditions the Protective System puts the Haemodialysis Equipment in a state, which is safe for the Patient, at least temporarily, and therefore such an Alarm Signal is indicated by a Low Priority Alarm Signal. Other Alarm Signals **should** be determined by the Manufacturer's Risk Management Process.

Subclause 208.6.3.1 General - If the Operator is allowed to configure the contents of the screen, the Manufacturer **has to** use constructive measures (and not notes in the instructions for use) to ensure that the **Alarm Conditions are indicated under any and all circumstances**.

Subclause 208.6.3.3.2 **Volume** of auditory **Alarm** Signals and **Information** Signals - It is intended to prevent the Operator from misusing the volume adjustment function for silencing Alarm Signals, since such a

silencing could not be terminated automatically. The **Responsible Organization, however, should have the possibility of adjusting the Alarm Signal volume to a reasonable value depending on the sound level on site**.

Subclause 208.6.3.3.101 Special characteristics of auditory Alarm Signals for Haemodialysis Equipment - **There are Alarm Conditions which do not present any Hazard if they are paused for more than 3 min, but where elimination of the cause of the Alarm Signal often takes more than 3 min**, e.g. in case of a conductivity Alarm Condition caused by an empty Dialysis Fluid Concentrate container. In this case, the Patient's state **will not** aggravate during the Alarm Signal Audio Paused period and the activated bypass mode.

MECA ALARM STANDARDS CROSS-REFERENCE

IEC 60601-2-18 Edition 3.0 2009-08 Particular requirements for the Basic Safety and Essential Performance of **Endoscopic Equipment**

201.12.3 Alarm Systems Addition:

NOTE 1: This particular standard **does not** specify an Alarm Condition **Priority**

NOTE 2: An Information Signal is any signal that is not an Alarm Signal or a Reminder Signal (as defined in IEC 60601-1-8)

IEC 60601-2-23 Edition 3.0 2011-02 Particular requirements for the Basic Safety and Essential Performance of **Transcutaneous Partial Pressure Monitoring Equipment**

201.7.9.2.101 Additional **instructions for use** - The operating instructions **shall** include the following: n) **advice** regarding testing of the ME Equipment and Accessories on a daily basis (by the clinical Operator) and on a scheduled basis (as a service activity). Emphasis **should** be placed on how the clinician **may test visual** and **auditory** Alarm Signals; q) * description of how to disable Alarm Signals for **Technical** Alarm Conditions if the Transducer or module is intentionally disconnected by the clinical Operator; r) the configuration procedure that allows the Alarm Signal **Inactivation states** (Alarm Paused, Audio Paused, Alarm Off or Audio Off) or the function **Alarm Reset** to be **controlled remotely** (see 208.6.11.101), if provided; s) advice on the preferred Alarm Settings and configurations of the Alarm System when its Intended Use includes the monitoring of Patients that are not continuously attended by a clinical Operator;

201.11.1.2.2.106 * Indication of **temperature deviation** in **Single Fault Condition** - When the temperature of the Applied Part Interface exceeds the Set Temperature by more than 0.6 °C in Normal Condition, **Technical** Alarm Condition **shall** be indicated.
Compliance is checked by causing the temperature of the Applied Part Interface to exceed the Set Temperature by more than 0.6 °C and verifying that a Technical Alarm Condition occurs

201.11.1.2.2.107 **Timer** indicating an elapsed time - ME Equipment **shall** be provided with a clinical Operator adjustable timer that initiates a **Technical** Alarm Condition when the adjusted time has been elapsed. This timer **may** also de-energize the Transducer. The elapsed time **shall** be visually indicated.
Compliance is checked by inspection and functional test

201.11.8 * **Interruption** of the **power supply** /Supply Mains to ME Equipment - Addition: If the Supply Mains to the ME Equipment in which there is **no** Internal Electrical Power Source is interrupted for **30 s** or less **and** the Transducer is energized, either a) the mode of operation and all Operator settings **shall not** be changed, or b) the Transducer **shall** be de-energized and any indication of partial pressure **shall** be cancelled. This de-energized state **shall** be indicated by a **Technical** Alarm Condition. This Technical Alarm Condition **shall** be indicated by **Latching** Alarm Signals.
NOTE: The ME Equipment does not have to be operating during the interruption of the Supply Mains.
Compliance is checked by observing the ME Equipment operating mode and interrupting the Supply Mains for a period of 10 s to 30 s, any ON-OFF switch on the ME Equipment being left in the "ON" position

201.11.8.101 * Protection against **depletion** of **battery** - ME Equipment powered from an Internal Electrical Power Source **shall not** cause a Hazardous Situation to the Patient when the state of discharge can no longer maintain the Normal Use of the ME Equipment (see 201.15.4.4.101). The ME Equipment **shall** provide a **Technical** Alarm Condition to inform the clinical Operator about the state of discharge and **shall** power down in a controlled manner as follows: a) The ME Equipment **shall** provide a **Technical** Alarm Condition at least **5 min prior** to the time that the ME Equipment can no longer function in accordance with the Manufacturer's specification when powered from the Internal Electrical Power Source.
Compliance is checked by functional test

208.6.1.2 * Alarm Condition **Priority** - Addition: ME Equipment that includes in its Intended Use/Intended Purpose monitoring of Patients that are not continuously attended by a clinical Operator in Normal Use **shall** treat Alarm Conditions that **may** result in **minor injury** and **delayed onset** of potential Harm as **Low Priority** Alarm Conditions (see Table 208.101). The Accompanying Documents **shall** describe how the Responsible Organization **may** enable or disable auditory Alarm Signals for **Low** Priority Alarm Conditions.

The requirements of 6.7 of IEC 60601-1-8:2006 apply.

NOTE: This adaptation of Table 1 of IEC 60601-1-8:2006 necessitated an additional configuration capability for this ME Equipment. This capability is **necessary** when the Responsible Organization needs **auditory** Alarm Signals for **Low** Priority Alarm Conditions such as for intensive care units when central monitoring is not being used

Table 208.101 modifies Table 1 – Alarm Condition priorities, for ME Equipment that includes in its Intended Use/Intended Purpose monitoring of Patients that are not continuously attended by a clinical Operator in Normal Use:

Table 208.101 – ALARM CONDITION priorities for ME EQUIPMENT intended to monitor PATIENTS who are not continuously attended by a clinical OPERATOR

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of potential HARM [a]		
	Immediate [b]	Prompt [c]	Delayed [d]
Death or irreversible injury	HIGH PRIORITY [e]	HIGH PRIORITY	MEDIUM PRIORITY
Reversible injury	HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
Minor injury or discomfort	MEDIUM PRIORITY	LOW PRIORITY	LOW PRIORITY

[a] Onset of potential HARM refers to when an injury occurs and not to when it is manifested.

[b] Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.

[c] Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

[d] Having the potential for the event to develop within an unspecified time greater than that given under "prompt".

[e] Where practicable, ME EQUIPMENT with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the ME EQUIPMENT. See also appropriate particular standards.

208.6.3.3 **Auditory** Alarm Signals 208.6.3.3.1 * Characteristics of auditory Alarm Signals Addition: For ME Equipment that includes in its Intended Use/Intended Purpose monitoring of Patients that are **not continuously attended** by a clinical Operator e footnote "d" from Table 3 of IEC 60601-1-8:2006). **– replace "> 15 s or no repeat"** with **"2.5 s to 30.0 s"** in the "Low Priority Alarm Signal" column of Table 3 of IEC 60601-1-8:2006. **– auditory** Alarm Signals **shall** annunciate for **Technical** Alarm Conditions Table 208.102 modifies Table 3 – Characteristics of the burst of auditory Alarm Signals, for ME Equipment that includes in its Intended Use/Intended Purpose monitoring of Patients that are **not continuously attended** by a clinical Operator in Normal Use:

Table 208.102 – Characteristics of the burst of auditory ALARM SIGNALS for ME EQUIPMENT intended to monitor PATIENTS who are not continuously attended by a clinical OPERATOR

Characteristic	HIGH PRIORITY ALARM SIGNAL	MEDIUM PRIORITY ALARM SIGNAL	LOW PRIORITY ALARM SIGNAL
Number of PULSES in BURST [a, d]	10	3	1 or 2
PULSE spacing (t_s) (see Table 208.101)			
between 1st and 2nd PULSE	x	y	y
between 2nd and 3rd PULSE	x	y	Not applicable
between 3rd and 4th PULSE	$2x + t_d$	Not applicable	Not applicable
between 4th and 5th PULSE	x	Not applicable	Not applicable
between 5th and 6th PULSE	0,35 s to 1,30 s	Not applicable	Not applicable
between 6th and 7th PULSE	x	Not applicable	Not applicable
between 7th and 8th PULSE	x	Not applicable	Not applicable
between 8th and 9th PULSE	$2x + t_d$	Not applicable	Not applicable
between 9th and 10th PULSE	x	Not applicable	Not applicable
INTERBURST INTERVAL [b, c] (t_b)	2,5 s to 15,0 s	2,5 s to 30,0 s	>2,5 s to 30 s
Difference in amplitude between any two PULSES	Maximum 10 dB	Maximum 10 dB	Maximum 10 dB

Where x shall be a value between 50 ms and 125 ms.

Where y shall be a value between 125 ms and 250 ms.

The variation of x and y within a BURST shall be ± 5 %.

MEDIUM PRIORITY $t_d + y$ shall be greater than or equal to HIGH PRIORITY $t_d + x$.

[a] See also Table 4 of IEC 60601-1-8:2006 for characteristics of the PULSE.

[b] Unless otherwise specified in a particular standard for a particular ME EQUIPMENT.

[c] MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application. Long INTERBURST INTERVALS can under certain conditions negatively affect the ability to correctly discern, in a timely manner, the source of the ALARM CONDITION.

[d] Unless inactivated by the clinical OPERATOR, MEDIUM PRIORITY and LOW PRIORITY auditory ALARM SIGNALS shall complete at least one BURST, and HIGH PRIORITY auditory ALARM SIGNALS shall complete at least half of one BURST.

The Accompanying Documents **shall** describe how the Responsible Organization **may** enable or disable **auditory** Alarm Signals for **Low** Priority Alarm Conditions and **may** restrict access to control over the **Interburst Interval** for all auditory Alarm Signals. The requirements of 6.7 of IEC 60601-1-8:2006 apply.

NOTE: This adaptation of Table 3 of IEC 60601-1-8:2006 necessitated an additional configuration capability for this ME Equipment. This capability is **necessary** when the Responsible Organization needs Auditory Alarm Signals for Low Priority Alarm Conditions such as for intensive care units when central monitoring is not being used.

Risk Management shall be applied to determine the **maximum Interburst Interval** for **auditory** Alarm Signals associated with High, Medium, and Low Priority Alarm Conditions.

Compliance is checked by inspection of the Risk Management File

208.6.3.3.2.101 * **Volume** of auditory Alarm Signals reducible to **zero** - If the clinical Operator reduces the volume of auditory Alarm Signals to zero (no sound pressure), the Alarm Signal inactivation state **Audio Off**

shall be indicated, unless ME Equipment is part of a Distributed Alarm System where the Alarm Signals are repeated at remote components of a Distributed Alarm System.
Compliance is checked by functional test

208.6.4.2 * **Delays** to or from a **Distributed Alarm System** - Addition: The Alarm Signal Generation Delay of Physiological Alarm Conditions and Technical Alarm Conditions at remote equipment **shall** be limited so that Patient treatment is not unacceptably delayed. Risk Management **shall** be applied to determine the **maximum** Alarm Signal delay time that is acceptable before presentation of Alarm Signals at remote components of a Distributed Alarm System.
Compliance is checked by inspection of the Risk Management File

208.6.6.1.102 **Resolution** of **Alarm Limit settings** The Alarm Limit settings **shall** be adjustable in steps **not exceeding** 2 mmHg below 100 mmHg and 5 mmHg above 100 mmHg.
Compliance is checked by inspection

208.6.6.1.103 **Time to alarm** for **pO2** and **pCO2** Alarm Conditions - The **Alarm Signal Generation Delay** for pO2 and pCO2 Alarm Signals **shall not exceed 15 s**.
*Compliance is checked by the following tests using the test setup of subclause 201.12.1.101.1: – Calibrate the ME Equipment according to the Accompanying Documents. – Apply test gas 1 and allow the readings to stabilize – Set the upper Alarm Limit for pO2 to a value above the pO2 reading of test gas 1 and the lower Alarm Limit for pO2 to a value between the pO2 reading of test gas 1 and test gas 2 – Apply test gas 2 and measure the time until the pO2 reading has under-run the lower Alarm Limit and the annunciation of Alarm Signals – Set the lower Alarm Limit for pO2 to a value below the pO2 reading of test gas 2 and the upper Alarm Limit for pO2 to a value between the pO2 reading of test gas 1 and test gas 2 Apply test gas 1 and measure the time until the pO2 reading has exceeded the upper Alarm Limit and the annunciation of Alarm Signals – Set the lower Alarm Limit for pCO2 to a value below the pCO2 reading of test gas 1 and the upper Alarm Limit for pCO2 to a value between the pCO2 reading of test gas 1 and test gas 2 – Apply test gas 2 and measure the time until the pCO2 reading has exceeded the upper Alarm Limit and the annunciation of Alarm Signals – Set the upper Alarm Limit for pCO2 to a value above the pCO2 reading of test gas 2 and the lower Alarm Limit for pCO2 to a value between the pCO2 reading of test gas 1 and test gas 2 – Apply test gas 1 and measure the time until the pCO2 reading has under-run the lower Alarm Limit and the annunciation of Alarm Signals The measured time interval **shall** not exceed 15 s*

208.6.6.1.104 * **Technical** Alarm Condition indicating inoperable ME Equipment - ME Equipment **shall** be provided with means to **indicate** that the ME Equipment is inoperable due to disconnected Transducer **within 10 s**.

208.6.6.1.105 **Assignment** of Alarm Condition **priority** - Alarm Signals of **Physiological** Alarm Conditions as specified in 208.6.6.1.101 **shall** be of **Medium** Priority.

208.6.8.101 * **Technical** Alarm Conditions - **Inactivation** of Alarm Signal (Alarm Paused and Alarm Off): a) **shall not** inactivate **visual** Alarm Signals of Technical Alarm Conditions that identify the specific Alarm Condition and its priority at a distance of **1 m** from the ME Equipment; b) **may** inactivate the **visual** Alarm Signal specified in subclause 6.3.2.2 b) of IEC 60601-1-8. In the case of a Technical Alarm Condition, any measured value(s) of the parameter(s) **shall** be displayed in such a way that the validity of the measured value(s) can be identified by the clinical Operator.
NOTE: During a Technical Alarm Condition, the physiological parameter(s) **might not** be capable of detecting Physiological Alarm Conditions
If the Transducer or modules are intentionally disconnected by the clinical Operator as specified by the Manufacturer, **Alarm Reset may disable** the **visual** Alarm Signal of those **Technical** Alarm Conditions. Such means **shall** be documented in the instructions for use (see 201.7.9.2.101 q)).
Compliance is checked by inspection

208.6.9 * **Alarm Reset** - Replacement: Means **shall** be provided for the clinical Operator to activate Alarm Reset of Alarm Signals. After activation of the Alarm Reset function a) the **auditory** Alarm Signals of **Physiological** Alarm Conditions **shall** cease, enabling the Alarm System to respond to a subsequent Alarm Condition. b) **visual** Alarm Signals for **Latching** Alarm Conditions that no longer exist **shall cease** (see 201.7.9.2.101 r) and 208.6.8.101). c) **visual** Alarm Signals for any existing Alarm Conditions **shall** continue as long as those Alarm Conditions exist. d) the Alarm System **shall** be enabled immediately so that it can respond to a subsequent Alarm Condition. e) the **visual** Alarm Signals of **Technical** Alarm Conditions **shall not cease** as long as the Technical Alarm Condition exists. The means of control of Alarm Reset **shall be marked** with symbol IEC 60417-5309 (2002-10) (see IEC 60601-1-8:2006 symbol 2 of Table C.1 and/or with the text string of marking 5 in Table C.2).
Compliance is checked by inspection

208.6.10 * **Non-Latching** and **Latching** Alarm Signals - Addition to the first paragraph: For ME Equipment that supports **mixtures** of Latching Alarm Signals and Non-Latching Alarm Signals, means **shall** be provided that allows the Responsible Organization to configure ME Equipment to have **all Latching** Alarm Signals or **all Non-Latching** Alarm Signals for **Physiological** Alarm Conditions and to restrict access to this configuration to the Responsible Organization...
NOTE: This requirement adds an additional configuration capability for use in intensive care units where the Responsible Organization needs Latching Alarm Signals for all Alarm Conditions
Compliance is checked by functional test

208.6.10.101 ***Non-Latching** Alarm Signals for **Technical** Alarm Conditions - Non-Latching Alarm Signals **shall** be assigned to **Technical** Alarm Conditions.

208.6.11 **Distributed Alarm System** 208.6.11.2.2 * **Failure** of **remote communication** of Alarm Conditions - Replacement of item b): b) **shall** create a **Technical** Alarm Condition in any affected parts of the Distributed Alarm System that can generate Alarm Signals. Addition: If, while the ME Equipment is in the Audio Off state, the ME Equipment detects a communication failure with the Distributed Alarm System, it **shall** terminate the Audio Off state and **shall** initiate a **Technical** Alarm Condition.

208.6.11.101 * **Inactivation/activation** of **Alarm Signals** at remote components of a **Distributed Alarm System** - If deemed acceptable by Risk Control for its intended environment of use, ME Equipment **may** be provided with means for the clinical Operator to activate and inactivate Alarm Signals of the ME Equipment or to change Alarm Limit Settings from remote components of a Distributed Alarm System by: **– enabling any inactivation states** that are configured on the ME Equipment (Alarm Paused, Audio Paused, Alarm Off or Audio Off) and **activating** the function **Alarm Reset** and **– termination** of the **inactivation state**. ME Equipment that provides means to remotely activate and inactivate Alarm Signals **shall** also provide means to configure (enable or disable) remote activation/inactivation for every provided inactivation state. To prevent the clinical Operator from changing that configuration, such means **shall** be restricted to the Responsible Organization (see 6.7 of IEC 60601-1-8:2006).
Compliance is checked by inspection

Subclause 201.7.9.2.101 q) - Alarm Signals of **Technical** Alarm Conditions are also indicated when Transducers, sensors, probes, or modules are intentionally disconnected by the clinical Operator because the ME Equipment **may** not distinguish between intentional and unintentional disconnection. In cases where a sensor, a probe, or a module is intentionally disconnected by the clinical Operator, a means is required that allows the Operator to **permanently** disable the **visual** Alarm Signals of those **Technical** Alarm Conditions.

Subclause 201.11.1.2.2.106 – **Indication** of **temperature deviation** in **Single Fault Condition** - To minimize the risk of thermal injury the ME Equipment **has to** alarm the Operator, if the actual temperature exceeds the Set Temperature by more than 0,6°C. The tolerance of 0,6°C is a compromise between increased Risk of thermal injury and the need to account for component tolerances and temperature overshoots caused by external disturbance and the corresponding reaction of the temperature regulator.

Subclause 201.11.8 – **Interruption** of **power supply**/Supply Mains to ME Equipment - Interruptions of the Supply Mains for **less than 30 s are mainly caused by switching to an emergency power supply**. Such power interruptions are considered **Normal Use** and consequently **should not** result in a Hazardous Situation to the Patient. When power returns, the ME Equipment needs to resume the same mode of operation, and restore all Operator settings and Patient data that were in use before the Supply Mains was interrupted. Examples of typical stored data that **may** impact Patient safety are operating mode, **Alarm Settings** (volume of auditory Alarm Signal, Alarm Limits, Alarm Off, etc.), and trend data. In contrast to these settings, the instantaneous pO2 and pCO2 or the displayed waveforms do not fall under stored data. ME Equipment without an Internal Electrical Power Source **may** not maintain the Set Temperature of the Transducer during interruption of the Supply Mains for less than 30 s. A **Technical** Alarm Condition notifies the clinical Operator that the Transducer is de-energized.

Subclause 208.6.1.2 – Alarm Condition **Priority** - The intersection of the 'Delayed' column and the 'Minor injury or discomfort' row in Table 1 of IEC 60601-1-8:2006 contains 'Low Priority or no Alarm Signal'. **Selection of 'no Alarm Signal' may be appropriate for these Alarm Conditions in environments of use where a clinical Operator continuously attends the Patient during Normal Use**. Such a selection is inappropriate for ME Equipment that is not continuously attended during Normal Use since failure to provide an auditory Alarm Signal effectively means that the Alarm System is disabled for those Alarm Conditions.

Subclause 208.6.3.3.1 – Characteristics of **auditory Alarm Signals** - An auditory **Alarm Signal** that only occurs once (or does not occur, per Table 1 of IEC 60601- 1-8:2006) **may be** appropriate for a **Low** Priority Alarm Condition in environments of use where the Patient is **continuously attended** by a clinical Operator in Normal Use. Such a selection is **inappropriate** for ME Equipment that is **not continuously attended** during Normal Use since not repeating the auditory Alarm Signals means that the Alarm Condition is not likely to be recognized.

Subclause 208.6.3.3.2.101 - **Volume** of auditory Alarm Signal reducible to **zero** - The **primary** Alarm Condition indicator that draws the attention to a clinical Operator is the **auditory** Alarm Signal **–** especially for ME Equipment that includes in its Intended Use/Intended Purpose monitoring of Patients that are not continuously attended by a clinical Operator. Typical environments of use where Patients are not continuously attended by health care professionals are intensive care units (ICU). Normally, a clinical Operator is caring for several Patients. Therefore, it is not possible to observe all Patient monitors at the same time to be aware of all visual Alarm Signals that are not associated with auditory Alarm Signals. In such an environment, reducing the volume of the auditory Alarm Signal to zero means that the Alarm System enters the Inactivation State 'Audio Off' that **must** be indicated. In such environments it is recommended to limit the adjustable volume of the auditory Alarm Signal to a minimum sound pressure. In a Distributed Alarm System where remote components of a Distributed Alarm System annunciate the Alarm Signal the volume of the auditory Alarm Signal **may** be reduced to zero (no sound pressure) depending on the use model (see second paragraph of rationale 208.6.11.101).

Subclause 208.6.4.2 – **Delays** to or from a **Distributed Alarm System** - Alarm generating ME Equipment annunciates Alarm Signals in response to Alarm Condition that it detects. If this ME Equipment is part of a Distributed Alarm System, the Distributed Alarm System **may** annunciate the Alarm Signals of that Alarm Condition at remote components of the Distributed Alarm System. It takes a finite amount of time for information related to an Alarm Condition to reach all components of a Distributed Alarm System. In many cases, this amount of time is very short, however, specific characteristics of a Distributed Alarm System can significantly delay annunciation of Alarm Signals at remote components of the Distributed Alarm System. Use models in intensive care units **may** require that remote equipment is operated as the primary *alarming* equipment (e.g. when the Alarm Signal generating ME Equipment is configured with the volume of its auditory Alarm Signal reduced to zero **–** no sound pressure). In such an environment of use the overall delay time before remote components of a Distributed Alarm System annunciate Alarm Signals **should** be limited to values that allow the clinician to respond to Physiological Alarm Conditions (such as cardiac arrest, ventricular fibrillation, high systolic pressure, etc.) in time. Inappropriate delay times for Alarm Signals in a Distributed Alarm System **may** delay treatment of Patients. It is strongly recommended that Risk Management be applied to identify adequate 'not to exceed' delay times of Alarm Signals to remote components of a Distributed Alarm System.

Subclause 208.6.8.101 – **Technical** Alarm Conditions - The Alarm Inactivation States Alarm Off and Alarm Paused support the functionality that is essential for Patient Monitoring Equipment: in both Alarm Inactivation States (Alarm Off and Alarm Paused), it is **necessary** for Transcutaneous Partial Pressure Monitoring Equipment that **visual** Alarm Signals of **Technical** Alarms Conditions are displayed. The purpose of these visual Alarm Signals is to inform the clinical Operator **–** even during the Alarm Inactivation States Alarm Off or Alarm Paused **–** that the ME Equipment (or a part of the ME Equipment) is not operating because a Technical Alarm Condition such as 'Transducer disconnected' interrupts the ECG monitoring of a Patient. A Technical Alarm Condition **may** influence the validity of a measured value. For instance, the Technical Alarm Condition 'Transducer disconnected' prevents the pO2 and pCO2, values from being calculated and displayed. Continuing to display the previously calculated pO2 and pCO2 values **may** lead to misinterpretations by the clinical Operator because this value is invalid during the Technical Alarm Condition. Appropriate means to indicate that the displayed pO2 and pCO2 values are invalid **might** be to display blank pO2 and pCO2 values or a symbol where these pO2 and pCO2 values are displayed.

Subclause 208.6.9 – **Alarm Reset** - The clinical Operator action Alarm Reset performs the following actions: First, it **stops** the **auditory** Alarm Signal. Second, it **stops visual Latching** Alarm Signals of Alarm Conditions that **no longer exist**. Third, it **does not affect visual** Alarm Signals for Alarm Conditions that **continue to exist** (those signals continue until the Alarm Conditions ceases). Fourth, it enables the Alarm System immediately to respond to a subsequent Alarm Condition. The fourth action 'enabling the Alarm System immediately' distinguishes the function Alarm Reset from the Alarm Inactivation States Alarm Paused, Audio Paused, Alarm Off and Audio Off. In contrast to the Alarm Inactivation States Alarm Paused, Audio Paused, Alarm Off and Audio Off that temporarily or permanently disable the Alarm System of ME Equipment, the function (clinical Operator action) Alarm Reset maintains the Alarm System in the 'ON'-state but applies the functions that are specified in subclause 208.6.9 a) to e). This stops the auditory Alarm Signals, controls the visual Alarm Signals depending on an existing or ceased Alarm Condition, and **–** as outlined before **–** keeps the Alarm System enabled. As a result, the Alarm System can respond immediately to a subsequent Alarm Condition without requiring additional clinical Operator actions to activate the Alarm System again. This also explains why Audio Paused is not the appropriate state because it does not allow the related control to perform these functions of Alarm Reset. With the function Alarm Reset the

clinical Operator acknowledges an active Alarm Condition once and does not need to be concerned about activating the Alarm System again because the Alarm System remains in the 'ON'-state. As a result the function Alarm Reset avoids the possibility that the clinical Operator **might** forget to activate the Alarm System again. In environments of use where Patients are not continuously attended by a clinical Operator, such as in intensive care units, this function is an essential requirement for the safety of Patients.

Subclause 208.6.10 – **Non-Latching** and **Latching** Alarm Signals- Different use models exist for ME Equipment that 1) is continually attended by a clinical Operator (such as in operating theatres/rooms) and 2) is not continually attended by a clinical Operator (such as in an ICU). In environments of use such as an ICU or emergency department, where Patients are not continuously attended, a clinical Operator normally cares for several Patients. Clinical Operator who are caring for several Patients cannot observe all of their Patients at the same time. Clinical Operator cannot easily identify short Alarm Conditions that occur on ME Equipment that provides Non-Latching Alarm Signals or for mixes of Non-Latching and Latching Alarm Signals. This inability to identify and quickly respond to important short Alarm Conditions (e.g., short tachycardias) puts Patients in Hazardous Situations. Configuring ME Equipment to only provide Latching Alarm Signals, forces clinical Operators to respond to every Alarm Condition. While this is conceptually a good idea, frequent false Alarm Conditions due to artefact or improperly set Alarm Limits can place a substantial administrative burden on the clinical Operator. **Latching** Alarm Signals **may be** desirable within **Distributed Alarm Systems** where remote equipment of an ME System is **not continuously attended** by a clinical Operator. **Non-Latching** Alarm Signals **may** be desirable in an environment of use where the ME Equipment is **continuously attended** by a clinical Operator**.**

Subclause 208.6.10.101 – **Non-Latching** Alarm Signals for **Technical** Alarm Conditions - A Technical Alarm Condition indicates that a physiological measurement is not ready or has been interrupted for technical reasons. Such technical interruptions of a measurement **may** be caused by an unintentional disconnection of a Transducer or a sensor. For instance, the Technical Alarm Condition indicating that the Transducer is disconnected prevents the pO2 and pCO2 values from being calculated and displayed. This implies that the pO2 and pCO2 values are not being monitored and as consequence potential Alarm Conditions **may** not be indicated. Requiring Non-Latching Alarm Signals for Technical Alarm Conditions means those Alarm Signals are being displayed as long as the Alarm Condition exists and cease without clinical Operator interaction when the Transducer is reconnected.

Subclause 208.6.11.2.2 – **Failure** of **remote communication** of Alarm Conditions - ME Equipment as part of a Distributed Alarm System is essential for reliable alarming in an unattended environment of use. For that reason ME Equipment that falls under the scope of this particular standard **has to** be so designed that it detects a communication failure and indicates the Alarm Signals of the corresponding **Technical** Alarm Condition. Labelling of such an ME Equipment with a warning to the effect that it **shall not** be relied upon for receipt of Alarm Signals is **not** appropriate to mitigate the Risk of critically ill Patients they are exposed to. The revised requirement 208.6.11.2.2 b) does only apply for ME Equipment that falls under the scope of this particular standard. The same applies of the entire content of this particular standard. Other components or parts of a Distributed Alarm System such as handheld devices, paging systems or even cellular phones **do not** fall under the **scope** of this particular standard; for those devices IEC 60601-1-8 applies.

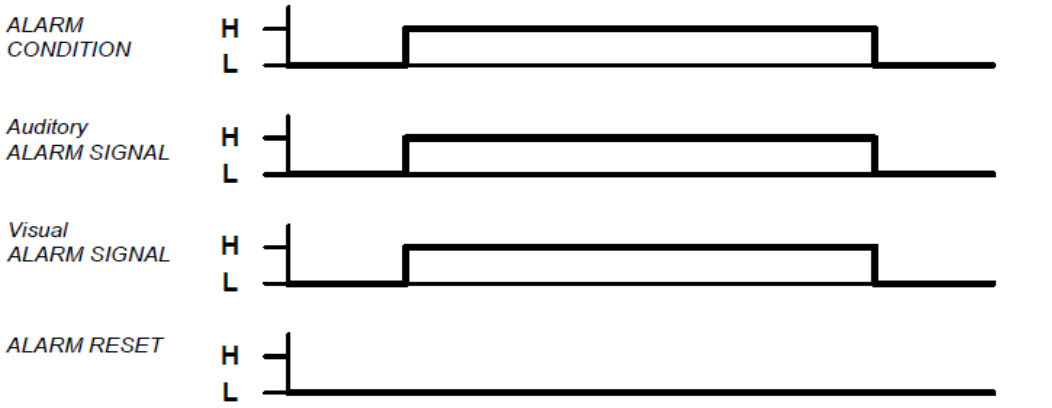
Subclause 208.6.11.101 **Inactivation/Activation** of Alarm Signals at remote components of a **Distributed Alarm System –** A Distributed Alarm System duplicates Alarm Signals at remote components of a Distributed Alarm System such as a central station. Depending on the use model where the remote

components of a Distributed Alarm System are being actively used as part of a Distributed Alarm System it makes sense to activate/terminate the inactivation state Alarm Paused, Audio Paused, Alarm Off or Audio Off (depending on the configuration) and to activate Alarm Reset at remote components of a Distributed Alarm System. As indicated before, this remote control functionality depends on the use model in certain environments of use such as in intensive care units. For this reason, only the Responsible Organization **should have** access to the corresponding configuration. The configuration that enables the function of remote activation and termination of global inactivation states (Alarm Paused, Audio Paused, Alarm Off or Audio Off) and remote activation of **must** be protected. '**Protected**' means that the clinical Operator of the ME Equipment **must not** have access in Normal Use to the selection of the capability to activate and terminate global inactivation states (Alarm Paused, Audio Paused, Alarm Off or Audio Off) and activation of Alarm Reset at remote components of a Distributed Alarm System. Adequate protection mechanisms are described in subclause 6.7 of IEC 60601-1-8:2006.

Annex BB
(informative)

Alarm diagrams of Clause 208/IEC 60601-1-8:2006

The following alarm status diagrams illustrate the auditory and visual ALARM SIGNALS for LATCHING and NON-LATCHING ALARM SIGNALS as defined in subclause 6.10 of IEC 60601-1-8:2006 and subclause 208.6.9 of this particular standard.



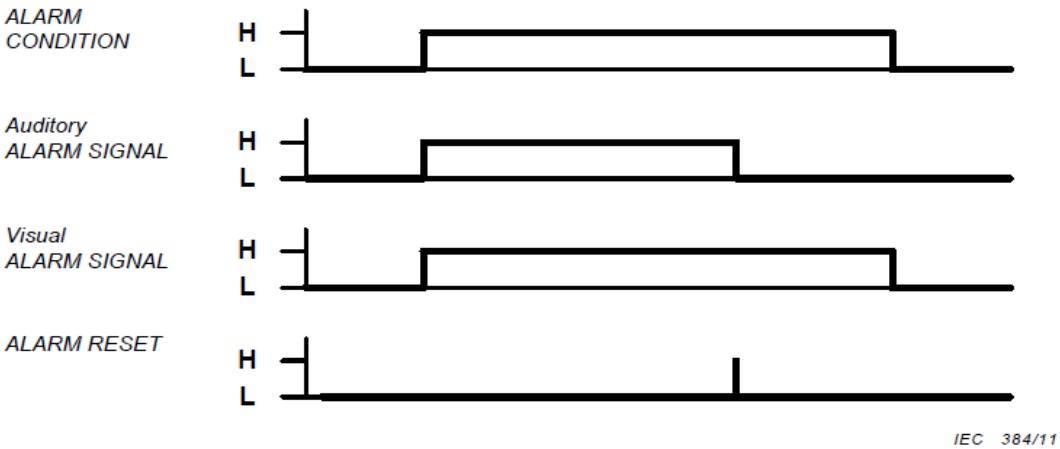
Key

H Activated state

L Deactivated state

Figure BB.1 – NON-LATCHING ALARM SIGNALS without ALARM RESET

Illustration of NON-LATCHING ALARM SIGNALS (Figure BB.1) as specified in IEC 60601-1-8 subclause 6.10: without OPERATOR interaction, the auditory and visual ALARM SIGNALS are indicated as long as the ALARM CONDITION exists. As soon as the ALARM CONDITION ceases, the auditory and visual ALARM SIGNALS are terminated automatically without any OPERATOR interaction.



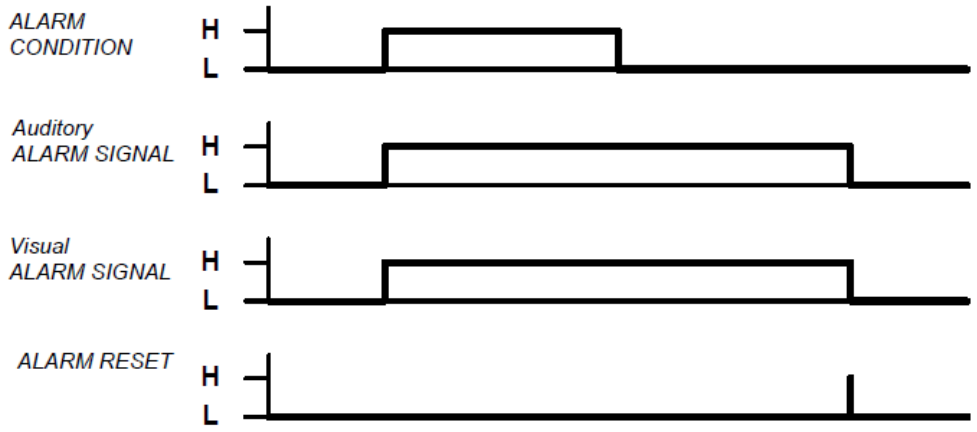
Key

H Activated state

L Deactivated state

Figure BB.2 – NON-LATCHING ALARM SIGNALS with ALARM RESET

Illustration of LATCHING ALARM SIGNALS with ALARM RESET (Figure BB.2) as specified in IEC 60601-1-8 subclause 6.10 and in subclause 208.6.9 of this particular standard: activating ALARM RESET stops the auditory ALARM SIGNAL. As soon as the ALARM CONDITION ceases the visual ALARM SIGNAL is terminated.



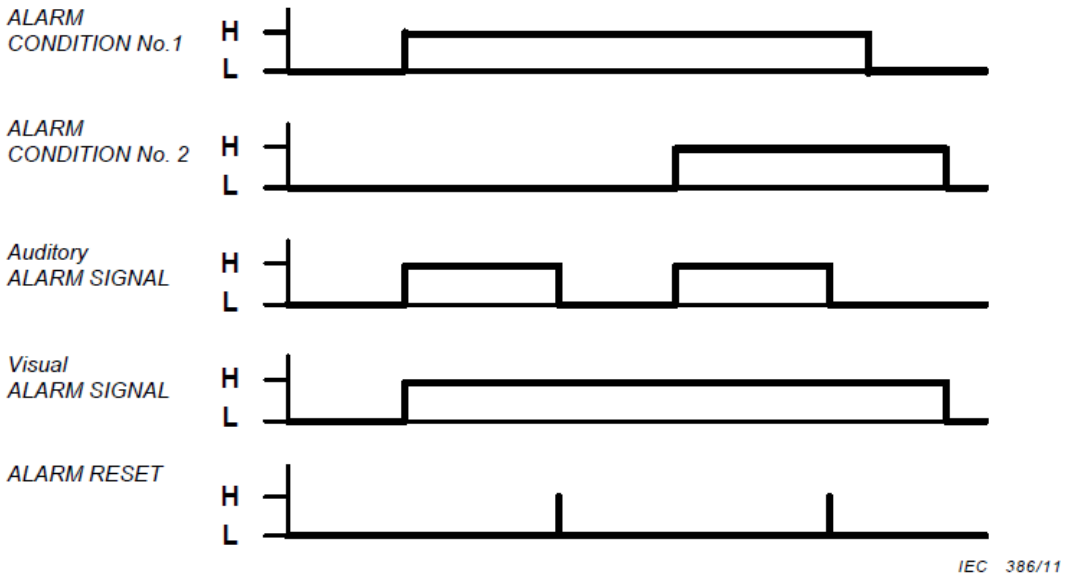
Key

H Activated state

L Deactivated state

Figure BB.3 – LATCHING ALARM SIGNALS with ALARM RESET

Illustration of LATCHING ALARM SIGNALS with ALARM RESET (Figure BB.3) as specified in IEC 60601-1-8 subclause 6.10 and in subclause 208.6.9 of this particular standard: without OPERATOR interaction, the auditory and visual ALARM SIGNALS are activated for an unlimited time. The OPERATOR is forced to reset the ALARM SIGNALS of a PHYSIOLOGICAL ALARM CONDITION by activating the function ALARM RESET. After activating ALARM RESET the alarm behaviour compares to NON-LATCHING ALARM SIGNALS.



Key

H Activated state

L Deactivated state

Figure BB.4 – TWO ALARM CONDITIONS with ALARM RESET

IEC 60601-2-24 Edition 2.0 2012-10 Particular requirements for the Basic Safety and Essential Performance of **Infusion Pumps and Controllers**

201.7.9.2.101 Additional **instructions for use** - The instructions for use **shall** also include the following: **–** a statement of the Occlusion Alarm Condition **Threshold** of the ME Equipment; **–** a statement of the **maximum time** for activation of the occlusion Alarm Signal when the ME Equipment is operating at the Minimum Rate, Intermediate Rate and the Minimum Selectable Rate and at the **minimum** and **maximum** selectable Occlusion Alarm Condition Threshold (see 201.12.4.4.104). The Manufacturer **shall** also state that temperature and l length of Administration Set affect the time, if applicable; **–** a statement of the Unintended Bolus at the Intermediate Rate at the minimum and maximum Occlusion **Alarm Thresholds** (see also 201.12.4.4.104); **–** a **list** of Alarm **Signals** and their operating **conditions**; **–** the rate obtained when the prime/purge or Bolus control is operated, and a **statement** of any Alarm Signal disabled; **–** if applicable, **guidance** on tests to permit the Operator to check the **correct functioning** of Alarm Signals and the operational safety of the ME Equipment;

201.11.8.101.1 Supply **Mains interruption Technical** Alarm Condition - For ME Equipment that is powered from the Supply Mains **only**, if the ME Equipment is in operation and there is an accidental disconnection or failure of the Supply Mains the ME Equipment **shall** give an Alarm Signal of **Low** Priority. Under that condition, the Alarm Signal **shall** be maintained for at least **3 min or until power is restored**, whichever is the less.
NOTE: Medical Equipment **may** stop infusion
Compliance is checked by inspection and functional tests

201.11.8.101.2 Internal Electrical **Power Source depletion Technical** Alarm Condition - ME Equipment which utilizes an Internal Electrical Power Source either as a primary or standby supply **shall** give an Alarm Signal of **Low** Priority at least **30 min** before delivery ceases due to battery exhaustion. The **visual** Alarm Signal indication **does not** apply to Infusion Pumps for Ambulatory Use e.g. using insulin.
Compliance is checked by inspection and functional tests when the ME Equipment is operated at the Intermediate Rate and with a new and fully charged battery
If the Supply Mains and the Internal Electrical Power Source **both fail** the ME Equipment **shall** give an Alarm Signal of **High** Priority and cease delivery. The Alarm Signal **shall** be maintained for the duration of at least **3 min**. This requirement does not apply to Infusion Pumps for Ambulatory Use e.g. using insulin.
Compliance is checked by inspection and functional test

201.12.4.4.101 **Protection against overinfusion** - Means **shall** be provided in the ME Equipment to protect against overinfusion under Single Fault Conditions. An **Alarm Signal** according to Table 208.101 **shall** be initiated in the event of overinfusion and the ME Equipment **shall** either cease delivery of infusion liquid or reduce the delivery rate to the Keep Open Rate or less. Single Fault Conditions occurring in those protective systems specified **shall** become obvious to the Operator within the Administration Set Change Interval.
Compliance is checked by inspection and functional tests

201.12.4.4.104 **Protection against Unintended Bolus volumes** and by **occlusion** - **Means shall** be provided in the ME Equipment to protect the Patient from underinfusion resulting from occlusion.
NOTE: An acceptable method of complying with this requirement is at Occlusion Alarm Threshold to activate an Alarm Signal of **High** Priority and terminate the infusion liquid flow
Means shall be provided in the ME Equipment to protect the Patient from Unintended Bolus following activation of the **Alarm Signal for occlusion**.

201.12.4.4.106 ME Equipment and **drop sensor** orientation - This test applies only to Infusion Pumps with a particular Accessory (drop sensor), Safe operation of the ME Equipment **shall not** be affected by: **–** the mispositioning or removal of a drop sensor, and **–** operating the ME Equipment with a tilted or incorrectly filled drop chamber. Under these conditions the ME Equipment **shall** either: **–** maintain the accuracy of delivery, or **–** stop the flow and generate an **Alarm Signal** according to Table 208.101.

201.12.4.4.107 *Protection against **air infusion** - This requirement does not apply to Infusion Pumps For Ambulatory Use using a subcutaneous access, Enteral Nutrition Pumps and Syringe or Container Pumps. The ME Equipment **shall** protect the Patient from air infusion which can cause an unacceptable Risk due to air embolism.
Compliance is checked by inspection and functional tests in accordance with the Manufacturer's specification (see first dashed item of 201.7.9.3.101)
After the initiation of an **Alarm Signal** for **Air detection** Alarm Condition, it **shall not** be possible to recommence liquid delivery by a single action.
Compliance is checked by inspection and functional test

201.15.101 **Fitting** of the **syringe/container** - If a syringe/container can be fitted by the Operator, means **shall** be provided to ensure correct clamping and location of a syringe/container and pumping mechanism to prevent Free Flow. In the event of incorrect location of a syringe/container the pump **shall not** start and an **Alarm Signal** according to Table 208.101 **shall** be activated.

201.15.102 **Fitting** of the **Administration Set** - Where appropriate, means **shall** be provided to ensure correct fitting of the Administration Set into the ME Equipment. In the event of incorrect location of the Administration Set the Infusion Pump **shall not** start and deliver fluid and an Alarm Signal according to Table 208.101 **shall** be activated.

201.15.103 ***Use errors** - At least two distinctive and separate actions **shall** be required before Free Flow can occur in Normal Use. The first action **shall** stop the flow and initiate an **Alarm Signal** according to Table 208.101

Table 208.101 – ALARM CONDITION priorities and related situations

Situation	For type of ME EQUIPMENT	ALARM CONDITION priority	Auditory	Visual
ME EQUIPMENT FAILURE	All types of pumps	HIGH PRIORITY	Yes	Yes
Prior end of infusion alarm	SYRINGE OR CONTAINER PUMP, PROFILE PUMP	LOW PRIORITY	Repeating Between 15 s and 30 s interburst interval Three tones Acknowledged by AUDIO PAUSED by a single action of OPERATOR REMINDER SIGNAL.	Yes
End of infusion alarm	PROFILE PUMP SYRINGE OR CONTAINER PUMP, VOLUMETRIC INFUSION CONTROLLER VOLUMETRIC INFUSION PUMP	HIGH PRIORITY	Yes	Yes
Occlusion alarm	PROFILE PUMP, SYRINGE OR CONTAINER PUMP, VOLUMETRIC INFUSION CONTROLLER VOLUMETRIC INFUSION PUMP	HIGH PRIORITY	Yes	Yes
Air in line alarm	PROFILE PUMP, VOLUMETRIC INFUSION CONTROLLER VOLUMETRIC INFUSION PUMP	HIGH PRIORITY	Yes	Yes
Battery alarm	PROFILE PUMP SYRINGE OR CONTAINER PUMP, VOLUMETRIC INFUSION CONTROLLER, VOLUMETRIC INFUSION PUMP ENTERAL NUTRITION PUMP	LOW PRIORITY	Repeating Between 15 s and 30 s interburst interval Three tones Acknowledged by AUDIO PAUSED by on single action of OPERATOR REMINDER SIGNAL.	Yes

Situation	For type of ME EQUIPMENT	ALARM CONDITION priority	Auditory	Visual
ME EQUIPMENT FAILURE	All types of pumps	HIGH PRIORITY	Yes	Yes
No action with the pump	PROFILE PUMP, SYRINGE OR CONTAINER PUMP, VOLUMETRIC INFUSION CONTROLLER, VOLUMETRIC INFUSION PUMP	LOW PRIORITY	Repeating Between 15s and 30s interburst interval Three tones Acknowledged by AUDIO PAUSED by on single action of OPERATOR REMINDER SIGNAL.	Yes

Table 208.102 – * Characteristics of the PULSE of auditory ALARM SIGNALS

Characteristic	Value
PULSE FREQUENCY (f_o)	150 Hz to 3 000 Hz
Number of harmonic components in the range 300 Hz to 4 000 Hz	Minimum 1
Effective PULSE duration (t_d) HIGH PRIORITY MEDIUM and LOW PRIORITY	 75 ms to 200 ms 125 ms to 250 ms
RISE TIME (t_r)	10 % – 20 % of t_d
FALL TIME[a] (t_f)	$t_f \leq t_s - t_r$
NOTE The relative sound pressure level of the harmonic components should be within 15 dB above or below amplitude at the PULSE FREQUENCY.	
[a] Prevents overlap of PULSES.	

208.6.3.3.2.101 **Volume** of auditory Alarm Signals - For other than Infusion Pumps For Ambulatory Use, unless the Infusion Pump is connected to a Distributed Alarm System that is providing auditory Alarm Signals, the volume of auditory Alarm Signals **shall** generate a sound-pressure level of at least **45 dB(A)** at **1 m**, and **shall not** be adjustable by the Operator without the use of a Tool below **45 dB(A)** at **1 m**. For Infusion Pumps For Ambulatory Use, the volume of auditory Alarm Signals **shall** generate a sound-pressure level of at least **45 dB(A)** at **1 m**, and **shall not** be adjustable without either the use of a Tool or by special means by the Operator.

208.6.3.3.2.102 * **Audio Paused period** - The duration of Audio Paused required by this standard **shall not exceed 120 s** without Operator intervention. This requirement **does not** apply to Infusion Pumps For Ambulatory Use.

NOTE: **This permits an Operator to extend deliberately the duration of Audio Paused by direct action**

For Infusion Pumps For Ambulatory Use the maximum time for Audio Paused is specified according to the **Risk Assessment** of the Manufacturer the Audio Paused **shall** be indicated **visually** during the Audio Paused period.

Compliance is checked by inspection and functional test

IEC 60601-2-27 Edition 3.0 2011-03 Particular requirements for the Basic Safety and Essential Performance of **Electrocardiographic Monitoring Equipment**

201.7.9.2.9.101 Additional **instructions for use** - a) The operating instructions **shall** include the following: 7) * advice regarding **testing** of the ME Equipment and Accessories on a daily basis (by the clinical Operator) and on a scheduled basis (as a service activity). Emphasis **should** be placed on how the clinician **may** test **visual** and **auditory** Alarm Signals; 8) explanation of **Technical** Alarm Conditions (see 208.6.8.101); 10) the **default settings** (e.g. Alarm Settings, modes, and filter); 11) the configuration procedure that allows the Alarm Signal **Inactivation States** (Alarm Paused, Audio Paused, Alarm Off, Audio Off) and the function **Alarm Reset** to be controlled remotely (see 208.6.11.101), if provided; 15) description of how to **disable** Alarm Signals for **Technical** Alarm Conditions if Lead Wires or modules are **intentionally disconnected** by the clinical Operator; 16) advice on the preferred Alarm **Settings** and **configurations** of the Alarm System when its Intended Use includes the monitoring of Patients that are not continuously attended by a clinical Operator. 6) **Time to alarm** for tachycardia. Disclosure **shall** be made of the time to alarm for the two ventricular tachycardia waveforms B1 and B2 shown in Figure 201.101, following a normal 80 1/min rate with the upper Alarm Limit set closest to 100 1/min and the lower Alarm Limit set closest to 60 1/min. Disclosure **shall** also be made of ME Equipment failure to alarm on either of these waveforms. In addition, the time to alarm **shall** be disclosed for these waveforms when their amplitudes are one-half and twice the indicated amplitudes. 8) **Visual** and **auditory** Alarm Signal disclosure. The Manufacturer **shall** disclose the **location** where Alarm Signals are displayed (i.e., central station, bedside, or both), **colour, size,** and **modulation** (flashing), and the **frequency** or other descriptive characteristics of the sounds.

201.11.8.101 * Protection against **depletion** of **battery** - ME Equipment powered from an Internal Electrical Power Source **shall not** cause a Hazardous Situation to the Patient when the state of discharge can no longer maintain the Normal Use of the ME Equipment. The ME Equipment **shall** provide a **Technical** Alarm Condition to inform the clinical Operator about the state of discharge and **shall** power down in a controlled manner as follows: a) The ME Equipment **shall** provide a **Technical** Alarm Condition at least **5 min** prior to the time that the ME Equipment can no longer function in accordance with the Manufacturer's specification when powered from the Internal Electrical Power Source.
Compliance is checked by functional test

208.6.1.2 * Alarm Condition **Priority** - Addition: ME Equipment that includes in its Intended Use monitoring of Patients that are not continuously attended by a clinical Operator in Normal Use **shall** treat Alarm Conditions that **may** result in minor injury and delayed onset of potential Harm as **Low** Priority Alarm Conditions (see Table 208.101). The Accompanying Document **shall** describe how the Responsible Organization **may** enable or disable auditory Alarm Signals for **Low** Priority Alarm Conditions. The requirements of 6.7 of IEC 60601-1-8:2006 apply.
NOTE: This adaptation of Table 1 of IEC 60601-1-8:2006 necessitated an additional configuration capability for this ME Equipment. This capability is **necessary** when the Responsible Organization needs auditory Alarm Signals for Low Priority Alarm Conditions such as for intensive care units when central monitoring is not being used

Table 208.101 modifies Table 1 – Alarm Condition **Priorities**, for ME Equipment that includes in its Intended Use monitoring of Patients that are not continuously attended by a clinical Operator in Normal Use:

Table 208.101 – ALARM CONDITION priorities *for ME EQUIPMENT that includes in its INTENDED USE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR*

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of potential HARM [a]		
	Immediate [b]	Prompt [c]	Delayed [d]
Death or irreversible injury	HIGH PRIORITY [e]	HIGH PRIORITY	MEDIUM PRIORITY
Reversible injury	HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
Minor injury or discomfort	MEDIUM PRIORITY	LOW PRIORITY	LOW PRIORITY

[a] Onset of potential HARM refers to when an injury occurs and not to when it is manifested.

[b] Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.

[c] Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

[d] Having the potential for the event to develop within an unspecified time greater than that given under "prompt".

[e] Where practicable, ME EQUIPMENT with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the ME EQUIPMENT. See also appropriate particular standards.

208.6.3.3.1 * Characteristics of **Auditory** Alarm Signals - Addition: For ME Equipment that includes in its Intended Use monitoring of Patients that are not continuously attended by a clinical Operator in Normal Use: **– Auditory** Alarm Signals **shall** annunciate for **Low** Priority Alarm Conditions (delete footnote "d" from Table 3 of IEC 60601-1-8:2006). **–** Replace "> 15 s or no repeat" with "2,5 s to 30,0 s" in the "Low Priority Alarm Signal" column of Table 3 of IEC 60601-1-8:2006. **–** Auditory Alarm Signals **shall** annunciate for **Technical** Alarm Conditions. Table 208.102 modifies Table 3 **–** Characteristics of the **burst** of **auditory** Alarm Signals, for ME Equipment that includes in its Intended Use monitoring of Patients that are **not continuously attended** by a clinical Operator in Normal Use:

Table 208.102 – Characteristics of the BURST of auditory ALARM SIGNALS for ME EQUIPMENT that includes in its INTENDED USE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR

Characteristic	HIGH PRIORITY ALARM SIGNAL	MEDIUM PRIORITY ALARM SIGNAL	LOW PRIORITY ALARM SIGNAL
Number of PULSES in BURST [a, e]	10	3	1 or 2
PULSE spacing (t_s) (see Table 208.101)			
between 1st and 2nd PULSE	x	y	y
between 2nd and 3rd PULSE	x	y	Not applicable
between 3rd and 4th PULSE	$2x + t_d$	Not applicable	Not applicable
between 4th and 5th PULSE	x	Not applicable	Not applicable
between 5th and 6th PULSE	0,35 s to 1,30 s	Not applicable	Not applicable
between 6th and 7th PULSE	x	Not applicable	Not applicable
between 7th and 8th PULSE	x	Not applicable	Not applicable
between 8th and 9th PULSE	$2x + t_d$	Not applicable	Not applicable
between 9th and 10th PULSE	x	Not applicable	Not applicable
INTERBURST INTERVAL [b, c] (t_b)	2,5 s to 15,0 s	2,5 s to 30,0 s	>15 s to 60 s
Difference in amplitude between any two PULSES	Maximum 10 dB	Maximum 10 dB	Maximum 10 dB
Where x shall be a value between 50 ms and 125 ms. Where y shall be a value between 125 ms and 250 ms. The variation of x and y within a BURST shall be ± 5 %. MEDIUM PRIORITY $t_d + y$ shall be greater than or equal to HIGH PRIORITY $t_d + x$.			
[a] See also Table 4 of IEC 60601-1-8:2006 for characteristics of the PULSE. [b] Unless otherwise specified in a particular standard for a particular ME EQUIPMENT. [c] MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application. Long INTERBURST INTERVALS can under certain conditions negatively affect the ability to correctly discern, in a timely manner, the source of the ALARM CONDITION. [e] Unless inactivated by the clinical OPERATOR, MEDIUM PRIORITY and LOW PRIORITY auditory ALARM SIGNALS shall complete at least one BURST, and HIGH PRIORITY auditory ALARM SIGNALS shall complete at least half of one BURST.			

The Accompanying Documents **shall** describe how the Responsible Organization **may** enable or disable **auditory** Alarm Signals for **Low** Priority Alarm Conditions and **may** restrict access to control over the **Interburst Interval** for all **auditory** Alarm Signals. The requirements of 6.7 of IEC 60601-1-8:2006 apply.

NOTE: This adaptation of Table 3 of IEC 60601-1-8:2006 necessitated an additional configuration capability for this ME Equipment. This capability is **necessary** when the Responsible Organization needs auditory Alarm Signals for Low Priority Alarm Conditions such as for intensive care units when central monitoring is not being used. Risk Management **shall** be applied to determine the maximum Interburst Interval for auditory Alarm Signals associated with High, Medium, and Low Priority Alarm Conditions

Compliance is checked by inspection of the Risk Management File

208.6.3.3.2.101 * **Volume** of auditory Alarm Signals reducible to **zero** - If the clinical Operator reduces the **volume** of auditory Alarm Signals to **zero** (no sound pressure), the Alarm Signal's Inactivation State **Audio Off shall be indicated**, unless ME Equipment is part of a Distributed Alarm System where the Alarm Signals

are repeated at remote components of a Distributed Alarm System.
Compliance is checked by functional test

208.6.4.2 * **Delays** to or from a **Distributed Alarm System** - Addition: The Alarm Signal Generation Delay of Physiological Alarm Conditions **and** Technical Alarm Conditions at remote components of a Distributed Alarm System **shall** be limited so that Patient treatment is **not unacceptably delayed**. Risk Management **shall** be applied to determine the **maximum** Alarm Signal **delay** time that is acceptable before presentation of Alarm Signals at remote components of a Distributed Alarm System.
Compliance is checked by inspection of the Risk Management File

208.6.6.2.101 Adjustment **range** of heart rate **Alarm Limits** - ME Equipment **shall** be equipped with means to adjust upper and lower heart rate Alarm Limits. For **adult** Patients, the upper Alarm Limit settings **shall** be adjustable to at least between 100 1/min and 200 1/min and the lower Alarm Limit settings **shall** be adjustable at least between 30 1/min and 100 1/min. For **neonatal** and **paediatric** Patients, the upper Alarm Limit settings **shall** be adjustable at least between 100 1/min and 250 1/min and the lower Alarm Limit settings **shall** be adjustable at least between 30 1/min and 150 1/min.
Compliance is checked by inspection

208.6.6.2.102 Resolution of **Alarm Limit** Settings - The Alarm Limit settings **shall** be adjustable in steps **not exceeding ±5 1/min**.
Compliance is checked by inspection

208.6.6.2.103 **Time to alarm** for heart rate **Alarm Conditions** - The Alarm Signal Generation Delay for cardiac standstill (asystole) **shall not** exceed **10 s**. The sum of Alarm Condition Delay and Alarm Signal Generation Delay for Alarm Signals for low heart rate or high heart rate Alarm Conditions **shall not** exceed **10 s**.
*Compliance is checked by the following tests: For all tests, a simulated ECG signal of 1 mV QRS amplitude and 70 ms QRS duration is applied. The deviation of the input heart rate from the nominal value **shall** be less than 5 %. Low heart rate Alarm Condition: Set the heart rate to 80 1/min and the lower Alarm Limit to 60 1/min. Change the heart rate in a step function manner from 80 1/min to 40 1/min. Measure the time interval between the heart rate change and the time that the Alarm Signals indicate that low limit Alarm Condition. High heart rate Alarm Condition: Set the heart rate to 80 1/min and the upper Alarm Limit to 100 1/min. Change the heart rate in a step function manner from 80 1/min to 120 1/min. Measure the time interval between the heart rate change and when Alarm Signals indicate that high limit Alarm Condition. Cardiac standstill: Set the heart rate to 80 1/min and the lower Alarm Limit to 60 1/min. Change the heart rate in a step function manner from 80 1/min to 0 1/min. Measure the time interval between the heart rate change and when Alarm Signals indicate the cardiac standstill Alarm Condition*

208.6.6.2.104 * **Technical** Alarm Condition indicating inoperable ME Equipment - ME Equipment **shall** be provided with means to indicate **within 10 s** that the ME **Equipment is inoperable due to an overload or saturation** of any part of the ECG amplifier and due to disconnected ECG Lead Wires.
Compliance is checked by the following test using the test circuit of Figure 201.105. Set the Gain to 10 mm/mV and the sweep speed to 25 mm/s. Close switches S, S2 and set S4 in position B. Connect the signal generator between the R (RA) Lead Wire and all other Lead Wires connected to the N (RL) Lead Wire. In series with the signal generator, connect a d.c. power supply capable of providing a –5 V to +5 V output. Adjust the signal generator to provide a 10 Hz signal. Apply a 10 Hz, 1 mV signal superimposed on a d.c. voltage variable from –5 V to +5 V. Starting from zero, increase the d.c. voltage at a rate of approximately 1 V/s in increments from 0 V to +5 V and –5 V, using any deblocking facility of the ME Equipment to restore the trace. If the 10 Hz signal is not visible within 10 s, with an amplitude of at least 0,5 mV referred to the input, verify that a Technical Alarm Condition indicates that the ME Equipment is inoperable. Disconnect all Lead Wires. Verify that within 10 s a Technical Alarm Condition indicates that the ME Equipment is inoperable

208.6.6.2.105 Assignment of Alarm Condition **priority** - Alarm Signals of heart rate Alarm Conditions **shall** be at least of **Medium** Priority. The **Physiological** Alarm Conditions cardiac standstill (asystole), ventricular

tachycardia and ventricular fibrillation **shall** be of **High Priority**. Priorities of other **Physiological** Alarm Conditions such as arrhythmias (VPCs, ventricular bigeminy or irregular HR etc.) or whether those events **may** be treated as Information Signals **shall** be determined by **Risk Management**.
Compliance is checked by inspection and functional tests

208.6.8.101 * **Technical** Alarm Conditions - **Inactivation** of Alarm Signals (Alarm Paused, and Alarm Off) a) **shall not inactivate visual** Alarm Signals of **Technical** Alarm Conditions that identify the specific Alarm Condition and its priority at a distance of **1 m** from the ME Equipment; b) **may inactivate** the visual Alarm Signal specified in subclause 6.3.2.2 b) of IEC 60601-1-8. In the case of a **Technical** Alarm Condition the any measured value(s) of the parameter(s) **shall** be displayed in such a way that the validity of the measured value(s) can be identified by the clinical Operator.
NOTE: During a Technical Alarm Condition, the physiological parameter(s) **might not** be capable of detecting Physiological Alarm Conditions
If Lead Wires, Patient Cable or modules are **intentionally disconnected** by the clinical Operator as specified by the Manufacturer, **Alarm Reset may** be used to **disable** the **visual** Alarm Signal of those **Technica**l Alarm Conditions. Such means **shall** be documented in the instructions for use (see subclause 201.7.9.2.9.101 a) 14).
Compliance is checked by inspection and functional tests

208.6.9 * **Alarm Reset** - Replacement: Means **shall** be provided for the clinical Operator to activate **Alarm Reset** of Alarm Signals. After activation of the Alarm Reset function a) the auditory Alarm Signals of **Physiological** Alarm Conditions **shall** cease, enabling the Alarm System to respond to a subsequent Alarm Condition. b) **visual** Alarm Signals for **Latching** Alarm Conditions that no longer exist **shall** cease (see 201.7.9.2.9.101 14) and 208.6.8.101)). c) **visual** Alarm Signals for any existing Alarm Conditions **shall** continue as long as those Alarm Conditions exist. d) the Alarm System **shall** be enabled immediately so that it can respond to a subsequent Alarm Condition. e) the **visual** Alarm Signals of **Technical** Alarm Conditions **shall not** cease as long as the technical Alarm Condition exists. The means of control of Alarm Reset **shall** be marked with symbol IEC 60417-5309 (2002-10) (see IEC 60601-1-8-2006 symbol 2 of Table C.1 and/or with the text string of marking 5 in Table C.2.).
Compliance is checked by inspection

208.6.10 * **Non-Latching** and **Latching** Alarm Signals - Addition to the first paragraph: For ME Equipment that supports **mixtures** of Latching Alarm Signals and Non-Latching Alarm Signals, **means shall** be provided that allows the Responsible Organization to configure ME Equipment to have **all Latching** Alarm Signals or **all Non-Latching** Alarm Signals for **Physiological** Alarm Conditions and to restrict access to this configuration to the Responsible Organization.
NOTE: This requirement adds an additional configuration capability for use in intensive care units where the Responsible Organization needs Latching Alarm Signals for **all** Alarm Conditions.
Compliance is checked by functional test

208.6.10.101 * **Non-Latching** Alarm Signals for **Technical** Alarm Conditions- Non-Latching Alarm Signals **shall** be assigned to **Technical** Alarm Conditions.

208.6.11 **Distributed Alarm System** - 208.6.11.2.2 * **Failure of remote communication** of Alarm Conditions **-** Replacement of item b): b) **shall** create a **Technical** Alarm Condition in any affected parts of the Distributed Alarm System that can generate Alarm Signals. Addition: If, while the ME Equipment is in the Audio Off state, the ME Equipment detects a communication failure with the Distributed Alarm System, it **shall** terminate the Audio Off state and **shall** initiate a Technical Alarm Condition. Additional subclause:

208.6.11.101 * **Inactivation/activation** of Alarm Signals at **remote components** of a **Distributed Alarm System -** If deemed acceptable by Risk Management for its intended environment of use, ME Equipment **may** be provided with **means** for the clinical Operator to activate and inactivate Alarm Signals of the ME Equipment or to change **Alarm Limit** Settings from remote components of a Distributed Alarm System by: **–** enabling any **Inactivation States** that are configured on the ME Equipment (Alarm Paused, Audio Paused, Alarm Off or Audio Off) and activating the function **Alarm Reset** and **– termination** of the **inactivation state**. ME Equipment that provides means to remotely activate and inactivate Alarm Signals **shall** also provide means to configure (enable or disable) remote inactivation/activation for every provided inactivation state. To prevent the clinical Operator from changing that configuration, such means **shall** be restricted to the Responsible Organization (see 6.7 of IEC 60601-1- 8:2006).
Compliance is checked by inspection

Subclause 201.11.8 – **Interruption** of the **power supply**/ Supply Mains to the ME Equipment - Interruptions of the Supply Mains for **less than 30 s are mainly caused by switching to an emergency power supply**. Such power interruptions are considered **Normal Use** and consequently **should not** result in Hazards to the Patient. When power returns, the ME Equipment **needs to** resume the same mode of operation and restore all Operator settings and Patient data that were in use before the Supply Mains was interrupted. Examples of typical stored data that **may** impact Patient safety are operating mode, **Alarm Settings** (volume of auditory Alarm Signal, Alarm Limits, Alarm Off, etc.), trend data, and pacemaker pulse rejection, if Operator selectable. In contrast to these settings, the instantaneous heart rate or the displayed ECG waveform do not fall under stored data.

Subclause 202.6.2.101 – **Electrosurgery Interference** - Disturbances caused by HF Surgical Equipment are considered **Normal Use** and consequently **should not** result in Hazards to the Patient. Therefore, after an appropriate recovery time the ME Equipment **should** resume normal operation without loss of stored data. Examples of typical **stored data** that **may** impact Patient safety are operating mode, **Alarm Settings** (volume of auditory Alarm Signal, Alarm Limits, Alarm Off, etc.), and pacemaker pulse rejection if Operator selectable. In contrast to these settings, the instantaneous heart rate or the displayed ECG waveform do not fall under stored data.

Subclause 208.6.1.2 – Alarm Condition **Priority** - The intersection of the 'Delayed' column and the 'Minor injury or discomfort' row in Table 1 of IEC 60601-1-8:2006 contains 'Low Priority or no Alarm Signal'. Selection of **'no Alarm Signal**' **may be** appropriate for these Alarm Conditions in environments of use where a clinical Operator **continuously** attends the Patient during **Normal Use**. Such a selection is **inappropriate** for ME Equipment that is **not continuously** attended during Normal Use since failure to provide an auditory Alarm Signal effectively means that the Alarm System is **disabled** for those Alarm Conditions.

Subclause 208.6.3.3.1 – Characteristics of **auditory** Alarm Signals - **An auditory Alarm Signal that only occurs once (or does not occur, per Table 1 of IEC 60601- 1-8:2006) may be appropriate for a Low Priority Alarm Condition** in environments of use where the Patient is continuously attended by a clinical Operator in Normal Use. Such a selection is **inappropriate** for ME Equipment that is **not continuously attended** during Normal Use since not repeating the auditory Alarm Signals means that the Alarm Condition is not likely to be recognized.
Subclause 208.6.3.3.2.101 **– Volume** of auditory Alarm Signals reducible to **zero** - The **primary Alarm Condition indicator that draws the attention to a clinical Operator is the auditory Alarm Signal –** especially for ME Equipment that includes in its Intended Use/ Intended Purpose monitoring of Patients

that are not continuously attended by a clinical Operator. Typical environments of use where Patients are not continuously attended by health care professionals are intensive care units (ICU). Normally, a clinical Operator is caring for several Patients. Therefore, it is not possible to observe all Patient monitors at the same time to be aware of all visual Alarm Signals that are not associated with auditory Alarm Signals. In such an environment, reducing, the volume of the auditory Alarm Signal to zero means that the Alarm System enters the inactivation state Audio Off that **must** be indicated. In such environments it is recommended to limit the adjustable volume of the auditory Alarm Signal to a minimum sound pressure. In a Distributed Alarm System where remote components of a Distributed Alarm System annunciate the Alarm Signals the volume of the auditory Alarm Signal **may** be reduced to zero (no sound pressure) depending on the use model (see second paragraph of rationale 208.6.4.2).
Subclause 208.6.4.2 – **Delays** to or from a **Distributed Alarm System** - Alarm Signal generating ME Equipment annunciates Alarm Signals in response to Alarm Conditions that it detects. If this ME Equipment is part of a Distributed Alarm System, the Distributed Alarm System **may** annunciate the Alarm Signals of that Alarm Condition at remote components of the Distributed Alarm System. It takes a finite amount of time for information related to an Alarm Condition to reach all components of a Distributed Alarm System. In many cases, this amount of time is very short, however, specific characteristics of a Distributed Alarm System can significantly delay annunciation of Alarm Signals at remote components of the Distributed Alarm System. Use models in intensive care units **may** require that remote equipment is operated as the primary alarming equipment (e.g. when the Alarm Signal generating ME Equipment is configured with the volume of its auditory Alarm Signal reduced to zero **–** no sound pressure). In such an environment of use the **overall** delay time before remote components of a Distributed Alarm System annunciate Alarm Signals **should** be limited to values that allow the clinician to respond to **Physiological** Alarm Conditions (such as cardiac arrest, ventricular fibrillation, high systolic pressure, etc.) in time. **Inappropriate delay times for Alarm Signals in a Distributed Alarm System may delay treatment of Patients**. Therefore, it is strongly recommended that **Risk Management** be applied to identify adequate 'not to exceed' delay times of Alarm Signals to remote components of a Distributed Alarm System. Subclause 208.6.6.2.104 **– Technical** Alarm Condition indicating inoperable ME Equipment, ME Equipment that is inoperable **should** indicate this state on or adjacent to the display. This **may** be fulfilled by the absence of a visible trace.

Subclause 208.6.8.101 – **Technical** Alarm Conditions - The Alarm **Inactivation States** Alarm Off and Alarm Paused support the functionality that is **essential** for Patient Monitoring Equipment: in both Alarm Inactivation States (Alarm Off and Alarm Paused), it is **necessary** for Electrocardiographic Monitoring Equipment that **visual** Alarm Signals of Technical Alarms Conditions are displayed. The purpose of these visual Alarm Signals is to inform the clinical Operator **–** even during the Alarm Inactivation States Alarm Off or Alarm Paused **–** that the ME Equipment (or a part of the ME Equipment) is not operating because a Technical Alarm Condition such as 'ECG leads-off' interrupts the ECG monitoring of a Patient. A Technical Alarm Condition **may** influence the validity of a measured value. For instance, the Technical Alarm Condition 'ECG leads-off' prevents the heart rate from being calculated and displayed. Continuing to display the previously calculated heart rate **may** lead to misinterpretations by the clinical Operator because this value is invalid during the Technical Alarm Condition. Appropriate means to indicate that the heart rate is invalid **might** be to display a blank heart rate value or a symbol where the heart rate is displayed. In other cases, the tolerance of the measured values **might** be influenced or the measurement **might** be unreliable. In those cases, the clinical Operator **should** be informed that the currently displayed value **might** be questionable. The displayed value **should** be marked accordingly.

Subclause 208.6.9 – **Alarm Reset** - The clinical Operator action Alarm Reset performs the following actions: First, it stops the **auditory** Alarm Signal. Second, it stops **visual Latching** Alarm Signals of Alarm Conditions that **no longer exist**. Third, it does not affect **visual** Alarm Signals for Alarm Conditions that continue to exist (those signals continue until the Alarm Conditions ceases). Fourth, it enables the Alarm System immediately to respond to a subsequent Alarm Condition. The fourth action '**enabling the Alarm System immediately' distinguishes the function Alarm Reset from the Alarm Inactivation States Alarm Paused, Audio Paused, Alarm Off and Audio Off**. In contrast to the Alarm Inactivation States Alarm Paused, Audio Paused, Alarm Off and Audio Off that temporarily or permanently disable the Alarm System of ME Equipment, the function (clinical Operator action) Alarm Reset maintains the Alarm System in the 'ON'-state but applies the functions that are specified in subclause 208.6.9 a) to e). This function stops the auditory Alarm Signals, controls the visual Alarm Signals depending on an existing or ceased Alarm Condition, and **–** as outlined before **–** keeps the Alarm System enabled. As a result, the Alarm System can respond immediately to a subsequent Alarm Condition without requiring additional clinical Operator actions to activate the Alarm System again. This also explains why Audio Paused is not the appropriate state because it does not allow the related control to perform these functions of Alarm Reset. With the function Alarm Reset the clinical Operator acknowledges an active Alarm Condition once and does not need to be concerned about activating the Alarm System again because the Alarm System remains in the 'ON'-state. As a result, the function Alarm Reset avoids the possibility that the clinical Operator **might** forget to activate the Alarm System again.

Subclause 208.6.10 – **Non-Latching** and **Latching** Alarm Signals - Different use models exist for ME Equipment, Equipment that 1) is continually attended by a clinical Operator (such as in operating theatres/rooms) and 2) is not continually attended by a clinical Operator (such as in an ICU). In environments of use such as an ICU or emergency department, where Patients are not continuously attended, a clinical Operator normally cares for several Patients. Clinical Operators who are caring for several Patients cannot observe all of their Patients at the same time. Clinical Operators cannot easily identify short Alarm Conditions that occur on ME Equipment that provides Non-Latching Alarm Signals or for mixes of Non-Latching and Latching Alarm Signals. This inability to identify and quickly respond to important short Alarm Conditions (e.g., short tachycardias) puts Patients in Hazardous Situations. Configuring ME Equipment to only provide Latching Alarm Signals, forces clinical Operators to respond to every Alarm Condition. While this is conceptually a good idea, frequent false Alarm Conditions due to artefact or improperly set Alarm Limits can place a substantial administrative burden on the clinical Operator. **Latching Alarm Signals may be desirable within Distributed Alarm Systems where remote equipment of an ME System is not continuously attended by a clinical Operator. Non-Latching Alarm Signals may be desirable in an environment of use where the ME Equipment is continuously attended by a clinical Operator.**

Subclause 208.6.10.101 – **Non-Latching** Alarm Signals for **Technical** Alarm Conditions - A Technical Alarm Condition indicates that a physiological measurement is not ready or has been interrupted for technical reasons. Such technical interruptions of a measurement **may** be caused by an unintentional disconnection of a Transducer or a Lead Wire. For instance, the Technical Alarm Condition 'ECG leads-off' prevents the heart rate from being calculated and displayed. This implies that the heart rate is not being monitored and as consequence potential Alarm Conditions **may not** be indicated. Requiring Non-Latching Alarm Signals for Technical Alarm Conditions means those Alarm Signals are displayed as long as the Alarm Condition exists and cease without clinical Operator interaction when the Technical Alarm Condition is corrected.

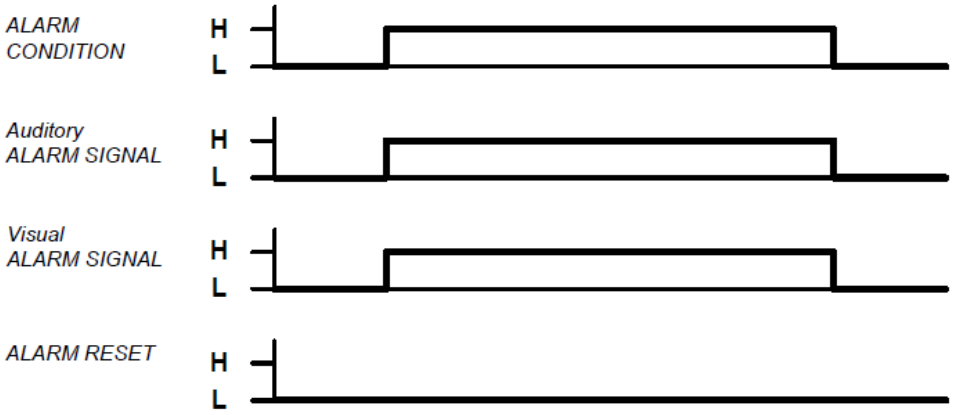
Subclause 208.6.11.2.2 – **Failure** of **remote communication** of Alarm Conditions - ME Equipment as part of a Distributed Alarm System is **essential** for reliable alarming in an **unattended** environment of use. For that reason ME Equipment that falls under the scope of this particular standard **has to** be so designed that it detects a communication failure and indicates the Alarm Signals of the corresponding Technical Alarm Condition. Labelling of such an ME Equipment with a warning to the effect that it **shall not** be relied upon for receipt of Alarm Signals is not appropriate to mitigate the Risk of critically ill Patients they are exposed to. The revised requirement 208.6.11.2.2 b) does only apply for ME Equipment that falls under the scope of this particular standard. The same applies of the entire content of this particular standard. Other components or parts of a Distributed Alarm System such as handheld devices, paging systems or even cellular phones do not fall under the scope of this particular standard; for those devices IEC 60601-1-8 applies.

Subclauses 208.6.11.101 – **Inactivation/activation** of Alarm Signals at remote components of a **Distributed Alarm System** - Distributed Alarm Systems duplicate Alarm Signals at remote components of a Distributed Alarm System such as a central station. Depending on the use model where the remote components of a Distributed Alarm System are being actively used it makes sense to activate/terminate the inactivation state Alarm Paused, Audio Paused, Alarm Off or Audio Off (depending on the configuration) and to activate Alarm Reset at remote components of a Distributed Alarm System. As indicated before, this remote control functionality depends on the use model in certain environments of use such as in intensive care units. For this reason, only the Responsible Organization **should** have access to the corresponding configuration. The configuration that enables the function of remote activation and termination of global inactivation states (Alarm Paused, Audio Paused, Alarm Off or Audio Off) and remote activation of Alarm Reset **must** be protected. '**Protected' means that the clinical Operator of the ME Equipment must not have access in Normal Use to the selection of the capability to activate and terminate global inactivation states** (Alarm Paused, Audio Paused, Alarm Off or Audio Off) **and activation of Alarm Reset at remote components of a Distributed Alarm System**. Adequate protection mechanisms are described in subclause 6.7 of IEC 60601-1-8:2006.

Annex BB
(informative)

Alarm diagrams of Clause 208/IEC 60601-1-8:2006

The following alarm status diagrams illustrate the auditory and visual ALARM SIGNALS for LATCHING and NON-LATCHING ALARM SIGNALS as defined in subclause 6.10 of IEC 60601-1-8:2006 and subclause 208.6.9 of this particular standard.



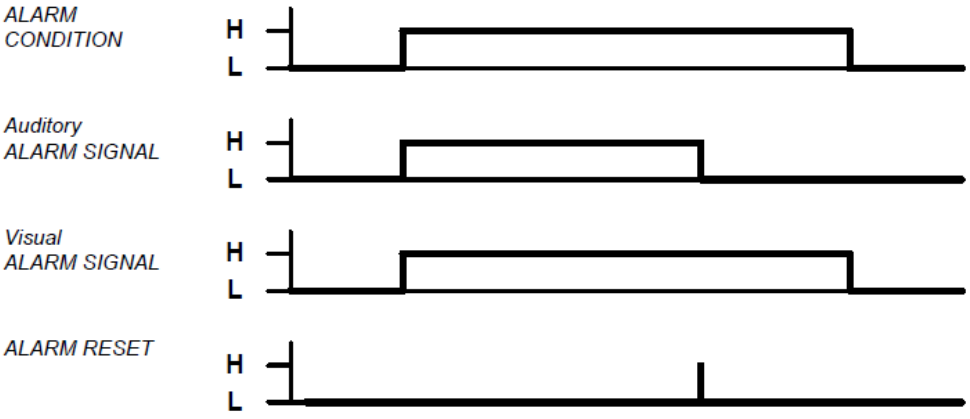
Key

H Activated state

L Deactivated state

Figure BB.101 – NON-LATCHING ALARM SIGNALS without ALARM RESET

Illustration of NON-LATCHING ALARM SIGNALS (Figure BB.101) as specified in IEC 60601-1-8 subclause 6.10: without OPERATOR interaction, the auditory and visual ALARM SIGNALS are indicated as long as the ALARM CONDITION exists. As soon as the ALARM CONDITION ceases, the auditory and visual ALARM SIGNALS are terminated automatically without any OPERATOR interaction.



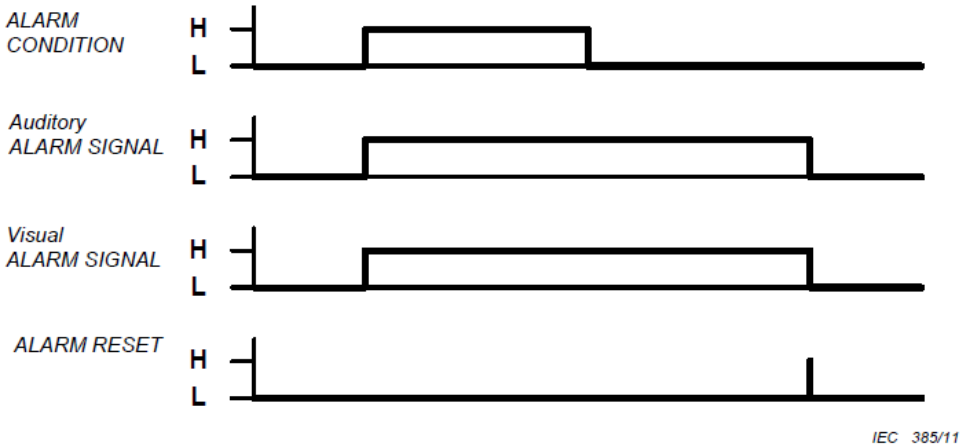
Key

H Activated state

L Deactivated state

Figure BB.102 – NON-LATCHING ALARM SIGNALS with ALARM RESET

Illustration of NON-LATCHING ALARM SIGNALS with ALARM RESET (Figure BB.102) as specified in IEC 60601-1-8, subclause 6.10 and in subclause 208.6.9 of this particular standard: Activating ALARM RESET stops the auditory ALARM SIGNAL. As soon as the ALARM CONDITION ceases the visual ALARM SIGNAL is terminated.



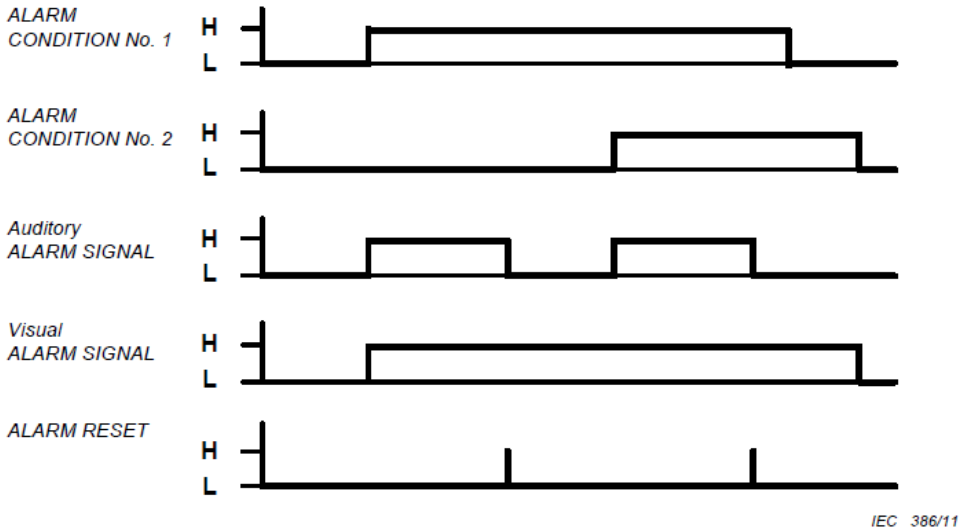
Key

H Activated state

L Deactivated state

Figure BB.103 – LATCHING ALARM SIGNALS with ALARM RESET

Illustration of LATCHING ALARM SIGNALS with ALARM RESET (Figure BB.103) as specified in IEC 60601-1-8, subclause 6.10, and in subclause 208.6.9 of this particular standard: without OPERATOR interaction, the auditory and visual ALARM SIGNALS are activated for an unlimited time. The OPERATOR is forced to reset ALARM SIGNALS of a PHYSIOLOGICAL ALARM CONDITION by activating the function ALARM RESET. After activating ALARM RESET the alarm behaviour compares to NON-LATCHING ALARM SIGNALS.



Key

H Activated state

L Deactivated state

Figure BB.104 – TWO ALARM CONDITIONS with ALARM RESET

Illustration of two Alarm Conditions with Alarm Reset (Figure BB.104) as specified in IEC 60601-1-8 subclause 6.10 and in subclause 208.6.9 of this particular standard: a subsequent Alarm Condition of another physiological parameter reactivates the auditory Alarm Signal.

IEC 80601-2-30 Edition 1.1 2013-07 Particular requirements for the Basic Safety and Essential Performance of **Automated Non-Invasive Sphygmomanometers**

201.11.8.102 **Supply Mains** - When Supply Mains is restored, the Automated Sphygmomanometer **shall**: b) **shall -** remain inoperative, and **-** if equipped provided with Short-Term Automatic Mode or Long-Term Automatic Mode, be equipped with an Alarm System that includes **a Technical** Alarm Condition that indicates the Automated Sphygmomanometer is inoperative. An Automated Sphygmomanometer that **automatically switches** over to operation from an **Internal Electrical Power** Source and continues to operate normally **shall be exempt** from these requirements.

201.12.1.101 **Measuring and display ranges** - The measuring and display ranges of the Cuff pressure **shall** be equal to the Rated range for Cuff pressure. Values of Blood Pressure outside the Rated range for Blood Pressure **shall not** be displayed and the Automated Sphygmomanometer **shall** be equipped with an Alarm System that includes a **Technical** Alarm Condition that indicates when the determined Blood Pressure is outside the Rated range.

201.12.3.101 Additional **Alarm System** requirements - If an Automated Sphygmomanometer has an Alarm System that includes **Physiological** Alarm Conditions, it **shall** have both a Physiological Alarm Condition for low Blood Pressure and a Physiological Alarm Condition for high Blood Pressure of at least **Medium** Priority. These Alarm Conditions **may** be for Systolic Blood Pressure, Diastolic Blood Pressure, or Mean Arterial Pressure.

Compliance is checked by inspection and functional testing

IEC 60601-2-33 Edition 3.1 2013-04 **Magnetic Resonance** Equipment for Medical Diagnosis

Concerning 201.7.9.3.101 c) – Safety provisions in the event of a quench, Examination room configuration – An automated **warning** to the Operator can be considered in all situations. The fitting of an oxygen monitor, wired to **audible** and **visual** alarms, in the ceiling of the examination room to give an early warning of the escape of helium gas is **recommended**.

- Door of the examination room opens inwards, To address this situation the following alternatives are available… An oxygen detector and **alarm can be** hardwired to an emergency air extraction system to turn on automatically to maximum air extraction power when in alarm mode due to a too low oxygen level.

IEC 60601-2-34 Edition 3.0 2011-05 Particular requirements for the Basic Safety and Essential Performance of **Invasive Blood Pressure Monitoring Equipment**

201.7.9.2.9.101 Additional **instructions for use** - The operating instructions **shall** include the following: l) * advice regarding testing of the ME Equipment and Accessories on a daily basis (by the clinical Operator) and on a scheduled basis (as a service activity). Emphasis **should** be placed on how the clinician **may test visual** and **auditory** Alarm Signals; n) the **default settings** (e.g. Alarm Settings, modes, and filter); o) performance specification (e.g. accuracy, bandwidth, measurement range) of ME Equipment including specified Transducers and adjustment ranges of all **physiological** Alarm Settings (see 208.6.6.2.101); p) explanation of **Technical** Alarm Conditions (see 208.6.6.2.102 and 208.6.6.2.103); q) the configuration **procedure** that allows the Alarm Signal inactivation states (Alarm Paused, Audio Paused, Alarm Off or Audio Off) or the function **Alarm Reset** to be controlled remotely (see 208.6.11.101), if provided; t) * description of how to disable Alarm Signals for Technical Alarm Conditions if Transducers or modules are **intentionally disconnected** by the clinical Operator (see 208.6.8.101); u) advice on the preferred Alarm Settings and configurations of the Alarm System when the Intended Use includes monitoring of Patients that are **not continuously** attended by a clinical Operator;

201.11.8.101 * Protection against **depletion** of **battery** - ME Equipment powered from an Internal Electrical Power Source **shall not** cause a Hazardous Situation to the Patient when the state of discharge can no longer maintain the Normal Use of the ME Equipment. The ME Equipment **shall** provide a **Technical** Alarm Condition to inform the clinical Operator about the state of discharge and **shall** power down in a controlled manner as follows: a) The ME Equipment **shall** provide a **Technical** Alarm Condition at least **5 min** prior to the time that the ME Equipment can no longer function in accordance with the Manufacturer's specification when powered from the Internal Electrical Power Source.
Compliance is checked by functional test

201.12.3 Alarm **Systems** - Addition: IEC 995/11 ME Equipment **shall** be equipped with an Alarm System as specified in Clause 208 of this particular standard. Catheterization laboratory ME Equipment is **excluded** from this requirement.

208.6.1.2 * Alarm Condition **Priority** - Addition: ME Equipment that includes in its **Intended Use** monitoring of Patients that are **not continuously** attended by a clinical Operator in **Normal U**se **shall** treat Alarm Conditions that **may** result in minor injury and delayed onset of potential Harm as **Low** Priority Alarm Conditions (see Table 208.101). The Accompanying Documents **shall** describe how the Responsible Organization **may** enable or disable auditory Alarm Signals for **Low** Priority Alarm Conditions. The requirements of subclause 6.7 of IEC 60601-1-8:2006 apply.
NOTE: This adaptation of Table 1 of IEC 60601-1-8:2006 necessitated an additional configuration capability for this ME Equipment. This capability is **necessary** when the Responsible Organization needs auditory Alarm Signals for Low Priority Alarm Conditions such as for intensive care units when central monitoring is not being used

Table 208.101 modifies Table 1 – Alarm Condition **priorities**, for ME Equipment that includes in its Intended Use monitoring of Patients that are **not continuously** attended by a clinical Operator in **Normal Use**:

Table 208.101 – ALARM CONDITION priorities for ME EQUIPMENT intended to monitor PATIENTS who are not continuously attended by a clinical OPERATOR

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of potential HARM [a]		
	Immediate [b]	Prompt [c]	Delayed [d]
Death or irreversible injury	HIGH PRIORITY [e]	HIGH PRIORITY	MEDIUM PRIORITY
Reversible injury	HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
Minor injury or discomfort	MEDIUM PRIORITY	LOW PRIORITY	LOW PRIORITY

[a] Onset of potential HARM refers to when an injury occurs and not to when it is manifested.

[b] Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.

[c] Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

[d] Having the potential for the event to develop within an unspecified time greater than that given under "prompt".

[e] Where practicable, ME EQUIPMENT with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the ME EQUIPMENT. See also appropriate particular standards.

208.6.3.3.1 * Characteristics of **auditory** Alarm Signals - Addition: For ME Equipment that includes in its **Intended Use** monitoring of Patients that are **not continuously** attended by a clinical Operator in **Normal Use**: **–** auditory Alarm Signals **shall** annunciate for **Low** Priority Alarm Conditions (delete footnote "d" from Table 3 of IEC 60601-1-8:2006); **–** replace "> 15 s or no repeat" with "2,5 s to 30,0 s" in the "**Low** Priority Alarm Signal" column of Table 3 of IEC 60601-1-8:2006; **–** auditory Alarm Signals **shall** annunciate for **Technical** Alarm Conditions. Table 208.102 modifies Table 3 **–** Characteristics of the **burst** of **auditory** Alarm Signals, for ME Equipment that includes in its Intended Use monitoring of Patients that are **not continuously** attended by a clinical Operator in Normal Use:

Table 208.102 – Characteristics of the BURST of auditory ALARM SIGNALS for ME EQUIPMENT intended to monitor PATIENTS who are not continuously attended by a clinical OPERATOR

Characteristic	HIGH PRIORITY ALARM SIGNAL	MEDIUM PRIORITY ALARM SIGNAL	LOW PRIORITY ALARM SIGNAL
Number of PULSES in BURST [a, e]	10	3	1 or 2
PULSE spacing (t_s) (see Table 208.101)			
between 1st and 2nd PULSE	x	y	y
between 2nd and 3rd PULSE	x	y	Not applicable
between 3rd and 4th PULSE	$2x + t_d$	Not applicable	Not applicable
between 4th and 5th PULSE	x	Not applicable	Not applicable
between 5th and 6th PULSE	0,35 s to 1,30 s	Not applicable	Not applicable
between 6th and 7th PULSE	x	Not applicable	Not applicable
between 7th and 8th PULSE	x	Not applicable	Not applicable
between 8th and 9th PULSE	$2x + t_d$	Not applicable	Not applicable
between 9th and 10th PULSE	x	Not applicable	Not applicable
INTERBURST INTERVAL [b, c] (t_b)	2,5 s to 15,0 s	2,5 s to 30,0 s	>2,5 s to 30 s
Difference in amplitude between any two PULSES	Maximum 10 dB	Maximum 10 dB	Maximum 10 dB

Where x shall be a value between 50 ms and 125 ms.

Where y shall be a value between 125 ms and 250 ms.

The variation of x and y within a BURST shall be ± 5 %.

MEDIUM PRIORITY $t_d + y$ shall be greater than or equal to HIGH PRIORITY $t_d + x$.

[a] See also Table 4 of IEC 60601-1-8:2006 for characteristics of the PULSE.

[b] Unless otherwise specified in a particular standard for a particular ME EQUIPMENT.

[c] MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application. Long INTERBURST INTERVALS can under certain conditions negatively affect the ability to correctly discern, in a timely manner, the source of the ALARM CONDITION.

[e] Unless inactivated by the clinical OPERATOR, MEDIUM PRIORITY and LOW PRIORITY auditory ALARM SIGNALS shall complete at least one BURST, and HIGH PRIORITY auditory ALARM SIGNALS shall complete at least half of one BURST.

The Accompanying Documents **shall** describe how the Responsible Organization **may** enable or disable **auditory** Alarm Signals for **Low** Priority Alarm Conditions and **may** restrict access to control over the Interburst Interval for **all auditory** Alarm Signals. The requirements of 6.7 of IEC 60601-1-8:2006 apply.

NOTE: This adaptation of Table 3 of IEC 60601-1-8:2006 necessitated an additional configuration capability for this ME Equipment. This capability is **necessary** when the Responsible Organization needs auditory Alarm Signals to repeat for Low Priority Alarm Conditions such as for intensive care units when central monitoring is not being used

Risk Management **shall** be applied to determine the **maximum Interburst Interval** for **auditory** Alarm Signals associated with **High**, **Medium**, and **Low** Priority Alarm Conditions.

Compliance is checked by inspection of the Risk Management File

208.6.3.3.2.101 * **Volume** of auditory Alarm Signals reducible to **zero** - If the clinical Operator reduces the volume of auditory Alarm Signals to zero (no sound pressure), the Alarm Signal inactivation state **Audio Off shall** be initiated, unless ME Equipment is part of a Distributed Alarm System where the Alarm Signals are repeated at remote components of a Distributed Alarm System.
Compliance is checked by functional test

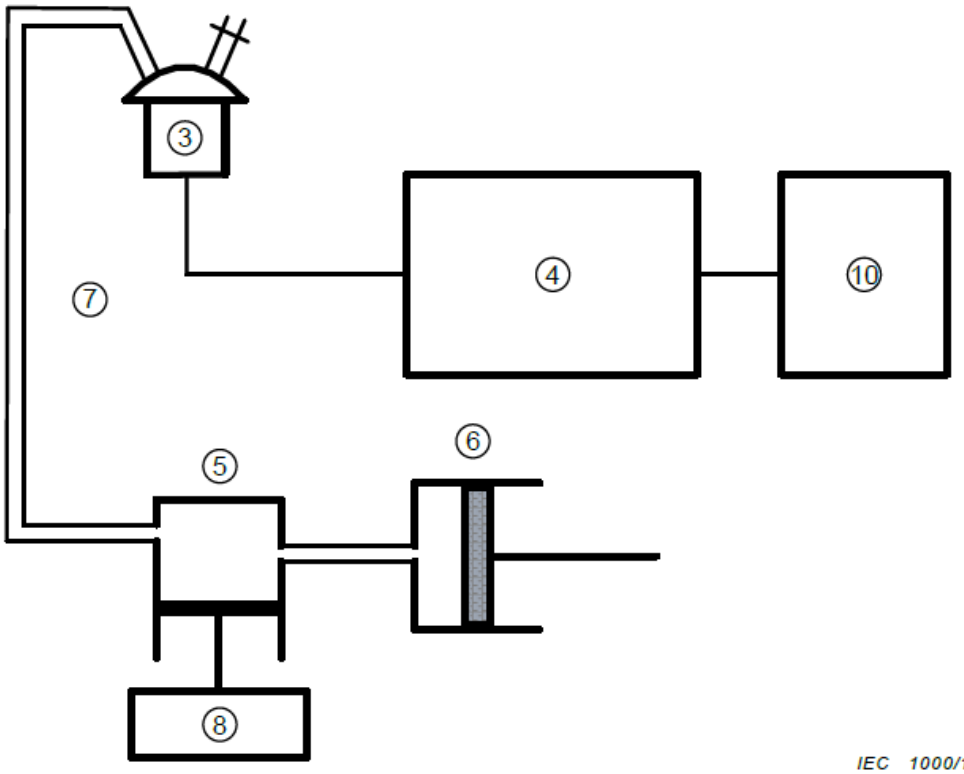
208.6.4.2 * **Delays** to or from a **Distributed Alarm System** - Addition: The Alarm Signal Generation Delay of Physiological Alarm Condition **and** Technical Alarm Conditions at remote equipment **shall** be limited so that Patient treatment is not unacceptably delayed. Risk Management **shall** be applied to determine the **maximum** Alarm Signal delay time that is acceptable before presentation of Alarm Signals at remote components of a Distributed Alarm System.
Compliance is checked by inspection of the Risk Management File

208.6.6 Alarm Limit 208.6.6.2 **Adjustable Alarm Limit** - Addition: 208.6.6.2.101 * Physiological Alarm Conditions, Alarm Limits and delay time of physiological Alarm Signals a) ME Equipment **shall** provide at least one of the following **physiological** parameters for **alarm selection**: **–** Systolic pressure **–** Diastolic pressure **–** Mean pressure b) The Alarm Limits of Physiological Alarm Condition **shall** be adjustable. The range of adjustment **shall** cover the specified measurement range for the **physiological** pressures provided by the ME Equipment.
Compliance is checked by inspection and testing
c) Time to alarm - The sum of Alarm Condition Delay and Alarm Signal Generation Delay **shall not exceed 20 s** for a value of pressure that exceeds the high Alarm Limit or falls below the low Alarm Limit

Figure 208.101 describes the test configuration for compliance. Although actual pressure sources are shown, any equivalent means (i.e. electrical pressure simulators) of generating sinusoidal or physiological pressures **may** be used. Sinusoidal or simulated pressure signals are to be 1 Hz.
*Compliance is determined as follows: Pressures are set to within ± 5 % of their indicated values to allow pressure steps of less than 2 s. Upper systolic Alarm Limit: Disable the diastolic, mean and lower systolic pressure Alarm Limits. Set the upper systolic Alarm Limit to 50 % of the arterial measurement range (AMR). Using static and sine-wave pressure sources, generate an output reading of systolic pressure of (25 ± 5) % of the AMR (see Figure 208.102 a). Within less than 2 s, vary the static and sine-wave pressures until a systolic pressure of (75 ± 5) % of the AMR is reached. Record the time to generate an Alarm Signal. Lower systolic Alarm Limit: Disable the diastolic, mean and upper systolic pressure Alarm Limits. Set the lower systolic Alarm Limit to 45 % of the AMR. Using the static and sine-wave pressure sources to generate an output reading of systolic pressure of 75 % of the AMR (see Figure 208.102 b). By using a step of less than 2 s, vary the static and sine-wave pressures until a systolic pressure of 25 % of the AMR is reached. The time to generate Alarm Signals **must not** exceed 20 s. Upper diastolic Alarm Limit: Disable the systolic, mean and lower diastolic Alarm Limits. Set the upper diastolic Alarm Limit to 50 % of the AMR. Using static and sine-wave pressure sources to generate an output reading of diastolic pressure of 25 % of the AMR (see Figure 208.102 c). By using a step of less than 2 s, vary the static and sine-wave pressures until a diastolic pressure of 75 % of the AMR is reached. The time to generate Alarm Signals **must not** exceed 20 s. Lower diastolic Alarm Limit: Disable the systolic, mean and upper diastolic Alarm Limits. Set the lower diastolic Alarm Limit to 45 % of the AMR. Using static and sine-wave pressure sources to generate an output reading of diastolic pressure of 75 % of the AMR (see Figure 208.102 d). By using a step of less than 2 s, vary the static and sine-wave pressures until a diastolic pressure of 25 % of the AMR is reached. The time to generate Alarm Signals **must not** exceed 20 s. Upper mean Alarm Limit: Disable the systolic, diastolic and lower mean Alarm Limits. Set the upper mean Alarm Limit to 50 % of the AMR. Using static and sine-wave pressure sources to generate an output reading of mean pressure of 25 % of the AMR (see Figure 208.102 e). By using steps of less than 2 s, vary the static and sine-wave pressures until a mean pressure of 75 % of the AMR is reached. The time to generate Alarm Signals **must not** exceed 20 s. Lower mean Alarm Limit: Disable the systolic, diastolic and upper mean Alarm Limits. Set the lower mean Alarm Limit to 45 % of the AMR. Using static and sine-wave pressure*

sources to generate an output reading of mean pressure of 75 % of the AMR (see Figure 208.102 f). By using steps of less than 2 s, vary the static and sine-wave pressures until a mean pressure of 25 % of the AMR is reached. The time to generate Alarm Signals

must not *exceed 20 s.*



Key

3	TRANSDUCER with DOME under test; stopcock closed
4	ME EQUIPMENT under test
5	Hydraulic system filled with water
6	Static pressure source with accuracy of ± 0,5 mmHg
7	Tubing
8	Sine-wave generator 1 Hz
10	1 Hz sine-wave display

Figure 208.101 – Test for delay times of ALARM SIGNALS indicating PHYSIOLOGICAL ALARM CONDITIONS
(see 208.6.6.1.101)

208.6.6.2.102 Detection of **Transducer** and **Transducer cable fault** - Means **shall** be provided to detect Transducer faults. A **Technical** Alarm Condition of **Medium** Priority **shall** be activated when any wire in the Transducer or Transducer cable is **opened** or **shorted** to any other wire that causes other than normal operation, or when the Transducer connector is unplugged. The **sum** of and Alarm Signal Generation Delay **shall not** exceed **10 s**. The detection of a short between the Transducer output terminals is exempted.
Compliance is checked by the following tests: Short each wire inside the Transducer and Transducer cable in turn to any other wire. Also open each wire in turn. After each fault verify that a Technical Alarm Condition is indicated with the sum of Alarm Condition Delay and Alarm Signal Generation Delay not exceeding 10 s. Unplug the connector of the Transducer. Verify that a Technical Alarm Condition is indicated with the sum of Alarm Condition Delay and Alarm Signal Generation Delay not exceeding 10 s.

208.6.6.2.103 * Detection of **disconnected catheter** - Means **shall** be provided to detect a disconnected arterial catheter indicated by a rapid pressure drop of the mean pressure below 10 mmHg that does not show cardiac activity (e.g. lat line). Rapid arterial pressure drops **shall** activate an Alarm Condition of **High** Priority. The sum of Alarm Condition Delay and Alarm Signal Generation Delay **shall not** exceed **10 s**.
Compliance is checked by the following test: Apply a simulated arterial pressure of 120/80 mmHg according to Figure 208.101. After the display stabilizes change the simulated arterial pressure within 2 s to a mean value (flat line) below 10 mmHg. Record the time to generate a High Priority Alarm Signal

208.6.6.2.104 Assignment of Alarm Condition **priority** - Alarm Signals of **Physiological** Alarm Conditions as specified in 208.6.6.2.101 **shall** be at least of **Medium** Priority.
Compliance is checked by inspection and functional tests

208.6.8 Alarm Signal **inactivation states** - Additional subclause: 208.6.8.101 * **Technical** Alarm Conditions **Inactivation** of Alarm Signals (Alarm Paused and Alarm Off): a) **shall not inactivate visual** Alarm Signals of **Technical** Alarm Conditions that identify the specific Alarm Condition and its priority at a distance of **1 m** from the ME Equipment; b) **may** inactivate the **visual** Alarm Signal specified in subclause 6.3.2.2 b) of IEC 60601-1-8. In the case of a Technical Alarm Condition the any measured value(s) of the parameter(s) **shall** be displayed in such a way that the validity of the measured value(s) can be identified by the clinical Operator.
NOTE: During a Technical Alarm Condition, the physiological parameter(s) **might not** be capable of detecting **Physiological** Alarm Conditions
If the Transducer, adapter cable, or modules are intentionally disconnected by the clinical Operator as specified by the Manufacturer, Alarm Reset **may** be used to disable the **visual** Alarm Signal of those **Technical** Alarm Conditions. Such means **shall** be documented in the instructions for use (see 201.7.9.2.9.101 t)).
Compliance is checked by inspection and functional tests

208.6.9 * **Alarm Reset** - Replacement: **Means shall** be provided for the clinical Operator to activate Alarm Reset of Alarm Signals. After activation of the Alarm Reset function a) the **auditory** Alarm Signals of Alarm Conditions **shall cease**, enabling the Alarm System to respond to a subsequent Alarm Condition; b) **visual** Alarm Signals for **Latching** Alarm Conditions that no longer exist **shall** cease (see 201.7.9.2.9.101 t) and 208.6.8.101)); c) **visual** Alarm Signals for any existing Alarm Condition **shall** continue as long as those Alarm Conditions exist; d) the Alarm System **shall** be enabled immediately so that it can respond to a subsequent Alarm Condition; e) the **visual** Alarm Signals of **Technical** Alarm Conditions **shall not** cease as long as the Technical Alarm Condition exists. The means of control of **Alarm Reset shall** be **marked** with symbol IEC 60417-5309 (2002-10) (see IEC 60601-1-8-2006 symbol 2 of Table C.1 and/or with the text string of marking 5 in Table C.2).
Compliance is checked by inspection

208.6.10 * **Non-Latching** and **Latching** Alarm Signals - Addition to the first paragraph: For ME Equipment that supports **mixtures** of Latching Alarm Signals and Non-Latching Alarm Signals, **means shall** be provided that allows the Responsible Organization to configure ME Equipment to have **all Latching** Alarm Signals or **all Non-Latching** Alarm Signals for **Physiological** Alarm Conditions and to restrict access to this configuration to the **Responsible Organization**.
NOTE: This requirement adds an additional configuration capability for use in intensive care units where the Responsible Organization needs Latching Alarm Signals for all Alarm Conditions
Compliance is checked by functional test

208.6.10.101 * Non-Latching Alarm Signal for Technical Alarm Conditions - **Non-Latching** Alarm Signals **shall** be assigned to **Technical** Alarm Conditions.

208.6.11 **Distributed Alarm System** - 208.6.11.2.2 * **Failure** of remote **communication** of Alarm Conditions Replacement of item b): b) **shall** create a **Technical** Alarm Condition in any affected parts of the Distributed Alarm System that can generate Alarm Signals. Addition: If, while the ME Equipment is in the Audio Off state, the ME Equipment detects a communication failure with the Distributed Alarm System, it **shall terminate** the **Audio Off** state and **shall** initiate a **Technical** Alarm Condition. Additional subclause:

208.6.11.101 * **Inactivation/activation** of Alarm Signals at **remote components** of a **Distributed Alarm System** - If deemed acceptable by Risk Management for its intended environment of use, ME Equipment **may** be provided with means for the clinical Operator to activate and inactivate Alarm Signals of the ME Equipment or to change Alarm Limit Settings from remote components of a Distributed Alarm System by: **– enabling any inactivation states** that are configured on the ME Equipment (Alarm Paused, Audio Paused, Alarm Off or Audio Off) and activating the function Alarm Reset and **– termination** of the **inactivation state**. ME Equipment that provides means to remotely activate and inactivate Alarm Signals **shall** also provide means to configure (enable or disable) remote inactivation/activation for every provided inactivation state. To prevent the clinical Operator from changing that configuration, such means **shall** be restricted to the Responsible Organization (see 6.7 of IEC 60601-1-8:2006).
Compliance is checked by inspection

Subclause 201.7.9.2.9.101 - item t) **– Operating instructions** - Alarm Signals of **Technical** Alarm Conditions are also indicated when sensors, probes, or modules are **intentionally disconnected** by the clinical Operator because the ME Equipment **may not** distinguish between intentional and unintentional disconnection. In cases where a Transducer, a probe, or a module is **intentionally disconnected** by the clinical Operator, a means is required that allows the Operator to disable permanently the **visual** Alarm Signals of those **Technical** Alarm Conditions. A possible situation is, for instance, that an invasive blood pressure measurement is intentionally discontinued because a non-invasive pressure measurement is adequate and associated with a lower risk for the Patient.

Subclause 201.11.8 **– Interruption** of **power supply**/ Supply Mains to the ME Equipment - Interruptions of the Supply Mains for less than **30 s** are mainly caused by switching to an emergency power supply. Such power interruptions are considered **Normal Use** and consequently **should not** result in Hazardous Situations to the Patient. When power returns, the ME Equipment needs to resume the same mode of operation and restore all Operator settings and Patient data that were in use before the Supply Mains was interrupted. Examples of typical stored data that **may** impact Patient safety are operating mode, Transducer calibration, **Alarm Settings** (volume of auditory Alarm Signals, Alarm Limits, Alarm Off, etc.), and trend data, if Operator selectable. In contrast to these settings, the instantaneous pressure values (systolic, diastolic and mean pressure) or the displayed Pressure waveform do not fall under stored data.

Subclause 208.6.1.2 **– Alarm Condition Priority** - The intersection of the 'Delayed' column and the 'Minor injury or discomfort' row in Table 1 of IEC 60601-1-8:2006 contains 'Low Priority or no Alarm Signal'. Selection of 'no Alarm Signal' **may** be appropriate for these Alarm Conditions in environments of use where a clinical Operator continuously attends the Patient during Normal Use. Such a selection is inappropriate for ME Equipment that is **not continuously attended** during Normal Use since failure to provide an **auditory** Alarm Signal effectively means that the Alarm System is disabled for those Alarm Conditions.

Subclause 208.6.3.3.1 – Characteristics of **auditory** Alarm Signals - **An auditory Alarm Signal that only occurs once (or does not occur, per Table 1 of IEC 60601- 1-8:2006) may be appropriate for a Low Priority Alarm Condition** in environments of use where the Patient is continuously attended by a clinical Operator in Normal Use. Such a selection is inappropriate for ME Equipment that is not continuously attended during Normal Use since not repeating the auditory Alarm Signals means that the Alarm Condition is not likely to be recognized.

Subclause 208.6.3.3.2.101 – **Volume** of auditory Alarm Signals reducible to **zero**, **The primary Alarm Condition indicator that draws the attention to a clinical Operator is the auditory Alarm Signal** – Especially for ME Equipment that includes in its Intended Use monitoring of Patients that are not continuously attended by a clinical Operator. Typical environments of use where Patients are not continuously attended by health care professionals are intensive care units (ICU). Normally, a clinical Operator is caring for several Patients. Therefore, it is not possible to observe all Patient Monitoring Equipment at the same time to be aware of all visual Alarm Signals that are not associated with auditory Alarm Signals In such an environment, reducing the volume of the auditory Alarm Signal to zero means that the Alarm System enters the inactivation state Audio Off that **must** be indicated. In such environments it is recommended to limit the adjustable volume of the auditory Alarm Signal to a minimum sound pressure. In a Distributed Alarm System where remote components of a Distributed Alarm System annunciate the Alarm Signals the volume of the auditory Alarm Signal **may** be reduced to zero (no sound pressure) depending on the use model (see second paragraph of rationale 208.6.4.2).

Subclause 208.6.4.2 – **Delays to** or from a **Distributed Alarm System** - Alarm Signal generating ME Equipment annunciates Alarm Signals in response to Alarm Conditions that it detects. If this ME Equipment is part of a Distributed Alarm System, the Distributed Alarm System **may** annunciate the Alarm Signals of that Alarm Condition at remote components of the Distributed Alarm System. It takes a finite amount of time for information related to an Alarm Condition to reach all components of a Distributed Alarm System. In many cases, this amount of time is very short, however, specific characteristics of a Distributed Alarm System can significantly delay annunciation of Alarm Signals at remote components of the Distributed Alarm System. Use models in intensive care units **may require** that remote equipment is operated as the primary *alarming* equipment (e.g. when the Alarm Signal generating ME Equipment is configured with the volume of its auditory Alarm Signal reduced to zero – no sound pressure). In such an environment of use the overall delay time before remote components of the Distributed Alarm System annunciate Alarm Signals **should** be limited to values that allow the clinician to respond to **Physiological** Alarm Conditions (such as cardiac arrest, ventricular fibrillation, high systolic pressure, etc.) in time. Inappropriate delay times for Alarm Signals in a Distributed Alarm System **may** delay treatment of Patients. It is strongly **recommended** that Risk Management be applied to identify adequate 'not to exceed' delay times of Alarm Signals to remote components of a Distributed Alarm System.

Subclause 208.6.6.2.101 – **Physiological** Alarm Conditions, Alarm Limits and delay time of physiological Alarm Signals - Systolic (S) and diastolic (D) averaging of such a huge pressure step leads to a very long Alarm Delay time even if the set Alarm Limit is 50 % of the AMR. This huge pressure change (step function) simulates a worst case condition that exceeds real physiological blood pressure changes by far and reduces the amount of testing. Only one test is required for S, D, and for each direction.

Subclause 208.6.6.2.103 – Detection of **disconnected catheter** - This Alarm Condition detects a rapid arterial pressure drop that is caused by disconnected arterial catheter. There is a **high likelihood** that a disconnected arterial catheter leads to a loss of blood that **may** develop a Hazardous Situation for the

Patient within a short time. This Hazardous Situation needs an immediate clinical Operator response, so a High Priority Alarm Signal is assigned to this Alarm Condition. The sum of Alarm Condition Delay and Alarm Signal Generation Delay is limited accordingly. Opening the stopcock to atmospheric pressure (as is needed e.g. for pressure zeroing) **may** also cause this Alarm Condition**. This False Alarm may be prevented by inactivation of the Alarm System** (Alarm Off, Audio Off, Alarm Paused, Audio Paused) or disabling pressure Alarm Signals because this procedure is an intended clinical Operator action. **The benefit of this Alarm Condition for the Patient exceeds the disadvantage of a rare false Alarm Condition.**

Subclause 208.6.8.101 – **Technical** Alarm Conditions - The Alarm **Inactivation States** Alarm Off and Alarm Paused support the functionality that is **essential** for Patient Monitoring Equipment: in both Alarm Inactivation States (Alarm Off and Alarm Paused), it is **necessary** for Invasive Blood Pressure Monitoring Equipment that **visual** Alarm Signals of **Technical** Alarms Conditions are displayed. The purpose of these visual Alarm Signals is to inform the clinical Operator **–** even during the Alarm Inactivation States Alarm Off or Alarm Paused **–** that the ME Equipment (or a part of the ME Equipment) is not operating because a Technical Alarm Condition such as 'disconnected Transducer' interrupts the invasive pressure monitoring of a Patient. A Technical Alarm Condition **may** influence the validity of a measured value. For instance, the Technical Alarm Condition 'Transducer disconnected' prevents the systolic, diastolic and mean pressure values from being calculated and displayed. Continuing to display the previously calculated systolic, diastolic and mean pressure **may** lead to misinterpretations by the clinical Operator because this value is invalid during the Technical Alarm Condition. Appropriate means to indicate that the displayed pressure values are invalid **might** be to display blank systolic, diastolic and mean pressure values or a symbol where these pressure values are displayed. In other cases, the tolerance of the measured values **might** be influenced or the measurement **might** be unreliable. In those cases, the clinical Operator **should** be informed that the currently displayed values **might** be questionable. The displayed value **should** be marked accordingly.

Subclause 208.6.9 – **Alarm Reset** - The clinical Operator action Alarm Reset does the following actions: First, it stops the **auditory** Alarm Signal. Second, it stops **visua**l Latching Alarm Signals of Alarm Conditions that **no longer exist**. Third, it does not affect **visual** Alarm Signals for Alarm Conditions that **continue to exist** (those signals continue until the Alarm Conditions ceases). Fourth, it **enables** the Alarm System immediately to respond to a subsequent Alarm Condition. The fourth action 'enabling the Alarm System immediately' distinguishes the function Alarm Reset from the Alarm Inactivation States Alarm Paused, Audio Paused, Alarm Off and Audio Off. In contrast to the Alarm Inactivation States Alarm Paused, Audio Paused, Alarm Off and Audio Off that temporarily or permanently disable the Alarm System of ME Equipment, the function (clinical Operator action) Alarm Reset maintains the Alarm System in the 'ON'-state but applies the functions that are specified in subclause 208.6.9 a) to e). This function stops the auditory Alarm Signals, controls the visual Alarm Signals depending on an existing or ceased Alarm Condition, and **–** as outlined before **–** keeps the Alarm System enabled. As a result, the Alarm System can respond immediately to a subsequent Alarm Condition without requiring additional clinical Operator actions to activate the Alarm System again. This also explains why Audio Paused is not the appropriate state because it does not allow the related control to perform these functions of Alarm Reset. With the function Alarm Reset the clinical Operator acknowledges an Alarm Condition once and does not need to be concerned about activating the Alarm System again because the Alarm System remains in the 'ON'-state. As a result the function Alarm Reset avoids the possibility that the clinical Operator **might** forget to activate the Alarm System again.

Subclause 208.6.10 – **Non-Latching** and **Latching** Alarm Signals - Different use models exist for ME Equipment that 1) is **continually attended** by a clinical Operator (such as in operating theatres/rooms) and 2) is **not continually attended** by a clinical Operator (such as in an ICU). In environments of use such as an ICU or emergency department, where Patients are not continuously attended, a clinical Operator normally cares for several Patients. Clinical Operators who are caring for several Patients cannot observe all of their Patients at the same time. Clinical Operators cannot easily identify short Alarm Conditions that occur on ME Equipment that provides Non-Latching Alarm Signals or for **mixes** of Non-Latching and Latching Alarm Signals. This **inability to identify and quickly respond to important short Alarm Conditions (e.g., short tachycardias) puts Patients in Hazardous Situations.** Configuring ME Equipment to only provide Latching Alarm Signals, forces clinical Operators to respond to every Alarm Condition. While this is conceptually a good idea, frequent false Alarm Conditions due to artefact or improperly set Alarm Limits can place a substantial administrative burden on the clinical Operator. Latching Alarm Signals **may** be desirable within Distributed Alarm Systems where remote equipment of an ME System is **not continuously** attended by a clinical Operator. Non-Latching Alarm Signals **may** be desirable in an environment of use where the ME Equipment is continuously attended by a clinical Operator.

Subclause 208.6.10.101 – **Non-Latching** Alarm Signals for **Technical** Alarm Conditions - A Technical Alarm Condition indicates that a **physiological** measurement is not ready or has been interrupted for technical reasons. Such technical interruptions of a measurement **may** be caused by an unintentional disconnection of a Transducer, sensor or Lead Wire. For instance, the Technical Alarm Condition indicating that the Transducer is disconnected prevents the pressure values (systolic, diastolic and mean pressure) from being calculated and displayed. This implies that the pressure values are not being monitored and as consequence potential Alarm Conditions **may not** be indicated. Requiring Non-Latching Alarm Signals for Technical Alarm Conditions means those Alarm Signals are being displayed as long as the Alarm Condition exists and cease without clinical Operator interaction when the Transducer is reconnected.

Subclause 208.6.11.2.2 **Failure** of **remote communication** of Alarm Conditions - ME Equipment as part of a Distributed Alarm System is essential for reliable alarming in an unattended environment of use. For that reason ME Equipment that falls under the scope of this particular standard **has to** be so designed that it detects a communicate on failure and indicates the Alarm Signals of the corresponding Technical Alarm Condition. Labelling of such an ME Equipment with a warning to the effect that it **shall not** be relied upon for receipt of Alarm Signals is not appropriate to mitigate the Risk of critically ill Patients they are exposed to. The revised requirement 208.6.11.2.2 b) does only apply for ME Equipment that falls under the scope of this particular standard. The same applies of the entire content of this particular standard. Other components or parts of a Distributed Alarm System such as handheld devices, paging systems or even cellular phones do not fall under the scope of this particular standard; for those devices IEC 60601-1-8 applies.

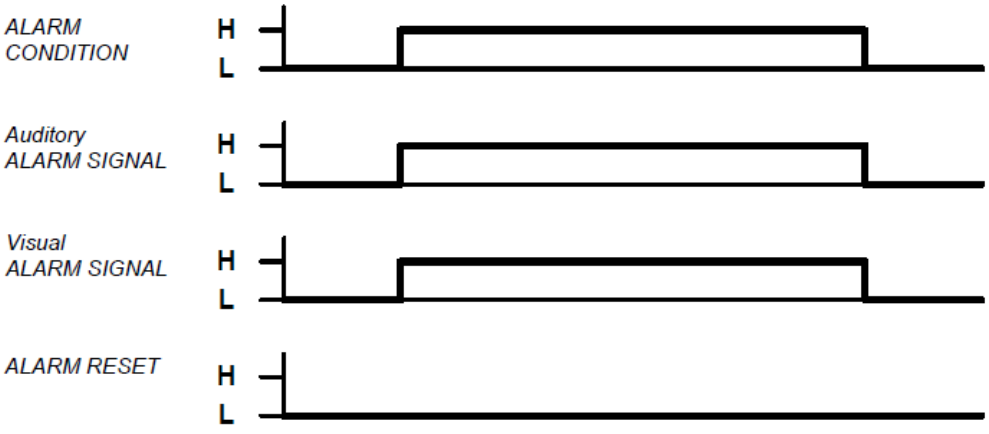
Subclause 208.6.11.101 – **Inactivation/activation** of Alarm Signals at remote components of a **Distributed Alarm System** - Distributed Alarm Systems duplicate Alarm Signals at remote components of a Distributed Alarm System such as a central station. Depending on the use model where the components of a Distributed Alarm System equipment are being actively used as part of a Distributed Alarm System it makes sense to activate/terminate the **inactivation state** Alarm Paused, Audio Paused, Alarm Off or Audio Off (depending on the configuration) and to activate **Alarm Reset** at remote components of a Distributed Alarm System. As indicated before, this remote control functionality depends on the use model in certain environments of use such as in intensive care units. For this reason, only the Responsible Organization **should** have access to the corresponding configuration. The configuration that enables the function of

remote activation and termination of **Global Inactivation States** (Alarm Paused, Audio Paused, Alarm Off or Audio Off) and remote activation of Alarm Reset **must** be protected. 'Protected' means that the clinical Operator of the ME Equipment **must not** have access in Normal Use to the selection of the capability to activate and terminate global inactivation states (Alarm Paused, Audio Paused, Alarm Off or Audio Off) and activation of Alarm Reset at remote components of a Distributed Alarm System. Adequate protection mechanisms are described in subclause 6.7 of IEC 60601-1-8:2006.

Annex BB
(informative)

Alarm diagrams 208/IEC 60601-1-8:2006

The following alarm status diagrams illustrate the auditory and visual ALARM SIGNALS for LATCHING and NON-LATCHING ALARM SIGNALS as defined in subclause 6.10 of IEC 60601-1-8:2006 and subclause 208.6.9 of this particular standard.



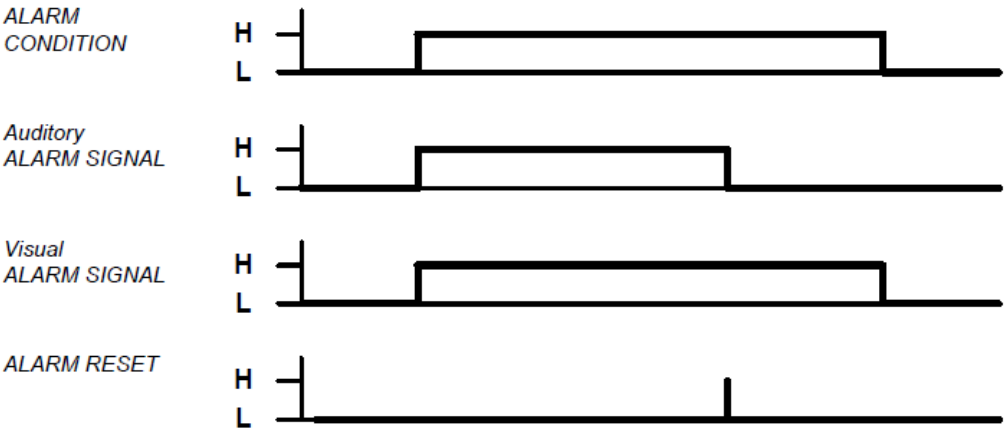
Key

H Activated state

L Deactivated state

Figure BB.101 – NON-LATCHING ALARM SIGNALS without ALARM RESET

Illustration of NON-LATCHING ALARM SIGNALS (Figure BB.101) as specified in subclause 6.10 of IEC 60601-1-8:2006: without OPERATOR interaction, the auditory and visual ALARM SIGNALS are indicated as long as the ALARM CONDITION exists. As soon as the ALARM CONDITION ceases, the auditory and visual ALARM SIGNALS are terminated automatically without any OPERATOR interaction.



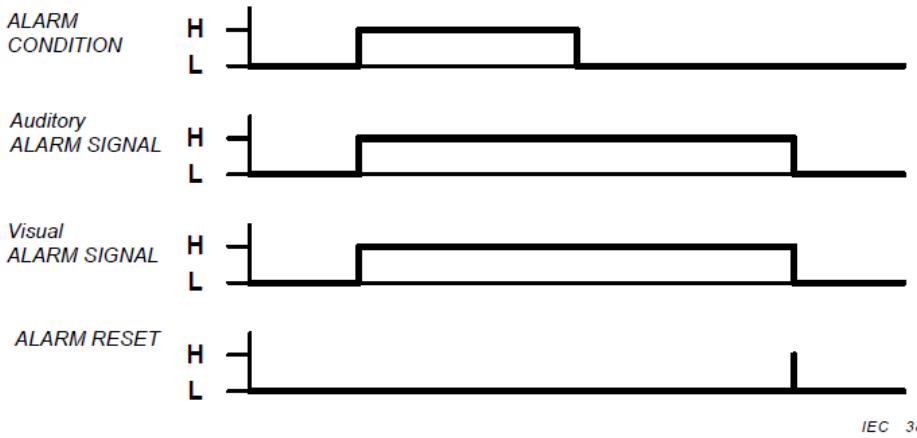
Key

H Activated state

L Deactivated state

Figure BB.102 – NON-LATCHING ALARM SIGNALS with ALARM RESET

Illustration of NON-LATCHING ALARM SIGNALS with ALARM RESET (Figure BB.102) as specified in subclause 6.10 of IEC 60601-1-8:2006 and in subclause 208.6.9 of this particular standard: Activating ALARM RESET stops the auditory ALARM SIGNAL. As soon as the ALARM CONDITION ceases the visual ALARM SIGNAL is terminated.



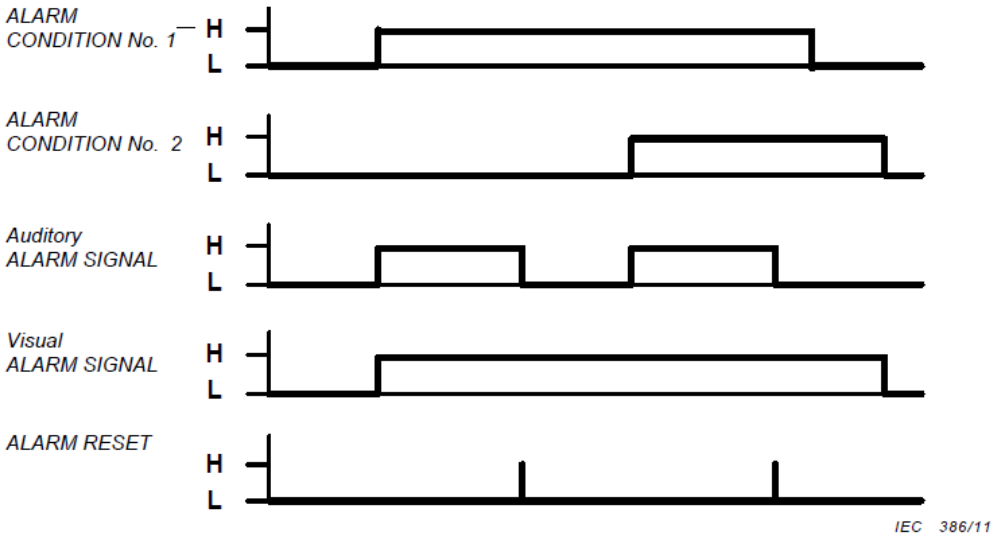
Key

H Activated state

L Deactivated state

Figure BB.103 – LATCHING ALARM SIGNALS with ALARM RESET

Illustration of LATCHING ALARM SIGNALS with ALARM RESET (Figure BB.103) as specified in IEC 60601-1-8:2006 subclause 6.10 and in subclause 208.6.9 of this particular standard: without OPERATOR interaction, the auditory and visual ALARM SIGNALS are activated for an unlimited time. The OPERATOR is forced to reset the ALARM SIGNALS of a PHYSIOLOGICAL ALARM CONDITION by activating the function ALARM RESET. After activating ALARM RESET the alarm behaviour compares to NON-LATCHING ALARM SIGNALS.



Key

H Activated state

L Deactivated state

Figure BB.104 – TWO ALARM CONDITIONS with ALARM RESET

Illustration of two ALARM CONDITIONS with ALARM RESET (Figure BB.104) as specified in 2006 subclause 6.10 of IEC 60601-1-8: and in subclause 208.6.9 of this particular standard: a subsequent ALARM CONDITION of another physiological parameter reactivates the auditory ALARM SIGNAL.

IEC 80601-2-35 Edition 2.0 2009-10 Particular requirements for the Basic Safety and Essential Performance of **Heating Devices Using Blankets, Pads or Mattresses and Intended for Heating in Medical Use**

201.7.9.2.2.101 Additional requirements for **warning** and **safety notices** - The **instructions for use shall** additionally contain the following: j) a statement that the Heating Device contains an Alarm System with an interruption of power supply/ Supply Mains **Alarm Condition**

201.7.9.2.9.101 Additional requirements for **start-up Procedure** - The **instructions for use shall** include a method for **testing** the function of the Alarm System for each of the **Alarm Conditions** specified in this standard, if not performed automatically during start up.

201.7.9.2.9.102 Additional requirements for **operating instructions** - The following **shall** appear in the **instructions for use**: b) a description of how and when to verify the functionality of the **Alarm System**.

201.11.1.2.1.102.3 * **Maximum Contact Surface Temperature** in **Single Fault Condition** - The Forced Air Device **shall** be equipped with an Alarm System that includes **at least** a **Low** Priority **Technical** Alarm Condition that indicates when the Thermal Cut-Out has activated.

201.11.8.101 * **Interruption** of **power supply**/Supply Mains Alarm Condition - Except for Low Heat Transfer Heating Devices (see Annexes CC and DD) and Forced Air Devices, the Heating Device **shall** be equipped with an Alarm System that includes at least a **Medium** Priority **Technical** Alarm Condition during any period of interruption of the Supply Mains to the Heating Device, or for **10 min**, whichever is shorter (see also rationale).
Compliance is checked by disconnection from the Supply Mains

201.12.3.101 **Overtemperature Alarm Condition** - Except for Forced Air Devices, the Heating Device **shall** be equipped with an Alarm System that includes at least a **Medium** Priority Technical Alarm Condition that indicates when either Thermal Cut-Out operates. The Alarm System **shall** also include at least a **Medium** Priority Technical Alarm Condition that indicates when the Heating Device is switched off after the Thermal Cut-Out has operated, and is then switched on again before the fault condition has been corrected.
Compliance is checked by inspection of the Accompanying Documents and functional testing

201.12.3.102 * **Contact Surface Temperature variation Alarm Condition** - Except for Forced Air Devices, Heating Devices with High Heat Transfer to the Patient (see Annexes CC and DD) **shall** be equipped with an Alarm System that includes at least a **Medium** Priority Technical Alarm Condition if the average value of the Contact Surface Temperature differs from the control setting by more than either: a) ± 1 °C in the case of Heating Devices having High Heat Transfer both inwards toward and outwards from the Patient; or b) +1 °C in the case of Heating Devices having High Heat Transfer inwards toward the Patient but Low Heat Transfer outwards from the Patient. A Heating Device having High Heat Transfer in both directions **may** be equipped with an **Alarm Pause** for up to **4 h** duration while the Heating Device is being heated from Cold Condition to the set temperature.
Compliance is checked by inspection and functional testing

201.12.3.103 **Visual** and **auditory** Alarm Signals - While **visual** Alarm Signals **shall** be designed with separate **Visual** Indicators, **auditory** Alarm Signals **may** be combined.
Compliance is checked by inspection and operation of the ME Equipment

201.12.3.104 **Disconnection** or **short-circuiting** of **sensors** Alarm Condition - The Heating Device **shall** switch off automatically if the leads to either the temperature control sensors or the Thermal Cut-Out sensors are damaged or otherwise disconnected from the control unit. The Heating Device **shall** be equipped with an Alarm System that includes at least a **Medium** Priority Technical Alarm Condition that indicates when leads to either the temperature control sensors or the Thermal Cut-Out sensors are damaged or otherwise disconnected from the control unit.
Compliance is checked by inspection and, if applicable, by the disconnection of the sensors one at a time

208.6.8.4.101 Additional requirements for **termination** of **inactivation** of **Alarm Signals** - The duration of **Audio Paused** for the Alarm Conditions required by this standard **shall not exceed 10 min** without Operator intervention.
NOTE: This permits an Operator to deliberately extend the Audio Paused by **direct action**.
Compliance is checked by functional testing

Subclause 201.11.8.101 **Interruption** of **power supply**/Supply Mains Alarm Condition - The Alarm Condition required in 201.11.8.101 in this particular standard is to indicate to the Operator that the Heating Device is no longer supplying heat to the Patient. A Low Heat Transfer Heating Device or Forced Air Device **may** be equipped with an Alarm System that includes a **Low** Priority Technical Alarm Condition that indicates a Supply Mains failure. For Low Heat Transfer Heating Devices and Forced Air Devices loss of Supply Mains and subsequent loss of therapy represents a low Risk of a harmful situation. Therefore a Low Priority Technical Alarm Condition is prudent and justified.

Subclause 201.12.3.102 **Contact Surface Temperature** variation Alarm Condition - The core temperature of a Patient, particularly, that of an Infant follows directly the Contact Surface Temperature of a High Heat Transfer Heating Device. Thus a decrease in the Contact Surface Temperature of more than 1 °C causes the temperature of the Patient to fall by nearly the same amount. The thermal regulation system of the Patient reacts against this influence by transferring some blood flow from the peripheral extremities to the core, with consequent lowering of the temperature of arms and legs. The Patient is then in a hypothermic condition. Conversely an increase in the Contact Surface Temperature by more than 1 °C results in a hyperthermic situation, comparable to a fever. The Patient reacts to this influence by sweating and an increase of the metabolic rate, pulse rate, etc. It will not be obvious to medical staff whether this change is the result of the clinical condition of the Patient or due to the Heating Device. Both of these situations cause extreme stress to a Patient and therefore such Heating Devices are required to have an Alarm Condition that indicates if the Contact Surface Temperature varies by more than ±1 °C. Clinical studies suggest that rectal temperatures between 36 °C and 38 °C represent the acceptable range (normothermia) between hypothermia and hyperthermia [7]. It follows that, if 37 °C is accepted as the normal rectal temperature, an **Alarm Condition** is **required** if the rectal temperature differs from this by more than ±1 °C. Correspondingly, because the core temperature directly follows the Contact Surface Temperature of a High Heat Transfer Heating Device, such an Alarm Condition needs to indicate when the Contact Surface Temperature differs by more than ±1 °C from the set temperature.

Subclause 201.14.13 Connection of **PEMS** by Network/Data Coupling to other equipment - A Heating Device **should** have a data interface to support a connection to a clinical information system.
Example 3: To acquire information on Alarm Condition (Alarm Condition, priority)
Example 4: To acquire the Alarm Signal Inactivation States (e.g. Audio Paused). A Heating Device **should** have a data interface to support connections for a remote human interface
Example 7: To support Distributed Alarm System

IEC 60601-2-37 Edition 2.0 2007-08 **Ultrasonic** Medical Diagnostic and Monitoring Equipment

201.13.1.2 * **Emissions, deformation** of Enclosure or exceeding maximum temperature
Addition at the end of the third dash: As an exception, for Transducer Assemblies intended for external use, the Applied Part temperature may exceed the value in 201.11.1.2.2 of this standard by up to 5 °C during a Single Fault Condition, if an **alarm** or indication is provided to the Operator, as described in 12.3 of the general standard, indicating that a Single Fault Condition causing the temperature rise has occurred;

MECA ALARM STANDARDS CROSS-REFERENCE

IEC 60601-2-39 Edition 2.0 2007-11 Particular requirements for Basic Safety and Essential Performance of **Peritoneal Dialysis Equipment**

201.7.9.2.101 The **instructions for use shall** additionally include the following: d) an explanation of the Operator's actions **required** to respond to Alarm Signals from any **Protective System**;.

201.7.9.3.101 The **technical** description **shall** additionally include the following: c) the **time** by which the **audible** Alarm Signal required in 201.12.4.101 b) **may** be delayed; d) the **audible** Alarm **Silence** period; e) the **range** of sound pressure levels of any adjustable **audible** Alarm Signal;

201.12.4.101 Dialysing **Solution temperature** - b) The operation of the Protective System **shall** achieve the following safe conditions: **–** stopping of the Dialysing Solution flow to the Patient; **–** activation of an **audible** and **visual** Alarm Signal.
NOTE: The audible Alarm Signal **may** be delayed, as specified by the manufacturer.
*Compliance is checked by measuring the temperature of the Dialysing Solution at the Patient end of the Applied Part. The test **shall** be carried out under the most unfavourable flow conditions*

201.12.4.103 **Air infusion** - b) The operation of the Protective System **shall** either stop air from entering the Applied Part, or achieve the following safe conditions: **–** stopping of the pump; **–** activation of an **audible** and **visual** Alarm Signal.
Compliance is checked by inspection of the Accompanying Documents and by functional tests

201.12.4.104 Dialysing **Solution overfill** - b) The operation of the Protective System **shall** achieve the following safe conditions: **–** stopping of the Dialysing Solution flow to the Patient; **–** activation of an **audible** and **visual** Alarm Signal.
Compliance is checked by inspection of the Accompanying Documents and by functional tests

Clause 208 General requirements, tests and guidance for Alarm Systems in medical electrical equipment and medical electrical systems - **PD Equipment is in most cases used in the home environment**. As the use in intensive care environments is very rare, the Alarm Systems for home care use need a different focus, as written in IEC 60601-1-8.

IEC 60601-2-47 Edition 2.0 2012-02 Particular requirements for the Basic Safety and Essential Performance of **Ambulatory Electrocardiographic Systems**

201.12.1.101.2.5 VF and AF comparisons - Additionally, the following information **shall** be disclosed for each record: b) whether an **Alarm Signal** was generated for the test record; c) what the **Alarm Condition** was, if one occurred (e.g., asystole, ventricular tachycardia, or ventricular fibrillation); d) the **gradation** of Alarm Conditions, if applicable; e) the **interval** between the onset of the arrhythmia to the time the Alarm Signal was activated, if one occurred. (This last requirement only applies to devices that perform real-time monitoring.)

IEC 60601-2-49 Edition 2.0 2011-02 Particular requirements for the Basic Safety and Essential Performance of **Multifunction Patient Monitoring Equipment**

201.4.5 * **Equivalent safety** for ME Equipment or ME Systems - Addition: When several particular standards simultaneously apply to Multi-Function Patient Monitoring Equipment, **all** relevant requirements from those standards **shall** be applied. If requirements from particular standards are in conflict, the Risk Management Process **shall** be used to identify which standard's requirement applies. In doing this, Manufacturers are strongly urged to give this particular standard's requirements additional weight whenever possible. If the Alarm System requirements specified in other particular standards on Multifunction Patient Monitoring Equipment conflict with those of this particular standard, the Alarm System requirements of this particular standard **shall** take priority over the others.

201.7.9.2.9.101 Additional **instructions for use** - The operating instructions **shall** include the following: h) * advice and procedures regarding testing of the ME Equipment and Accessories on a daily basis (by the clinical Operator) and on a scheduled basis (as a service activity). Emphasis **should** be placed on how the clinician **may test visual** and **auditory** Alarm Signals. j) the **default settings** (e.g. Alarm Settings, Alarm Presets, modes, and filter settings); m) **advice** on the preferred Alarm Settings and configurations of the Alarm System when Intended Use includes the monitoring of Patients that are **not continuously** attended by a clinical Operator; n) the configuration procedure that allows the Alarm Signal **Inactivation States** (Alarm Paused, Audio Paused, Alarm Off, Audio Off) and the function **Alarm Reset** to be **controlled remotely** (see 208.6.11.101), if provided; o) * description of how to **disable** Alarm Signals for **Technical** Alarm Conditions if sensors, probes, or modules are **intentionally disconnected** by the clinical Operator

201.11.8.101 Protection against **depletion** of **battery** - ME Equipment powered from an Internal Electrical Power Source **shall not** cause a Hazardous Situation to the Patient when the state of discharge can no longer maintain the Normal Use of the ME Equipment (see 201.15.4.4.101). The ME Equipment **shall** provide a **Technical** Alarm Condition to inform the clinical Operator about the state of discharge and **shall** power down in a controlled manner as follows: a) ME Equipment **shall** provide a **Technical** Alarm Condition at least **5 min** prior to the time that the ME Equipment can no longer function in accordance with the Manufacturer's specification when powered from the Internal Electrical Power Source.
Compliance is checked by functional test

208.6.1.2 * Alarm Condition **Priority** - Addition: ME Equipment that includes in its **Intended Use** monitoring of Patients that are **not continuously** attended by a clinical Operator in **Normal Use**, **shall** treat Alarm Conditions that **may** result in minor injury and delayed onset of potential Harm as **Low** Priority Alarm Conditions (see Table 208.101). The Accompanying Documents **shall** describe how the Responsible Organization **may** enable or disable auditory Alarm Signals for **Low** Priority Alarm Conditions. The requirements of 6.7 of IEC 60601-1-8:2006 apply.
NOTE: This adaptation necessitated an additional configuration capability for this ME Equipment. This capability is **necessary** when the Responsible Organization needs auditory Alarm Signals for Low Priority Alarm Conditions such as for intensive care units when central monitoring is not being used
Table 208.101 modifies Table 1, Alarm Condition priorities, for ME Equipment that includes in its Intended Use monitoring of Patients that are **not continuously** attended by a clinical Operator in Normal Use:

Table 208.101 – ALARM CONDITION priorities for ME EQUIPMENT that includes in its INTENDED USE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of potential HARM [a]		
	Immediate [b]	Prompt [c]	Delayed [d]
Death or irreversible injury	HIGH PRIORITY [e]	HIGH PRIORITY	MEDIUM PRIORITY
Reversible injury	HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
Minor injury or discomfort	MEDIUM PRIORITY	LOW PRIORITY	LOW PRIORITY

[a] Onset of potential HARM refers to when an injury occurs and not to when it is manifested.

[b] Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.

[c] Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

[d] Having the potential for the event to develop within an unspecified time greater than that given under "prompt".

[e] Where practicable, ME EQUIPMENT with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the ME EQUIPMENT. See also appropriate particular standards.

208.6.3.3.1 * Characteristics of **auditory** Alarm Signals - Addition: For ME Equipment that includes in its **Intended Use** monitoring of Patients that are not continuously attended by a clinical Operator in **Normal Use**: **– auditory** Alarm Signals **shall** annunciate for **Low** Priority Alarm Conditions (delete footnote "d" from Table 3 of IEC 60601-1-8:2006); **–** replace "> 15 s or no repeat" with "2,5 s to 30,0 s" in the "**Low** Priority Alarm Signal" column of Table 3 of IEC 60601-1-8:2006; **– auditory** Alarm Signals **shall** annunciate for **Technical** Alarm Conditions. Table 208.102 modifies Table 3, Characteristics of the burst of auditory Alarm Signals, for ME Equipment that includes in its Intended Use monitoring of Patients that are **not continuously attended** by a clinical Operator in Normal Use:

Table 208.102 – Characteristics of the burst of auditory ALARM SIGNALS for ME EQUIPMENT intended to monitor PATIENTS who are not continuously attended by a clinical OPERATOR

Characteristic	HIGH PRIORITY ALARM SIGNAL	MEDIUM PRIORITY ALARM SIGNAL	LOW PRIORITY ALARM SIGNAL
Number of PULSES in BURST [a, d]	10	3	1 or 2
PULSE spacing (t_s) (see Table 208.101)			
between 1st and 2nd PULSE	x	y	y
between 2nd and 3rd PULSE	x	y	Not applicable
between 3rd and 4th PULSE	$2x + t_d$	Not applicable	Not applicable
between 4th and 5th PULSE	x	Not applicable	Not applicable
between 5th and 6th PULSE	0,35 s to 1,30 s	Not applicable	Not applicable
between 6th and 7th PULSE	x	Not applicable	Not applicable
between 7th and 8th PULSE	x	Not applicable	Not applicable
between 8th and 9th PULSE	$2x + t_d$	Not applicable	Not applicable
between 9th and 10th PULSE	x	Not applicable	Not applicable
INTERBURST INTERVAL [b, c] (t_b)	2,5 s to 15,0 s	2,5 s to 30,0 s	>2,5 s to 30 s
Difference in amplitude between any two PULSES	Maximum 10 dB	Maximum 10 dB	Maximum 10 dB

Where x shall be a value between 50 ms and 125 ms.

Where y shall be a value between 125 ms and 250 ms.

The variation of x and y within a BURST shall be ± 5 %.

MEDIUM PRIORITY $t_d + y$ shall be greater than or equal to HIGH PRIORITY $t_d + x$.

[a] See also Table 4 of IEC 60601-1-8:2006 for characteristics of the PULSE.

[b] Unless otherwise specified in a particular standard for a particular ME EQUIPMENT.

[c] MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application. Long INTERBURST INTERVALS can under certain conditions negatively affect the ability to correctly discern, in a timely manner, the source of the ALARM CONDITION.

[d] Unless inactivated by the clinical OPERATOR, MEDIUM PRIORITY and LOW PRIORITY auditory ALARM SIGNALS shall complete at least one BURST, and HIGH PRIORITY auditory ALARM SIGNALS shall complete at least half of one BURST.

The **Accompanying Documents shall** describe how the Responsible Organization **may** enable or disable **auditory** Alarm Signals for **Low** Priority Alarm Conditions and **may** restrict access to control over the **Interburst Interval** for all auditory Alarm Signals. The requirements of 6.7 of IEC 60601-1-8:2006 apply.

NOTE: This adaptation of Table 3 of IEC 60601-1-8:2006 necessitated an additional configuration capability for this ME Equipment. This capability is **necessary** when the Responsible Organization needs Auditory Alarm Signals for Low Priority Alarm Conditions such as for intensive care units when central monitoring is not being used.

Risk Management shall be applied to determine the **maximum Interburst Interval** for **auditory** Alarm Signals associated with High, Medium, and Low Priority Alarm Conditions.

Compliance is checked by inspection of the Risk Management File

208.6.3.3.2.101 * **Volume** of auditory Alarm Signals reducible to **zero** - If the clinical Operator reduces the volume of **auditory** Alarm Signals to zero (no sound pressure), the Alarm Signal inactivation state **Audio Off shall** be indicated, unless ME Equipment is part of a Distributed Alarm System where the Alarm Signals are repeated at remote components of a Distributed Alarm System.
Compliance is checked by functional test

208.6.4.2 * **Delays** to or from a **Distributed Alarm System** - Addition: The **Alarm Signal Generation Delay** of Physiological Alarm Conditions and **Technical** Alarm Conditions at remote equipment **shall** be limited so that Patient treatment is not unacceptably delayed. Risk Management **shall** be applied to determine the **maximum** Alarm Signal delay time that is acceptable before presentation of Alarm Signals at remote components of a Distributed Alarm System.
Compliance is checked by inspection of the Risk Management File

208.6.6 **Alarm Limit** 208.6.6.1 General requirements - Addition: 208.6.6.1.101 Physiological Alarm Conditions, Alarm Limits and delay time of physiological Alarm Signals **-** The **Alarm Signal Generation Delay** of physiological Alarm Signals **may** be configurable. Configuring the Alarm Signal Generation Delay of physiological Alarm Signals **shall** be restricted to the Responsible Organization (see 6.7 of IEC 60601-1-8:2006).
Compliance is checked by inspection.
Adjustment ranges of Alarm Limits and resolution of Alarm Limit settings **shall** be specified in the Accompanying Documents (see 201.7.9.2.9.101 j))

208.6.8 Alarm Signal **Inactivation States** - 208.6.8.3 Global indefinite Alarm Signal Inactivation States - Addition: 208.6.8.3.101 * Global temporary Alarm Signal Inactivation states **-** Duration of global Alarm Paused and Audio Paused **-** The **duration** of the **maximum global** Alarm Paused and Audio Paused **interval may** be configurable. Said means **shall not** be adjustable by the clinical Operator in Normal Use (see 6.7 of IEC 60601-1-8:2006). Means of restricting access to the Responsible Organization to changing the duration of Alarm Paused and Audio Paused **shall** be described in the Accompanying Documents. The requirements of subclause 6.8.5 of IEC 60601-1-8:2006 apply. The duration of the **global Alarm Paused** and **Audio Paused** interval **shall** be the same for **all** Alarm Signals of Multifunction Patient Monitoring Equipment.
Compliance is checked by inspection and functional test

208.6.8.101 * **Technical** Alarm Conditions - **Inactivation** of Alarm Signals (Alarm Paused and Alarm Off): a) **shall not** inactivate visual Alarm Signals of **Technical** Alarm Conditions that identify the specific Alarm Condition and its priority at a distance of **1 m** from the ME Equipment; b) **may** inactivate the **visual** Alarm Signal specified in subclause 6.3.2.2 b) of IEC 60601-1-8. For **physiologica**l measurements for which no specific particular standards exists, Risk Control **shall** be applied to determine whether inactivating Alarm Signals (via Alarm Paused or Alarm Off) **should** also inactivate visual Alarm Signals of **Technical** Alarm Conditions In the case of a Technical Alarm Condition any measured value(s) of the parameter(s) **shall** be displayed in such a way that the validity of the measured value(s) can be identified by the clinical Operator.
NOTE: During a Technical Alarm Condition, the physiological parameter(s) **might not** be capable of detecting Physiological Alarm Conditions
If Transducers, Patient Cables, sensors, probes, or modules are **intentionally disconnected** by the clinical Operator as specified by the Manufacturer Alarm Reset **may** disable the **visual** Alarm Signal of **Technical** Alarm Conditions. Such means **shall** be documented in the **instructions for use** (see sub-clause 201.7.9.2.9.101 o).
Compliance is checked by inspection

208.6.9 * **Alarm Reset** - Replacement: **Means shall** be provided for the clinical Operator to activate Alarm Reset of Alarm Signals. **After activation** of the Alarm Reset function a) the **auditory** Alarm Signals of **Physiological** Alarm Conditions **shall** cease, **enabling** the Alarm System to respond to a subsequent Alarm Condition. b) **visual** Alarm Signals for **Latching** Alarm Conditions that **no longer exist shall** cease (see 201.7.9.2.9.101 o) and 208.6.8.101). c) **visual** Alarm Signals for any **existing** Alarm Conditions **shall** continue as long as those Alarm Conditions exist. d) the Alarm System **shall** be enabled immediately so that it can respond to a subsequent Alarm Condition. e) the **visual** Alarm Signals of **Technica**l Alarm Conditions **shall not** cease as long as the Technical Alarm Condition exists. The means of control of **Alarm Reset shall** be marked with symbol IEC 60417-5309 (2002-10) (see IEC 60601-1-8-2006, symbol 2 of Table C.1 and/or with the text string of marking 5 in Table C.2).
Compliance is checked by inspection

208.6.10 * **Non-Latching** and **Latching** Alarm Signals- Addition to the first paragraph: For ME Equipment that supports **mixtures** of Latching Alarm Signals and Non-Latching Alarm Signals, **means shall** be provided that allows the Responsible Organization to configure ME Equipment to have **all Latching** Alarm Signals or **all Non-Latching** Alarm Signals for Physiological Alarm Conditions and to restrict access to this configuration to the **Responsible Organization**.
NOTE: This requirement adds an additional configuration capability for use in intensive care units where the Responsible Organization needs Latching Alarm Signals for all Alarm Conditions
Compliance is checked by the functional test

208.6.10.101 * **Non-Latching** Alarm Signals for Technical Alarm Conditions - Non-Latching Alarm Signals **shall** be assigned to **Technical** Alarm Conditions, unless specified by other particular standards.

208.6.11 Distributed Alarm System 208.6.11.2.2 * **Failure of remote communication** of Alarm Conditions - Replacement of item b): b) **shall** create a **Technical** Alarm Condition in any affected parts of the Distributed Alarm System that can generate Alarm Signals. Addition: If, while the ME Equipment is in the Audio Off state, the ME Equipment detects a communication failure with the Distributed Alarm System, it **shall** terminate the Audio Off state and **shall** initiate a Technical Alarm Condition. Additional subclause:

208.6.11.101 * **Inactivation/activation** of Alarm Signals at remote components of a **Distributed Alarm System** - If deemed acceptable by Risk Control for its intended environment of use, the ME Equipment **may** be provided with means for the clinical Operator to activate and inactivate Alarm Signals of the ME Equipment or to change Alarm Limit Settings from remote components of a Distributed Alarm System by: **– enabling** any inactivation states that are configured on the ME Equipment (Alarm Paused, Audio Paused, Alarm Off or Audio Off) and activating the function **Alarm Reset** and **– termination** of the inactivation state. ME Equipment that provides means to remotely activate and inactivate Alarm Signals **shall** also provide means to configure (enable or disable) remote activation/inactivation for every provided inactivation state. To prevent the clinical Operator from changing that configuration, such means **shall** be restricted to the Responsible Organization (see 6.7 of IEC 60601-1- 8:2006).
Compliance is checked by inspection

Subclause 201.1.1 **– Scope** - This particular standard specifies Basic Safety and Essential Performance requirements for Multifunction Patient Monitoring Equipment as defined in 201.3.63. The key criteria for determining when to apply this particular standard are whether '**more than one Physiological Monitoring Unit**' exists and whether a need exists to 'detect Alarm Conditions and to generate Alarm Signals' (e.g., to perform Alarm System monitoring). While other ME Equipment such as catheter laboratory systems or stress test systems provide more than one Physiological Monitoring Unit, these systems do not perform

Alarm System monitoring and are, therefore, fall outside the definition of Multifunction Patient Monitoring Equipment.

Subclause 201.7.9.2.9.101 o) – Additional **instructions for use** Alarm Signals of **Technical** Alarm Conditions are also indicated when Transducers, sensors, probes, or modules are **intentionally disconnected** by the clinical Operator because the ME Equipment **may not** distinguish between intentional and unintentional disconnection. In cases where a Transducer, sensor, a probe, or a module is **intentionally disconnected** by the clinical Operator, a means is **required** that allows to disable permanently the **visual** Alarm Signals of those **Technical** Alarm Conditions. A possible situation is, for instance, that an invasive blood pressure measurement is intentionally discontinued because a noninvasive pressure measurement is adequate and associated with a lower risk for the Patient.

Subclause 201.11.8 – **Interruption** of the **power supply** / Supply Mains to ME Equipment - Interruptions of the Supply Mains for less than **30 s** are **mainly caused by switching to an emergency power supply**. Such power interruptions are considered **Normal Use** and consequently **should not** result in Hazardous Situation to the Patient. When power returns, the ME Equipment **needs to** resume the same mode of operation and restore all Operator settings and Patient data that were in use before the Supply Mains was interrupted.
Example: Examples of typical **stored data** that **may** impact Patient safety are operating mode, **Alarm Settings** (volume of auditory Alarm Signal, Alarm Limits, Alarm Off, etc.), trend data, and pacemaker pulse rejection, if Operator selectable. In contrast to these settings, the instantaneous heart rate or the displayed ECG waveform do not fall under stored data

Subclause 208.6.1.2 – Alarm Condition **Priority** - The intersection of the 'Delayed' column and the 'Minor injury or discomfort' row in Table 1 of IEC 60601-1-8:2006 contains 'Low Priority or no Alarm Signal'. Selection of 'no Alarm Signal' **may** be appropriate for these Alarm Conditions in environments of use where a clinical Operator **continuously attends** the Patient during Normal Use. Such a selection is **inappropriate** for ME Equipment that is **not continuously** attended during Normal Use since failure to provide an **auditory** Alarm Signal effectively means that the Alarm System is disabled for those Alarm Conditions.

Subclause 208.6.3.3.1 – Characteristics of **auditory** Alarm Signals - An auditory **Alarm Signal that only occurs once (or does not occur, per Table 1 of IEC 60601-1-8:2006) may be appropriate for a Low Priority Alarm Condition** in environments of use where the Patient is continuously attended by a clinical Operator in Normal Use. Such a selection is inappropriate for ME Equipment that is not continuously attended during Normal Use since not repeating the auditory Alarm Signals means that the Alarm Condition is not likely to be recognized.

Subclause 208.6.3.3.2.101 – **Volume** of auditory Alarm Signals reducible to **zero**, The **primary Alarm Condition indicator that draws the attention to a clinical Operator is the auditory Alarm Signal –** especially for ME Equipment that includes in its Intended Use/Intended Purpose monitoring of Patients that are not continuously attended by a clinical Operator. Typical environments of use where Patients are **not continuously** attended by health care professionals are intensive care units (ICU). Normally, a clinical Operator is caring for several Patients. Therefore, it is not possible to observe all patient monitors at the same time to be aware of all visual Alarm Signals that are not associated with auditory Alarm Signals. In such an environment, reducing the volume of the auditory Alarm Signal to zero means that the Alarm System enters the inactivation state 'Audio Off' that **must** be indicated. In such environments it is **recommended** to limit the adjustable volume of the auditory Alarm Signal to a minimum sound pressure. In a Distributed Alarm System where remote components of a Distributed Alarm System annunciate the Alarm Signals, the volume of the auditory Alarm Signal **may** be reduced to zero (no sound pressure) depending on the use model (see second paragraph of rationale 208.6.4.2).

Subclause 208.6.4.2 – **Delays** to or from a **Distributed Alarm System** - Alarm Signal generating ME Equipment annunciates Alarm Signals in response to Alarm Conditions that it detects. If this ME Equipment is part of a Distributed Alarm System, the Distributed Alarm System **may** annunciate the Alarm Signals of that Alarm Condition at remote components of the Distributed Alarm System. It takes a finite amount of time for information related to an Alarm Condition to reach all components of a Distributed Alarm System. In many cases, this amount of time is very short, however, specific characteristics of a Distributed Alarm System can significantly delay annunciation of Alarm Signals at remote components of the Distributed Alarm System. Use models in intensive care units **may require** that remote equipment is operated as the primary alarming equipment (e.g. when the Alarm Signal generating ME Equipment is configured with the volume of its auditory Alarm Signal reduced to zero **–** no sound pressure). In such an environment of use the overall delay time before remote components of the Distributed Alarm System annunciate Alarm Signals **should** be limited to values that allow the clinician to respond to Physiological Alarm Conditions (such as cardiac arrest, ventricular fibrillation, high systolic pressure, etc.) in time. Inappropriate delay times for Alarm Signals in a Distributed Alarm System **may** delay treatment of Patients. It is strongly **recommended** that Risk Management be applied to identify adequate 'not to exceed' delay times of Alarm Signals to remote components of a Distributed Alarm System.

Subclause 208.6.8.3.101 – **Global temporary Alarm Signal inactivation states –** Duration of global Alarm Paused and Audio Paused - The global inactivation states Audio Paused and Alarm Paused disable the auditory or the auditory and visual Alarm Signals of **all Physiological** Alarm Conditions and the **auditory indications** of **all Technical** Alarms Conditions for a predetermined time. The inactivation states Audio Paused and Alarm Paused allow the clinical Operator to prevent False Alarms under clinical conditions such as equipment set up, treatment of the Patient, suctioning, washing etc… in ICUs. Ideally, the typical duration of these clinical procedures **should** determine the duration of the Audio Paused and Alarm Paused states. Therefore, ME Equipment **should** provide means to adapt the duration of the states Audio Paused and Alarm Paused to the clinical needs; however, the duration **must** be the same for all Alarm Signals of Multifunction Patient ME Equipment. Specifying different duration times for different physiological measurements would negatively impact the quality of the ME Equipment.

Subclause 208.6.8.101 – **Technical** Alarm Conditions - The Alarm **Inactivation States** Alarm Off and Alarm Paused support the functionality that is **essential** for Patient Monitoring Equipment: in both Alarm Inactivation States (Alarm Off and Alarm Paused), it is **necessary** for Electrocardiographic Monitoring Equipment that **visual** Alarm Signals of **Technical** Alarms Conditions are displayed. The purpose of these **visual** Alarm Signals is to inform the clinical Operator **–** even during the Alarm Inactivation States Alarm Off or Alarm Paused **–** that the M ME Equipment (or a part of the ME Equipment) is not operating because a **Technical** Alarm Condition such as 'ECG leads-off' interrupts the ECG monitoring of a Patient. A Technical Alarm Condition **may** influence the validity of a measured value. For instance, the Technical Alarm Condition 'ECG leads-off' prevents the heart rate from being calculated and displayed. Continuing to display the previously calculated heart rate **may** lead to misinterpretations by the clinical Operator because this value is invalid during the Technical Alarm Condition. Appropriate means to indicate that the heart rate is invalid **might** be to display a blank heart rate value or a symbol where the heart rate is displayed. In other cases, the tolerance of the measured values **might** be influenced or the measurement **might** be unreliable. In those cases, the clinical Operator **should** be informed that the currently displayed value **might** be questionable. The displayed value **should** be marked accordingly.

Subclause 208.6.9 – **Alarm Reset** - The clinical Operator action Alarm Reset performs the following actions: First, it stops the **auditory** Alarm Signal. Second, it stops **visual Latching** Alarm Signals of Alarm Conditions

that no longer exist. Third, it does not affect **visual** Alarm Signals for Alarm Conditions that **continue to exist** (those signals continue until the Alarm Conditions ceases). Fourth, it **enables** the Alarm System immediately to respond to a subsequent Alarm Condition. The fourth action 'enabling the Alarm System immediately' distinguishes the function Alarm Reset from the Alarm Inactivation States Alarm Paused, Audio Paused, Alarm Off and Audio Off. In contrast to the Alarm Inactivation States Audio Paused, Alarm Paused, Audio Off and Alarm Off that temporarily or permanently disable the Alarm System of ME Equipment, the function (clinical Operator action) Alarm Reset maintains the Alarm System in the 'ON'-state but applies the functions that are specified in subclause 208.6.9 a) to e). This function stops the auditory Alarm Signals, controls the visual Alarm Signals depending on an existing or ceased Alarm Condition, and **–** as outlined before **–** keeps the Alarm System enabled. As a result, the Alarm System can respond immediately to a subsequent Alarm Condition without requiring additional clinical Operator actions to activate the Alarm System again. This also explains why Audio Paused is not the appropriate state because it does not allow the related control to perform these functions of Alarm Reset. With the function Alarm Reset the clinical Operator acknowledges an active Alarm Condition once and does not need to be concerned about activating the Alarm System again because the Alarm System remains in the 'ON'-state. As a result the function Alarm Reset avoids the possibility that the clinical Operator **might** forget to activate the Alarm System again.

Subclause 208.6.10 – **Non-Latching** and **Latching** Alarm Signals - Different use models exist for ME Equipment that 1) is **continually** attended by a clinical Operator (such as in operating theatres/rooms) and 2) is **not continually** attended by a clinical Operator (such as in an ICU). In environments of use such as an ICU or emergency department, where Patients are not continuously attended, a clinical Operator normally cares for several Patients. Clinical Operator who are caring for several Patients cannot observe all of their Patients at the same time. Clinical Operator cannot easily identify short Alarm Conditions that occur on ME Equipment that provides Non-Latching Alarm Signal or for mixes of Non-Latching and Latching Alarm Signals. This **inability to identify and quickly respond to important short Alarm Conditions (e.g., short tachycardias) puts Patients in Hazardous Situations**. Configuring ME Equipment to **only** provide **Latching** Alarm Signals, forces clinical Operators to respond to **every** Alarm Condition. While this is conceptually a good idea, frequent false Alarm Conditions due to artefact or improperly set Alarm Limits can place a substantial administrative burden on the clinical Operator. **Latching** Alarm Signals **may** be desirable within Distributed Alarm Systems where remote equipment of an ME System is **not continuously** attended by a clinical Operator. **Non-Latching** Alarm Signals **may** be desirable in an environment of use where the ME Equipment is **continuously** attended by a clinical Operator.

Subclause 208.6.10.101 – **Non-Latching** Alarm Signals for **Technical** Alarm Conditions - A Technical Alarm Condition indicates a **physiological** measurement is not ready or has been interrupted for technical reasons. Such technical interruptions of a measurement **may** be caused by an **unintentional disconnection** of a Transducer, or a Lead Wire. For instance, the Technical Alarm Condition indicating that a sensor is disconnected implies that the relevant physiological quantity is not being measured and displayed. This implies that the heart rate is not being monitored and as consequence potential **Alarm Conditions may not be indicated**. Requiring **Non-Latching** Alarm Signals for **Technical** Alarm Conditions means those Alarm Signals are being displayed as long as the Alarm Condition exists and cease without clinical Operator interaction when the Technical Alarm Condition is corrected or a Transducer is reconnected.

Subclause 208.6.11.2.2 – **Failure** of **remote communication** of Alarm Conditions - ME Equipment as part of a Distributed Alarm System is essential for reliable alarming in an unattended environment of use. For that reason ME Equipment that falls under the scope of this particular standard **has to** be so designed that it

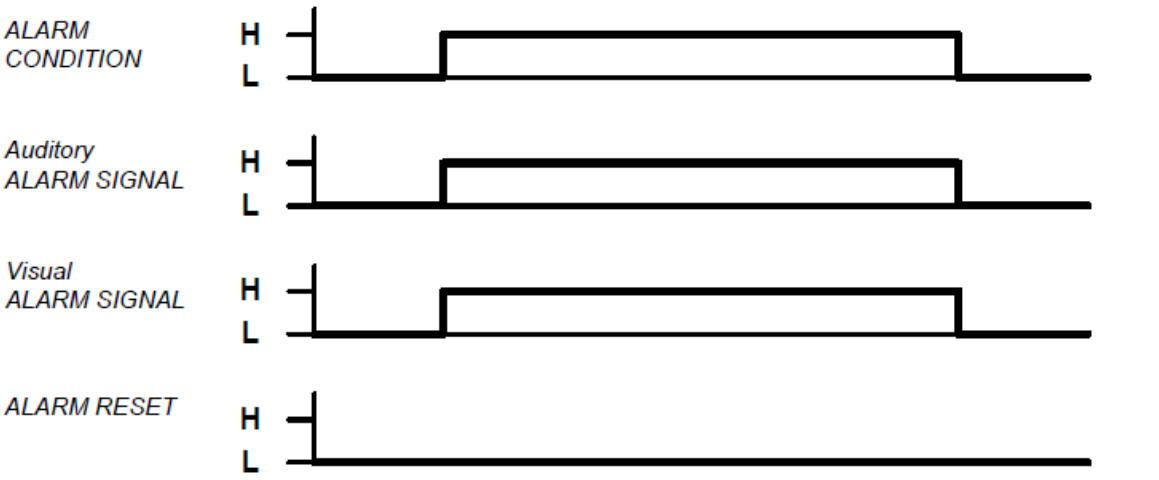
detects a communication failure and indicates the Alarm Signals of the corresponding **Technical** Alarm Condition. Labelling of such an ME Equipment with a warning to the effect that it **shall not** be relied upon for receipt of Alarm Signals is not appropriate to mitigate the Risk of critically ill Patients they are exposed to. The revised requirement 208.6.11.2.2 b) does only apply for ME Equipment that falls under the scope of this particular standard. The same applies of the entire content of this particular standard. Other components or parts of a Distributed Alarm System such as handheld devices, paging systems or even cellular phones do not fall under the scope of this particular standard; for those devices IEC 60601-1-8 applies.

Subclauses 208.6.11.101 – **Inactivation/activation** of Alarm Signals at remote components of a **Distributed Alarm System** - Distributed Alarm System duplicate Alarm Signals at remote components of a Distributed Alarm System such as a central station. Depending on the use model where the remote components of a Distributed Alarm System are being actively used as part of a Distributed Alarm System it makes sense to activate/terminate the inactivation state Alarm Paused, Audio Paused, Alarm Off or Audio Off (depending on the configuration) and to activate Alarm Reset at remote components of a Distributed Alarm System. As indicated before, this remote control functionality depends on the use model in certain environments of use such as in intensive care units. For this reason, **only the Responsible Organization should** have access to the corresponding configuration. The configuration that enables the function of remote activation and termination of global inactivation states (ALA Alarm Paused, Audio Paused, Alarm Off or Audio Off) and remote activation of Alarm Reset **must** be protected. **'Protected' means that the clinical Operator of the ME Equipment must not have access in Normal Use to the selection of the capability to activate and terminate global inactivation states** (Alarm Paused, Audio Paused, Alarm Off or Audio Off) and activation of Alarm Reset at components of a Distributed Alarm System. Adequate protection mechanisms are described in subclause 6.7 of IEC 60601-1-8:2006.

Annex BB
(informative)

Alarm diagrams of Clause 208/IEC 60601-1-8:2006

The following alarm status diagrams illustrate the auditory and visual ALARM SIGNALS for LATCHING and NON-LATCHING ALARM SIGNALS as defined in subclause 6.10 of IEC 60601-1-8:2006 and subclause 208.6.9 of this particular standard.



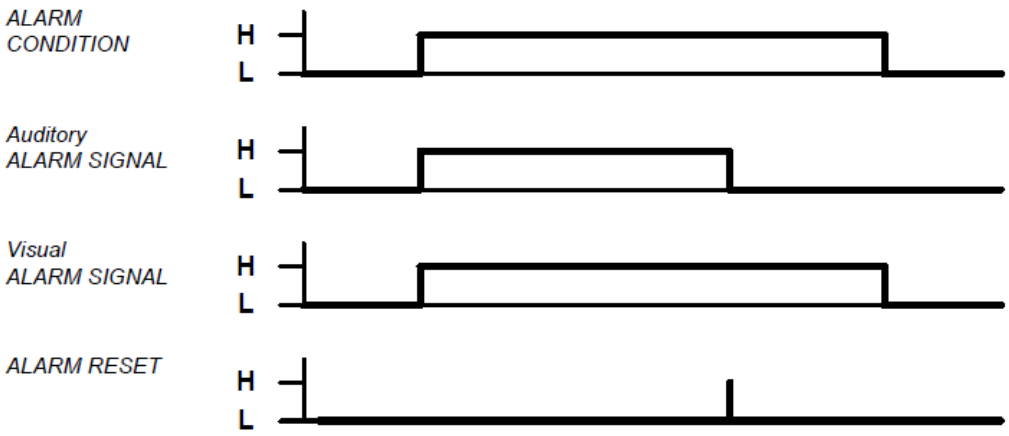
Key

H Activated state

L Deactivated state

Figure BB.1 – NON-LATCHING ALARM SIGNALS without ALARM RESET

Illustration of NON-LATCHING ALARM SIGNALS (Figure BB.1) as specified in IEC 60601-1-8:2006, subclause 6.10: without OPERATOR interaction, the auditory and visual ALARM SIGNALS are indicated as long as the ALARM CONDITION exists. As soon as the ALARM CONDITION ceases, the auditory and visual ALARM SIGNALS are terminated automatically without any OPERATOR interaction.



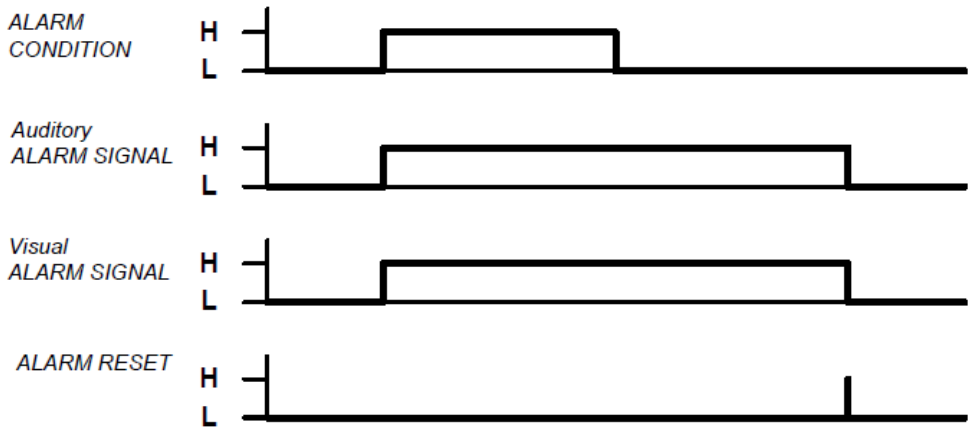
Key

H Activated state

L Deactivated state

Figure BB.2 – NON-LATCHING ALARM SIGNALS with ALARM RESET

Illustration of NON-LATCHING ALARM SIGNALS with ALARM RESET (Figure BB.2) as specified in IEC 60601-1-8:2006, subclause 6.10 and in subclause 208.6.9 of this particular standard: Activating ALARM RESET stops the auditory ALARM SIGNAL. As soon as the ALARM CONDITION ceases the visual ALARM SIGNAL is terminated.



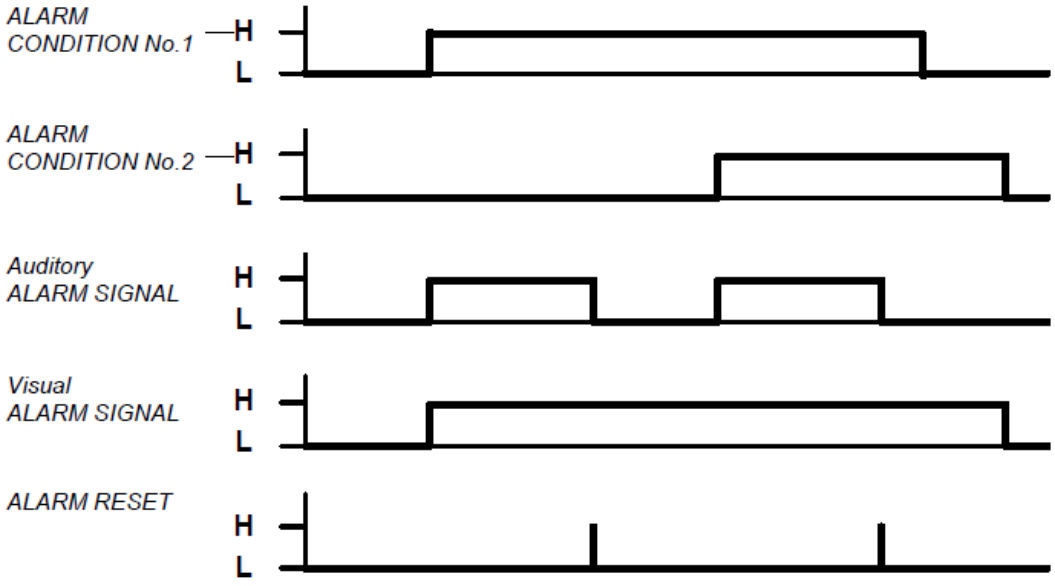
Key

H Activated state

L Deactivated state

Figure BB.3 – LATCHING ALARM SIGNALS with ALARM RESET

Illustration of LATCHING ALARM SIGNALS with ALARM RESET (Figure BB.3) as specified in IEC 60601-1-8:2006, subclause 6.10 and in subclause 208.6.9 of this particular standard: without OPERATOR interaction, the auditory and visual ALARM SIGNALS are activated for an unlimited time. The OPERATOR is forced to reset the ALARM SIGNALS of a PHYSIOLOGICAL ALARM CONDITION by activating the function ALARM RESET. After activating ALARM RESET the alarm behaviour compares to NON-LATCHING ALARM SIGNALS.



Key IEC 386/11

H Activated state

L Deactivated state

Figure BB.4 – Two ALARM CONDITIONS with ALARM RESET

Illustration of two ALARM CONDITIONS with ALARM RESET (Figure BB.4) as specified in IEC 60601-1-8:2006 subclause 6.10 and in subclause 208.6.9 of this particular standard: a subsequent PHYSIOLOGICAL ALARM CONDITION of another physiological parameter reactivates the auditory ALARM SIGNAL.

ISO 80601-2-55 First edition 2011-12-15 Particular requirements for the Basic Safety and Essential Performance of **Respiratory Gas Monitors**

201.7.9.2.8.101 * Additional requirements for **start-up procedure** - The instructions for use **shall** include: a) a **method** of verifying **all** Operator-adjustable Alarm System functions;

201.7.9.2.9.101* Additional requirements for **operating instructions** - The instructions for use **shall** include the following: a) the **range** of adjustment of the **Alarm Limits**;

201.11.8.101.1 * **Supply failure Technical** Alarm Condition - When the power supply falls outside the values for normal operation, an RGM **shall**: a) generate a **Medium** Priority Technical Alarm Condition;
NOTE: After the loss of power, the Alarm System is not expected to repeat Alarm Signals indefinitely
b) stop displaying the respiratory Gas Reading. If the function of the RGM is maintained by the switchover to an Internal Electrical Power Source, the supply failure **Medium** Priority Technical Alarm Condition **shall not** be generated. Any such switchover to an Internal Electrical Power Source **shall** be indicated by an **Information Signal** or a **Low** Priority Technical Alarm Condition.
Check compliance by means of functional testing

202.6.2.1.10 **Compliance criteria** - Replacement: Under the Immunity Test Levels specified in IEC 60601-1-2:2007, 6.2, the RGM **shall** continue to provide Basic Safety and **Essential Performance**.
NOTE: For the purposes of this International Standard, an RGM is not considered to be a Life-Supporting ME Equipment or ME System
The following conditions associated with Basic Safety and Essential Performance **shall** apply: aa) no permanent degradation or unrecoverable loss of function, due to damage of ME Equipment (components) or software, or loss of data **shall** be observed at any Immunity Test Level specified in IEC 60601-1-2:2007, 6.2 and in 202.6.2.3.1 a); bb) no change of operating mode; cc) operation within the specified Measurement Accuracy limits or generation of a **Technical** Alarm Condition

206.6.2.2.2 **Primary operating functions** - For an RGM, the following **shall** be considered Primary Operating Functions: aa) observing the Gas Reading; Example FiO2, CO2, anaesthetic agent concentration. bb) **setting Alarm Limits**; cc) **deactivating Alarm Signals**;

208 General requirements, tests and guidance for Alarm Systems in medical electrical equipment and medical electrical systems - IEC 60601-1-8:2006 applies except as follows:
208.6.1.2 * Alarm Condition **priority** Amendment (add before the compliance test):
NOTE: For the purposes of this International Standard, Minimum Alveolar Concentration (MAC) values are those listed in the drug package insert for each inhalational agent
For each respiratory gas that an RGM is designed to monitor, the Alarm System **shall** generate each Gas Reading Alarm Condition, with its **minimum** priority, as given in Table 201.106. If the RGM is capable of detecting the presence of more than one halogenated anaesthetic agent within a gas mixture, but not of quantifying Gas Levels and displaying the Gas Readings of that mixture, it **shall** be capable of generating a Medium Priority Alarm Condition in the presence of such a mixture (see Table 201.106). If the RGM is capable of detecting, quantifying and displaying a mixture of halogenated agents, the RGM **shall** generate a Low Priority Alarm Condition whenever the RGM detects a mixture of halogenated agents of less than 3 MAC (see Table 201.107), and generate a **Medium** Priority Alarm Condition whenever the RGM detects a mixture of halogenated agents equal to or greater than 3 MAC. An Alarm System that automatically

changes Alarm Condition priority without Operator intervention **shall not** change to a priority **lower** than that specified in this International Standard.

Table 201.106 — GAS READING ALARM CONDITIONS and priorities

Row number	GAS READING	ALARM CONDITION priority for low GAS READING	ALARM CONDITION priority for high GAS READING
1	Inspired halogenated anaesthetic agent	LOW PRIORITY[a]	MEDIUM PRIORITY
2	Exhaled CO_2	MEDIUM PRIORITY	MEDIUM PRIORITY
3	Inspired CO_2		MEDIUM PRIORITY
4	Inspired nitrous oxide	LOW PRIORITY[a]	MEDIUM PRIORITY[a]
5	Inspired O_2	MEDIUM PRIORITY	MEDIUM PRIORITY[a]
6	Inspired O_2 < 18 %	HIGH PRIORITY	
7	Multiple halogenated anaesthetic agents present[b]	MEDIUM PRIORITY	
8	Multiple halogenated anaesthetic agents value < 3 MAC[c]	LOW PRIORITY	
9	Multiple halogenated anaesthetic agents value ≥ 3 MAC[c]	MEDIUM PRIORITY	

NOTE The priorities listed are the minimum priority.

Exhaled GAS LEVEL ALARM CONDITIONS may also be provided.

[a] If this optional ALARM CONDITION is provided, it is required to be of the level of priority indicated.

[b] When the RGM is capable of detecting but not capable of quantifying and displaying a mixture of halogenated anaesthetic agents.

[c] When the RGM is capable of detecting, quantifying and displaying a mixture of halogenated anaesthetic agents.

208.6.5.1 * General requirements - Amendment (add as the last sentence in the subclause before the compliance test): It **shall not** be possible to set the **Alarm Limit** for the low inspired oxygen Gas Reading below **18 %** in an **Alarm Preset**.

208.6.6.2.101 * Additional requirements for **adjustable Alarm Limit** - The Alarm Limit(s) for every provided Gas Reading Alarm Condition, except for the high Gas Level for inspired nitrous oxide, **shall** be Operator-Adjustable. The Operator **shall** be required to take deliberate action to **adjust Alarm Limits**. An additional deliberate action **shall** be required to set the low **Alarm Limit** for the inspired oxygen Gas Reading below **18 %.**

Check compliance by means of inspection and functional testing

208.6.8.5.101 * Additional requirements for **Alarm Signal Deactivation States**, indication and access - The Manufacturer-configured default **Audio Paused** or **Alarm Paused** interval of the RGM **shall** not exceed **2 min**.

Check compliance by means of functional testing

Subclause 201.11.8.101.2 — **Settings** and **data storage** following **short interruptions** or **automatic switchover** - The selection of settings appropriate for the Patient customizes the RGM for that Patient. A sudden and unexpected loss of these settings, particularly when the Operator is working to solve an

unexpected loss in power, can be an unacceptable Risk for the Patient. As is required for Alarm Settings in IEC 60601-1-8:2006, **settings are expected to be maintained during short losses of Supply Mains or automatic switchover.**

Subclause 208.6.1.2 — Alarm Condition **priority** - This International Standard requires an RGM to generate an Alarm Condition when it detects more than one halogenated anaesthetic agent in the respired gas. This helps to identify cross-filled vaporizers and to detect a failure in vaporizer "lockout" systems. Multiple anaesthetic gases in a mixture **can** also occur when agents are deliberately changed during the course of anaesthesia. Two Alarm Condition monitoring requirements were established. A **Low** Priority Alarm Condition is required for an RGM with automatic identification of individual halogenated agents in a gas mixture containing more than one halogenated agent, and when the total MAC is less than 3. For an RGM that cannot automatically quantify the Gas Levels of individual halogenated agents but which can detect when a mixture is present, the **Alarm Condition** is required to be at least at **Medium** Priority. These requirements support changing halogenated agents without creating nuisance Alarm Signals. MAC values are defined to be the values listed by the manufacturer's drug package insert (for healthy adults) that is mandated and reviewed by the US FDA, or via any algorithm that a Manufacturer **might** choose to implement. MAC can be used to effectively compare halogenated anaesthetic agents and allow for any future such agents. The actual MAC value for an individual can be affected by age, health and other factors. Mandating age compensation would be design-restrictive, especially for Anaesthetic Workstations that only deliver one halogenated anaesthetic agent. The committee determined a 3 MAC level was reasonable, which happens to be the default high halogenated anaesthetic agent Alarm Limit for most RGMs. MAC can be used to effectively compare halogenated anaesthetic agents and allow for any such agents in the future.

Subclause 208.6.5.1 — General requirements - An inspired gas mixture with less than **18 % oxygen** is hypoxic and therefore dangerous. Although there are rare circumstances when such a mixture is needed, allowing an **Alarm Preset** to be set **below** this level is **clinically unsafe**. An Alarm System that permits such a low Alarm Preset for inspired oxygen **can mean that the Operator accidentally loses the notification they expect regarding delivery of a hypoxic gas mixture**.

Subclause 208.6.6.2.101 — Additional requirements for an **adjustable Alarm Limit** - The Operator needs to set the Alarm Limits appropriately for certain clinical procedures that require specific Gas Levels. To avoid accidental adjustment of these Alarm Limit settings, deliberate action is required of the Operator. Although rare, a specific clinical procedure **may** require an inspired gas mixture with less than 18 % oxygen, which means the Operator needs to be able to set the Alarm Limits appropriately in order to avoid having an unmonitored Patient. To avoid accidental selection of this otherwise dangerous setting, **a second deliberate action is required to set the Alarm Limit for low inspired oxygen below 18 %.**

Subclause 208.6.8.5.101 — Additional requirements for **Alarm Signal Deactivation States**, indication and access - **An interval of 2 min is the longest that Audio Paused or Alarm Paused should last without a deliberate choice by the Responsible Organization or Operator**.

MECA ALARM STANDARDS CROSS-REFERENCE

ISO 80601-2-56 First edition 2009-10-01 Particular requirements for Basic Safety and Essential Performance of **Clinical Thermometers For Body Temperature Measurement**

201.12.1.101 Additional requirements for accuracy of controls and instruments - When the Clinical Thermometer is not capable of indicating a temperature within the Laboratory Accuracy, it **shall** provide a **Technical** Alarm Condition or it **shall not** provide an Output Temperature. Alternatively a Clinical Thermometer **may** be marked with the ambient temperature operating range.

202.6.2.1.10 **Compliance criteria** - c) Laboratory **Accuracy** at any point in the Rated Output Range and in the Rated Extended Output Range as indicated in 201.101.2 or generation of either a **Technical** Alarm Condition or an indication of abnormal operation.

AA.201.4.3.101 Additional requirements for **Essential Performance** - Clinical Thermometers span the range from invasive ME Equipment with sophisticated Alarm Systems that continually monitor critically ill Patients to simple, inexpensive home healthcare environment ME Equipment. Every Clinical Thermometer measures or estimates the temperature of a Reference Body Site for the purpose of diagnosing or monitoring. These purposes can be the detection of fever, determination of the moment of ovulation, monitoring of the physiological response to medication and procedures, detection of life-threatening situations (e.g. malignant hyperthermia, sepsis) and many other applications. This standard considers it an unacceptable Risk for a Clinical Thermometer to present an Output Temperature that is not accurate without indicating that it is not accurate. Methods of indicating this degraded performance include generating a **Technical** Alarm Condition or not providing an Output Temperature. Additionally, to allow for affordable home healthcare Clinical Thermometers, this standard **permits the permissible** operating temperature range to be marked on the Clinical Thermometer.

MECA ALARM STANDARDS CROSS-REFERENCE

ISO 80601-2-61 First edition 2011-04-01 Particular requirements for Basic Safety and Essential Performance of **Pulse Oximeter Equipment**

201.7.2.101 Additional requirements for **marking** on the **outside** of ME Equipment or ME Equipment parts - ME Equipment, parts or Accessories **shall** be Clearly, Legibly marked as follows. d) If a Pulse Oximeter Monitor is **not** provided with a **low SpO2** Alarm Condition**,** a statement to the effect **"No SpO2 Alarm (Conditions)"** or Symbol IEC 60417-5319 (DB-2002-10) (see IEC 60601-1-8:2006, Table C.1, Symbol 3).

201.7.9.2.1.101 Additional general requirements - The **instructions for use shall** indicate the following: d) a description of the effect on displayed and transmitted SpO2 and pulse rate data values by: **–** data averaging and other signal processing, **–** the Data Update Period, **–** the **Alarm Condition Delay,** and **– Alarm Signal Generation Delay** including the effects of any selectable operating mode that affects these properties;
NOTE: Annex GG provides an example of how to assess and describe response time graphically

f) **if no Alarm System** that includes the capability to detect an SpO2 or pulse rate **Physiological** Alarm Condition is provided, a statement to that effect

201.7.9.2.8.101 Additional requirements for **start-up Procedure** - If an Alarm System that includes the capability to detect **Physiologica**l Alarm Conditions is provided and automatic self-test of **Alarm Signal generation is not provided**, the **instructions for use shall** include a method for Operator -initiated **testing** of **Alarm Signal** generation

201.7.9.2.9.101 Additional requirements for **operating instructions** - The **instructions for use shall** indicate the following: b) if the Pulse Oximeter Equipment is provided with adjustable **Alarm Limits**, the **range** of adjustment of the **Alarm Limits**;

201.11.8.101.1 **Supply failure Technical** Alarm Condition - If Pulse Oximeter Equipment is equipped with an Alarm System that detects a Physiological Alarm Condition the Alarm System **shall** provide at least a **Medium** Priority **Technical** Alarm Condition to indicate when the power supply falls outside the values specified for normal operation.
NOTE: After the loss of power, the Alarm System is not expected to repeat Alarm Signals indefinitely. If the function of the Pulse Oximeter Equipment is maintained by the switchover to an Internal Electrical Power Source, the supply failure Medium Priority Technical Alarm Condition **shall not** be activated. **Any such switchover** to an Internal Electrical Power Source **shall** be indicated by an Information Signal or a **Low** Priority Technical Alarm Condition.
Check compliance by functional testing

201.12.4.101 * **Data Update Period** - There **shall** be an **indication** that SpO2 or pulse rate data is not current when the Data Update Period is greater than **30 s**. The Data Update Period time **may** be shorter than 30 s. A maximum Data Update Period for saturation and pulse rate shorter than 30 s is recommended for continuous neonatal monitoring and diagnostic applications. If the Pulse Oximeter Equipment is equipped with an Alarm System that detects any **Physiological** Alarm Conditions, the Alarm System **shall provide** at least a **Low** Priority Alarm Condition to indicate when the Data Update Period exceeds 30 s. Pulse Oximeter Equipment that is not equipped with an Alarm System that detects any Physiological Alarm Condition **shall** indicate when the Data Update Period exceeds 30 s. The indication **shall** be described in the **instructions for use**.
Check compliance by inspection

201.12.4.102 * **Signal inadequacy** - An **indicator** of signal inadequacy **shall** be provided to the Operator when the displayed SpO2 or pulse rate value is potentially incorrect. Symbol ISO 7000-0435 (see Table D.2.101, Symbol 12) **may** be used for this indication. A description of the **indicator** and its function **shall** be provided in the **Accompanying Document**.
Example: Signal inadequacy indicated by a **visual Information Signal** or a **Low** Priority Alarm Signal

201.13.101 Detection of **Pulse Oximeter Probe faults** and **Probe Cable Extender faults** - If the Pulse Oximeter Equipment is equipped with an Alarm System to detect any **Physiological** Alarm Conditions, the Alarm System **shall** provide a **Technical Alarm Condition** to indicate when any wire in the Pulse Oximeter Probe cable or Probe Cable Extender is opened or shorted to any other wire in the Pulse Oximeter Probe cable or Probe Cable Extender that causes other than normal operation. Pulse Oximeter Equipment that is not equipped with an Alarm System that detects any Physiological Alarm Conditions **shall** visually indicate the presence of Pulse Oximeter Probe Faults. The indication **shall** be described in the **instructions for use**.
Example: Indication of abnormal operation by blank display
Check compliance with the following test: a) Disconnect the Pulse Oximeter Probe from the Pulse Oximeter Equipment and place it in series with a circuit with which each Pulse Oximeter Probe wire can be opened or shorted to any other Pulse Oximeter Probe wire. Do not test unused wires in the Pulse Oximeter Probe cable or Probe Cable Extender. b) Repeat for any Probe Cable Extender. c) Verify that either a Pulse Oximeter Probe Fault is indicated or that the Pulse Oximeter Equipment continues normal operation

201.103.2 **Connection** to **electronic health record** - Pulse Oximeter Equipment **should** be equipped with a Signal Input/Output Part that permits data transmission from the Pulse Oximeter Equipment to an electronic health record. The data transmitted **should** include: d) if Pulse Oximeter Equipment is equipped with an Alarm System that detects **any Alarm Conditions**, the Alarm System **status** including: **–** the **Alarm Limits**; **–** the presence of any **Alarm Conditions**; **–** the occurrence of any **Alarm Signal Inactivation**. The data transmission **should** be capable of being provided with a Network/Data Coupling in accordance with ASTM F2761-09.

201.103.3 **Connection** to a **Distributed Alarm System** - For Pulse Oximeter Equipment that is equipped with an Alarm System that detects a **Physiological** Alarm Condition, the Alarm System **should** be equipped with a Signal Input/Output Part that permits connection to a **Distributed Alarm System**. The data transmission **should** be capable of being provided with a Network/Data Coupling in accordance with ASTM F-2761-09.

202.6.2.1.10 * Requirements Subclause 6.2.1.10 of IEC 60601-1-2:2007 is replaced by: Under the **Immunity Test Levels** specified in IEC 60601-1-2:2007, 6.2, Pulse Oximeter Equipment **shall** be able to provide Basic Safety and **Essential Performance**. The following conditions associated with Basic Safety and Essential Performance **shall** apply: b) Operation within specified SpO2 Accuracy limits and pulse rate Accuracy limits or generation of either a **Technical Alarm Condition** or an indication of abnormal operation.

208.6.1.2.101 * Additional requirements for Alarm Condition **priority** - If the Pulse Oximeter Equipment is equipped with an Alarm System that detects a Physiological Alarm Condition, the Alarm System **shall** provide at least a **Medium** Priority Alarm Condition for low SpO2 level.
NOTE: A high SpO2 level Alarm Condition can enhance Patient safety for certain clinical applications, e.g. neonatal monitoring.
Check compliance by inspection

208.6.5.4.101 * Additional requirements for **Default Alarm Preset** - If the Pulse Oximeter Monitor is equipped with an Alarm System to detect a low SpO2 level **Physiologica**l Alarm Condition, the **Alarm Limit** in the Manufacturer-configured **Alarm Preset** for the SpO2 level Physiological Alarm Condition **shall not** be less than **85 %** SpO2 [30] [64]. Unless the low SpO2 Alarm Limit is displayed continuously, the low SpO2

Alarm Limit of any Operator configured Alarm Preset **shall not** be less than the low SpO2 Alarm Limit stored in the Default Alarm Preset.
Check compliance by functional testing

208.6.8.5.101 Additional requirements for **Alarm Signal Inactivation States**, indication and access - The Manufacturer-configured default Audio Paused or Alarm Paused interval of Pulse Oximeter Equipment **shall not exceed 2 min**.
Check compliance by functional testing

Subclause 208.6.5.4.101 — Additional requirements for **Default Alarm Preset** - **85 % SpO2 is a generally accepted lower Alarm Limit for most clinical situations**; however lower Alarm Limits **can** be desirable in particular clinical conditions. The **Operator is permitted to set lower Alarm Limits during Normal Use**. In selecting 85 % as the minimum Manufacturer-configured default Alarm Limit for the low SpO2 level Alarm Condition, a compromise was made between two clinical requirements. One requirement was that Pulse Oximeter Equipment **should** act as an early indicator of distress in a Patient with relatively normal oxygenation. In this situation, it would be good clinical practice to select a default Alarm Limit above the "knee" of the oxyhaemoglobin dissociation curve that provides as much margin of safety as is practical. The second requirement is to **avoid frequent Alarm Signals not necessarily requiring clinical intervention**, which **might** "desensitize" caregivers to Alarm Signals. In this case, one **might** argue for a default Alarm Limit low enough to guarantee that most Alarm Conditions would be meaningful by anyone's measure. It was acknowledged that in both clinical situations, many, if not most, Operators were likely to rely on the default low SpO2 Alarm Limit. Another factor that was considered is that many examples of Pulse Oximeter Equipment intended for continuous monitoring allow Responsible Organization -configured or Operator-configured default Alarm Limits and that for specific monitoring settings, default Alarm Limits that were more closely tailored to the needs of the Patients and Operators in that setting could be selected. Given these considerations, a lower limit of 85 % for the Manufacturer-configured default Alarm Limit was felt to be an acceptable compromise that best met both clinical requirements.

ME Alarm Dictionary

The definitions below have been gathered from multiple sources including:
60601-1, 60601-1-6, 60601-1-8, EN 475: 1995, ISO 3744, ISO 3745, ISO 80601-2-13, ISO 80601-2-55
and Frank Block's webpage - http://medicalalarms.wikifoundry.com/page/Glossary
In some instances, content has been modified for document consistency.
(★) indicates terms drafted by ECRI Institute and commented on by the Medical Device Alarms Summit planning group. They are largely based on longstanding Alarm System-related definitions published in ECRI Institute's Health Devices journal. These definitions have not been reviewed or approved by the FDA or any standards related committee.
(♪) indicates musical reference.

ACKNOWLEDGED - State of an Alarm System initiated by Operator action, where the auditory Alarm Signal associated with a currently active Alarm Condition is inactivated until the Alarm Condition no longer exists
NOTE 1: Acknowledged only affects Alarm Signals that are active at the time of the Operator action
NOTE 2: Acknowledged can terminate after a predetermined time interval has elapsed

ACTIVATE - To begin the annunciation of Alarm Signal, typically with audible and/or visual signals, when certain criteria are met

ADSR ENVELOPE♪ - In music, particularly synthesizer programming, this is the modulating shape of a note, standing for Attack, Decay, Sustain and Release corresponding to 60601-1-8 Alarm Signal Envelope parameters: Rise Time, (No Decay due to required envelope), Pulse Duration and Fall Time

ALARM – For the purposes of Medical Alarms Standards, the word "Alarm" is not a Noun, rather an Adjective describing an object as a term related to an Alarm System. E.g. Alarm Condition, Alarm Limit… From the Olde English "to arms"

ALARM COMMUNICATION MANAGEMENT, ACM – Framework for dealing with the device's Alarm System

ALARM CONDITION - State of the Alarm System when it has determined that a potential or actual hazardous situation exists for which Operator Awareness or response is required
NOTE 1: An Alarm Condition can be invalid, i.e. a False Positive Alarm Condition
NOTE 2: An Alarm Condition can be missed, i.e. a False Negative Alarm Condition

ALARM CONDITION DELAY - Time from the occurrence of a triggering event either in the Patient, for Physiological Alarm Conditions, or in the equipment, for Technical Alarm Conditions, to when the Alarm System determines that an Alarm Condition exists

ALARM ESCALATION PLAN★ - An Alarm Escalation Plan designates which caregiver(s) will receive the initial Alarm Condition notification, who receives back-up notification if the Alarm Signal is not responded to, and the time intervals for each escalation. (This term should not be confused with the IEC 60601-1-8:2006 definition for "escalation" specific to the devices/Alarm Systems, See "Escalation")

MECA ALARM STANDARDS CROSS-REFERENCE

ALARM FATIGUE★ - When staff members are exposed to an excessive number of Alarm Signals, this can result in sensory overload, causing staff to become desensitized to the Alarm Signals. Desensitization may result in delayed response or missed Alarm Signals

ALARM INTEGRATION MODEL★ - An ancillary Alarm Condition notification model in which designated clinical device Alarm Conditions are transmitted via an interface to the integration system (also known as middleware), which normally consists of hardware and software components, and then communicated to the appropriate care providers via a clinician-worn device, such as a pager or wireless phone. The interface may simply relay Alarm Conditions, or include some rules to attempt to filter out Alarm Conditions or Signals determined to be nuisance or False Alarms

ALARM LIMIT - Threshold used by an Alarm System to determine an Alarm Condition. May be non-adjustable, a simple Operator-adjustable setpoint or an algorithmically determined criterion

ALARM MANAGEMENT★ - Orchestration of the culture, staff responsibilities, technology, policies and procedures, practices, and other factors, tasks, and processes that are required to support prompt and efficacious Alarm Condition verification, notification, response, and documentation

ALARM OFF - State of indefinite duration in which an Alarm System or part of an Alarm System does not generate Alarm Signals. Audio and Video are not displayed for an indefinite time

ALARM PAUSED - State of limited duration in which the Alarm System or part of the Alarm System does not generate Alarm Signals. Audio and Video are not displayed for a definite time

ALARM PRESET - Set of stored configuration parameters, including selection of algorithms and initial values for use by algorithms, which affect or modify the performance of the Alarm System

ALARM PRIORITIZATION★ - Visual and audible differentiation of Alarm Conditions (e.g., life-threatening vs. other types of less serious events) in which the visual and auditory Alarm Condition prominence connotes the Level of Urgency with which clinicians should respond

ALARM RESET - Operator action that causes the cessation of an Alarm Signal for which no associated Alarm Condition currently exist;
NOTE: "Enabling the Alarm System immediately" distinguishes the function Alarm Reset from the Alarm Inactivation States Alarm Paused, Audio Paused, Alarm Off and Audio Off (IEC 60601-2-23, -27, -34, -49)

ALARM SETTINGS - Alarm System configuration, including but not limited to:
– Alarm Limits;
– the characteristics of any Alarm Signal Inactivation States; and
– the values of variables or parameters that determine the function of the Alarm System
NOTE: Some algorithmically-determined Alarm Settings can require time to be determined or re-determined

ALARM SIGNAL - Type of signal generated by the Alarm System to indicate the presence (or occurrence) of an Alarm Condition; Also a sound or signal calling attention to a situation which requires Operator action

when the Operator's attention is focused elsewhere
Note: Previously defined in EN 475, 1995, as: Signal indicating the onset and/or duration of a condition that requires a response by the Operator

ALARM SIGNAL GENERATION DELAY - Time from the onset of an Alarm Condition to the generation of its Alarm Signal(s)

ALARM SIGNAL INACTIVATION STATE – A condition of the UUT in which the Audio, Visual or Audio and Visual Generation of Alarm Signals is inactivated

ALARM SYSTEM - Parts of ME Equipment or a ME System that detect Alarm Conditions and, as appropriate, generate Alarm Signals

ALERT – Heightened State of Awareness; term often used to indicate a Technical Audio or Visual Information Signal; not defined in 60601-1-8, used as verb "alert the Operator" rather than noun or adjective

AMBIENCE – As Laboratory procedures indicate the term to mean the environmental near-field of operation of the EUT for measurements of Temperature or Humidity, Alarm Signal testing uses the term for Non-Alarm-Signal Visual and Audio Measurement, e.g. Lux values for the Lighting in a room used for Visual Alarm Signal Testing or dB(A) values for the room used for Audio Alarm Signal Testing

ANECHOIC CHAMBER, ANECHOIC ROOM – This is a room in which a free field is obtained, without echo

ATTACK ♪ – The A segment of time in the ADSR Envelope in which the sound is modified from its initial state to its Decay level. The Attack plus Decay segments are equivalent to Rise Time in 1-8

AUDIO INDICATOR – The sound-generating means by which the audio Alarm Signal is generated.
Example: Generally a speaker, other means are conceivable

AUDIO OFF – The state of indefinite duration in which the Alarm System or part of the Alarm System does not generate an auditory Alarm Signal. Visual Alarms Signals continue to propagate

AUDIO PAUSED - State of limited duration in which the Alarm System or part of the Alarm System does not generate an auditory Alarm Signal. Visual Alarm Signals continue to propagate

AWARENESS – Attention, see State of Awareness

BACKGROUND NOISE - Noise from all sources other than the UUT
NOTE: Background noise includes contributions from airborne sound, noise from structure-borne vibration, and electrical noise in the instrumentation

BASE STANDARD – ANSI/AAMI IEC 60601-1 Standard, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

MECA ALARM STANDARDS CROSS-REFERENCE

BASIC SAFETY - Freedom from unacceptable Risk directly caused by physical Hazards when ME Equipment is used under Normal Condition and Single Fault Condition

BURST - Group of Pulses with a distinctive rhythm or pattern, usually one complete instance of an Alarm Signal

BURST SPACING – Outdated term from EN 475:1995 – Time between the start of the first Pulse in one Burst and the start of the first Pulse of the next Burst

CLIPPING – Extreme form of Distortion resulting in an output that has been severely modified

dB(A) – Decibel with an A-weighting curve, applied to SPLs in an effort to account for the relative loudness perceived by the human ear

COLLATERAL STANDARD – specify general requirements for Basic Safety and Essential Performance applicable to:
– a subgroup of ME Equipment (e.g. radiological equipment);
– a specific characteristic of all ME Equipment not fully addressed in this standard
If a Collateral Standard applies to ME Equipment for which a Particular Standard exists, then the Particular Standard takes priority over the Collateral Standard

CONTACT QUALITY MONITOR, CQM - Circuit in HF Surgical Equipment or Associated Equipment intended for connection to a Monitoring NE providing an Alarm Signal in the event that Neutral Electrode (NE) contact with the Patient becomes insufficient

DANGER ZONE - Any zone within and/or around an Anaesthetic Workstation in which a person is subject to a Risk to their health or safety from the powered movement of the Anaesthetic Workstation or its components

DEACTIVATION STATE – See Alarm Signal Inactivation State

DECIBEL, dB - A logarithmic unit used to express the power or intensity of a sound

DECAY♪ - The segment of time in the ADSR Envelope in which the sound is transitioned from the Attack Level to the Sustain Level; ignored in 60601-1-8 Alarm Systems in favor of a smooth Rise Time

DECENTRALIZED ALARM COVERAGE MODEL★ - Staff rely on direct Alarm Condition notification from central stations, remote displays, or the medical devices themselves within the care area to provide Alarm System notification. Less common, some decentralized Alarm Signal coverage models utilize unit-based monitor watchers (e.g., monitor technicians, nurses) to continuously watch central station displays and provide Alarm Condition notification to the nurses or other care providers

DE-ESCALATION - Process by which an Alarm System decreases the priority of an Alarm Condition or decreases the sense of Urgency of an Alarm Signal

DEFAULT ALARM PRESET - Alarm Preset that can be activated by the Alarm System without Operator action

NOTE: Manufacturer or Responsible Organization -configured Alarm Presets are possible types of Default Alarm Presets

DISTORTION – Any aspect of the output signal which is not representative of the expectation provided as determined by the system and its input factors; also Noise

DISTRIBUTED ALARM SYSTEM – An Alarm System that involves more than one item of equipment of a ME System

NOTE: The parts of a Distributed Alarm System can be widely separated in distance

DUTY CYCLE – Per 60601-1-8, this is the percentage of time of a Visual Indicator's On-Time vs. Off-Time

ENABLED - State of the Alarm System in which it is able to generate Alarm Signals. This may occur in any of the following manners:

(1) Immediately after the device has been powered on, in certain devices; OR

(2) After (a) the device has been powered on AND (b) an "enabling algorithm" permits the alarms to be activated. If the Alarm System is unable to initiate Alarm Signals immediately after it is powered on, this state is called "not enabled." In this case, after an "enabling algorithm," the Alarm System is able to initiate Alarm Signals. OR

(3) After an Alarm System is in the Audio Pause or Alarm Pause state, and (a) a timed pause interval has ended or (b) an "enabling algorithm" has been satisfied. OR

(4) After an Alarm System is in the Audio Off or Alarm Off state, and an "enabling algorithm" has been satisfied. OR

(5) Upon action by the operator

ENABLING ALGORITHM - (1) An algorithm used by a device after it is powered on to change the state of the Alarm System from "not enabled" to "enabled." (2) An algorithm that causes the device to exit from the "Audio Pause" or "Alarm Pause" state that does not depend upon time. (3) An algorithm causes the device to exit from the "Audio Off" or "Alarm Off" state

END POINT – End of segment of time to be measured, E.g. time of the end of Pulse Duration

ENVELOPE – Most often found in synthesizer programming and musical instrument effect modules, the Envelope is the shape of the intensity of the output over time and includes the following elements: Attack, Decay, Sustain, and Release. In 60601-1-8, those elements correspond to the following parameters which together make up the Envelope of a Burst: Rise Time, (No Decay due to required 1-8 Envelope), Pulse Duration and Fall Time.

EUT – Equipment Under Test

ESCALATION - Process by which an Alarm System increases the priority of an Alarm Condition or increases the sense of Urgency of an Alarm Signal

ESSENTIAL PERFORMANCE – Performance of a clinical function, other than that related to Basic Safety, where loss or degradation beyond the limits specified by the Manufacturer results in an unacceptable Risk

FALL TIME – t_f, Interval over which the Pulse amplitude decreases from 90 % to 10 % of its maximum

FALSE ALARM★ - An Alarm Condition or Alarm Signal propagated by an Alarm System that has been determined to have been improperly implemented, See False Positive Alarm Condition, False Negative Alarm Condition

FALSE HARMONIC – Unintended Partial output by device, likely due to reflection or distortion

FALSE NEGATIVE ALARM CONDITION - Absence of an Alarm Condition when a true triggering event has occurred in the Alarm System

NOTE: An Alarm Condition can be rejected or missed because of spurious information produced by the Patient, the Patient-equipment interface, other equipment or the equipment itself

FALSE NEGATIVE ALARM SIGNAL - Absence of an Alarm Signal when a true triggering event has occurred in the Alarm System

FALSE POSITIVE ALARM CONDITION - Presence of an Alarm Condition when no true triggering event has occurred in the Alarm System

NOTE: A False Positive Alarm Condition can be caused by spurious information produced by the Patient, the Patient-equipment interface, other equipment or the Alarm System itself

FALSE POSITIVE ALARM SIGNAL - Presence of an Alarm Signal when no true triggering event has occurred in the Alarm System

FLASH-RATE, also FLASH FREQUENCY – Number of illuminating Cycles per Second for a Visual Indicator

FREE FIELD – A sound field in a homogeneous, isotropic medium, free of boundaries

FUNCTION- Clinically significant operation that the ME Equipment or ME System is intended to perform in the diagnosis, treatment or monitoring of a Patient or for compensation or alleviation of disease, injury or disability.

GLOBAL – Not a defined term in 60601-1-8. May be interpreted as referring to all the elements of a Distributed Alarm System, but at minimum refers to Alarm System

Note: (from clause 6.8.3) For the purposes of this standard (60601-1-8), a global Alarm Off or Audio Off Alarm Signal Inactivation State can affect all Alarm Conditions or all Physiological Alarm Conditions in an Alarm System

GLOBAL INACTIVATION STATE – Refers to all elements of an Alarm System or Distributed Alarm System Alarm Paused, Audio Paused, Alarm Off or Audio Off

HARM – Physical injury or damage to the health of people or animals, or damage to property or the environment

HARMONIC – Noun, An Overtone accompanying the Fundamental Frequency at a fixed interval; may refer to Fundamental Frequency itself

HAZARD – Potential source of Harm

HEMI-ANECHOIC CHAMBER, HEMI-ANECHOIC ROOM - This is a room in which a free field over a reflecting plane is obtained

HIGH PRIORITY - Indicating that immediate Operator response is required
NOTE: The priority is assigned through Risk Analysis

HORIZONTAL PLANE – This is another word for the floor or the Reflecting Plane of the Hemi-Anechoic Chamber

IFU – Instructions For Use, User Manual; may or may not include Service Manual

IMMEDIATE – While the word is found in 60601-1-8, it is not a defined term per 60601-1-8. Addressing a High Priority alarm "Immediately" is not doing so in a defined period of time. The 60601-1-8 rationale adds that "Immediate" category problems are those that are likely to cause Patient injury or death within seconds to several minutes if uncorrected. Few problems fall into the "immediate" category.
EXAMPLES: Asystole, Ventricular fibrillation, Failure of a cardiac support device (intra-aortic balloon pump, cardiopulmonary bypass machine), Sustained high airway pressure, Extreme hypoxemia, Sustained high-energy radiation beam

INFORMATION SIGNAL - Any signal that is not an Alarm Signal or a Reminder Signal
Example 1: ECG waveform
Example 2: SpO2 tone
Example 3: Fluoroscopy beam-on indication

INTELLIGENT ALARM SYSTEM - Alarm System that makes logical decisions based on monitored information without Operator intervention
Example 1: An Alarm System that changes priority based on the rate of change of a monitored variable
Example 2: An Alarm System that suppresses an Alarm Condition when a related Alarm Condition of higher priority has recently generated an Alarm Signal

INTENDED USE, INTENDED PURPOSE – Use for which a product, Process or service is intended according to the specifications, instructions and information provided by the Manufacturer
NOTE: Intended Use should not be confused with Normal Use. While both include the concept of use as intended by the Manufacturer, Intended Use focuses on the medical purpose while Normal Use incorporates not only the medical purpose, but maintenance, service, transport, etc. as well

INTERBURST INTERVAL, t_b – Period of time between the end of the last Pulse Duration of a Burst and the start of the first Pulse Duration of the next Burst of the same Alarm Signal

INTERPULSE INTERVAL – Period of time comprised of all of the portions of a Burst that are not Pulse Duration

LATCHING ALARM SIGNAL - Alarm Signal that continues to be generated after its triggering event no longer exists until stopped by deliberate Operator action

LEVEL OF URGENCY - This is the perceived amount of attention demanded by an Alarm System due to its respective Alarm Condition. The elements which determine Urgency include, but are not limited to, Speed, Number of Repeating Bursts, Syncopated vs. Regular Rhythm, Inter-Pulse Duration within a burst, Interburst Duration, Pitching up or down, Atonal vs Unresolved vs Resolved

LOW PRIORITY - Indicating that Operator Awareness is required. (Action not required, Audio component of Low Priority Alarm Signal optional)
NOTE: The priority is assigned through Risk Analysis

ME EQUIPMENT – Medical Electrical Equipment - Electrical equipment having an Applied Part or transferring energy to or from the Patient or detecting such energy transfer to or from the Patient and which is: a) provided with not more than one connection to a particular Supply Mains; and b) intended by its Manufacturer to be used: 1) in the diagnosis, treatment, or monitoring of a Patient; or 2) for compensation or alleviation of disease, injury or disability
NOTE 1 ME Equipment includes those Accessories as defined by the Manufacturer that are necessary to enable the Normal Use of the ME Equipment.
NOTE 2 Not all electrical equipment used in medical practice falls within this definition (e.g. some in vitro diagnostic equipment).
NOTE 3 The implantable parts of active implantable medical devices can fall within this definition, but they are excluded from the scope of this standard by appropriate wording in Clause 1.
NOTE 4 This standard uses the term “electrical equipment” to mean ME Equipment or other electrical equipment.
NOTE 5 See also 4.10.1, 8.2.1 and 16.3.

ME SYSTEM – Medical Electrical System - Combination, as specified by its Manufacturer, of items of equipment, at least one of which is ME Equipment to be inter-connected by Functional Connection or by use of a Multiple Socket Outlet
NOTE Equipment, when mentioned in this standard, should be taken to include ME Equipment.

MEDIUM PRIORITY - Indicating that prompt Operator response is required
NOTE: The priority is assigned through Risk Analysis

NOISE – With reference to Medical Device Alarm Systems, Noise is any sound that masks the Alarm Signal; With reference to Medical Devices in general, Noise is a term for excessive acoustic energy which may result in hearing fatigue or hearing loss. E.g. A device tries to propagate an audio Alarm Signal, but it is not heard above the pumping of the EUT. It should be noted that Harmonics more than 15 dB above the Pulse Frequency may be considered Noise, masking f_o

NOISE FLOOR – Noise from all sources other than the UUT; An audio term defining the quietest level in dB at which the non-Alarm-Signal output is measured unmodified by any distortion that is due to the Ambience, Signal Chain or EUT. The range for Background Noise may be measured from the Noise Floor upward to the quietest Alarm Signal; See Background Noise

NON-LATCHING ALARM SIGNAL - Alarm Signal that automatically stops being generated when its associated triggering event no longer exists

NORMAL USE - Operation, including routine inspection and adjustments by any Operator, and stand-by, according to the instructions for use.
NOTE: Normal Use **should not** be confused with Intended Use. While both include the concept of use as intended by the Manufacturer, Intended Use focuses on the medical purpose while Normal Use incorporates not only the medical purpose, but maintenance, service, transport, etc. as well

NOT ENABLED - State in which the device is powered on, but the Alarm System does not generate Alarm Signals because an "enabling algorithm" has not yet been satisfied. This term is NOT used when Operator action has placed the Alarm System in one of the four "Inactivation States."

NUISANCE ALARMS★ - Alarm Signals, perceived by staff to be annoying, that may interfere with patient care, and typically do not result from adverse or potential adverse patient conditions. Nuisance Alarms become a problem because Alarm Signals can distract caregivers from other tasks despite there not being any real patient condition requiring attention and can contribute to Alarm Fatigue

OFF-TIME – The period of time in which a Visual Indicator is not illuminated in any given cycle

ON-TIME – The period of time in which a Visual Indicator is illuminated in any given cycle

OPERATOR - Person handling the equipment

OPERATOR-EQUIPMENT INTERFACE – Includes all means of communication between the ME Equipment to the Operator and the Operator to the ME Equipment. These means include, but are not limited to: – Alarm Signals

OPERATOR'S POSITION - Intended position of the Operator with respect to the Alarm Signal generating part of the Alarm System
NOTE: A Distributed Alarm System can have multiple Operators' Positions

OVERALL VOLUME –SPL value measured in dB(A), indicating the complete available Audio spectrum to be measured, as opposed to SPL measure at a specific Frequency, see also Relative Volume

OVERTONE – Any Harmonic Partial higher in Frequency (Hz) than and not including f_o

PACE – Speed of Alarm Signal, due to setting of Pulse Spacing values. Even Pulse Spacings provide a regular Pace. Pulse Spacings which decrease through the course of the Burst create a Pace which is speeding up. Pulse Spacings which increase through the course of the Burst create a Pace which is slowing down.

PARTIAL - Any of the simple waves of which a complex tone is comprised

PARTICULAR STANDARD - May modify, replace or delete requirements contained in the 60601-1 Base Standard or any Collateral Standard as appropriate for the Particular ME Equipment under consideration,

and may add other Basic Safety and Essential Performance requirements; may be numbered as 60601-2-XX or 80601-2-XX depending on which committee administered the project

PATIENT – Living being (person or animal) undergoing a medical, surgical or dental Procedure

PATIENT-SIDE ALARM SIGNAL - An Alarm Signal on a device that is directly connected to (or in the immediate vicinity of) the patient

PEEP, POSITIVE END-EXPIRATORY PRESSURE- Positive Airway Pressure at the end of an expiratory phase; term used in ISO 80601-2-12 Critical Care Ventilators

PERIOD – Per 60601-1-8, this is the length of time for one complete Visual Indicator Flash Cycle

PHYSIOLOGICAL ALARM CONDITION - Alarm Condition arising from a monitored Patient-related variable; not a Technical Alarm Condition

Example 1: High exhaled anesthetic agent concentration
Example 2: Low exhaled tidal volume
Example 3: Low oxygen saturation measured by pulse oximetry
Example 4: High arterial pressure
Example 5: High heart rate

PRIMARY ALARM SYSTEM – The patient care device itself provides visual and aural indications of Alarm Signals that can be seen and heard in the immediate patient vicinity, and that are the authoritative primary indicators of Alarm Conditions resulting from monitoring the patient. It is understood that caregivers shall be in a position to take immediate action based on these primary Alarm Condition indications and shall not rely exclusively on secondary Alarm Systems for Alarm Condition notifications

PRIMARY OPERATING FUNCTION – A function that is directly related to the Basic Safety or Essential Performance of the ME Equipment in Normal Use or a function that is frequently used.

Examples of Primary Operating Function that directly relate to Basic Safety or Essential Performance include: – inactivating an Alarm Signal (temporarily or indefinitely); – setting Alarm Limits

PROMPT – While this term can be found in 60601-1-8, it is not a defined term per 60601-1-8. Addressing a High Priority alarm "Promptly" is not doing so in a defined period of time. The 60601-1-8 rationale adds that "Prompt" category problems do not cause Patient injury or death until at least several to many minutes have elapsed.

EXAMPLES: Many cardiac arrhythmias, Most cardiac arrhythmias would be prompt or delayed, High or low blood pressure, Apnea (unless prolonged or associated with extreme hypoxia), Mild hypoxemia, High or low pCO_2

PROTECTED SYSTEM – An Alarm System is Protected if the clinical Operator of the ME Equipment shall not have access in Normal Use to the selection of the capability to activate and terminate Global Inactivation States (Alarm Paused, Audio Paused, Alarm Off or Audio Off) and activation of Alarm Reset at remote components of a Distributed Alarm System

PULSE - Brief continuous sound having a specific spectral content

PULSE DURATION, t_d - Brief continuous sound having a specific spectral content identified as the time from the first instance of 90 % of Maximum Amplitude to its last instance of 90 % of its Maximum Amplitude

PULSE FREQUENCY, f_o – Fundamental frequency (first harmonic) of a Pulse

PULSE SPACING, t_s - The time from the end of one Pulse Duration to the start of the next, within the same Pulse

RADIUS, *r* – The radius of a spherical or hemi-spherical measurement surface

REFLECTING PLANE - Planar surface of the Acoustic Chamber above which the UUT is located; Horizontal Plane; Floor

RELATIVE VOLUME – Comparison between two or more Waveforms to determine the difference measured in dB, may be specific to a particular Frequency, Frequency-Band or for Overall Volume (SPL)

RELEASE♪ – The R portion of the ADSR Envelope, equivalent to Fall Time

REMINDER SIGNAL - Periodic Alarm Signal that reminds the Operator that the Alarm System is in an Alarm Signal Inactivation State

REMOTE ALARM SIGNAL - An Alarm Signal that is distant from the patient

REMOTE CENTRALIZED MONITORING SURVEILLANCE MODEL★ - Monitor watchers in a room separated from the care area. Monitor watchers provide Alarm Condition notification to the nurses and other care providers in the care areas via phones or pagers. This model is usually used to shield patients and direct caregivers from the noise and interruption of Nuisance Alarms

RESPONSIBLE ORGANIZATION - Entity accountable for the use and maintenance of medical electrical equipment or a medical electrical system; See User, Responsible Party
NOTE 1: The accountable entity can be, for example, a hospital, an individual clinician or a layperson. For in home use applications, the patient, Operator and Responsible Organization can be one and the same person.
NOTE 2: Education and training is included in "use."

RESPONSIBLE PARTY - See User, Responsible Organization

RISE TIME, t_r – Interval over which the Pulse increases from 10% to 90% of its maximum amplitude (see Figure 1)

RISK – Combination of the probability of occurrence of Harm and the Severity of that Harm

RISK CONTROL – Process through which decisions are reached and protective measures are implemented for reducing Risks to, or maintaining Risks within, specified levels

RISK MANAGEMENT – Systematic application of management policies, Procedures, and practices to the tasks of analyzing, evaluating, and controlling Risk

RITCHIE WHISTLE - A pneumatic device which sounds when oxygen pressure is 38 psi descending

SECONDARY ALARM SYSTEM – An Alarm System intended to give "best effort" notification of Alarm Conditions at additional locations, to additional persons, or for additional purposes such as archiving, but not intended to take the place of a primary Alarm System as the authoritative primary indicator of Alarm Signals resulting from monitoring the patient

SEMI-ANECHOIC CHAMBER – A type of Anechoic Chamber with a reflecting plane or floor; MECA uses this type of Room for testing Alarm Signals

SENSITIVITY – The level of detail that may be input to an algorithm utilized in an Alarm System

SET, ALARM – A completely defined group of Alarm Signals and their attributes

SIGNAL CHAIN – Series of components, each modifying the Alarm Signal in some way; a term used to trace sequential elements of a circuit

SMART ALARM SYSTEM – See Intelligent Alarm System

SOUND PRESSURE, p – Difference between instantaneous pressure and static pressure
NOTE 1: Adapted from ISO 80000-8:2007[21 1, 8-9.2.]
NOTE 2: Sound pressure is expressed in pascals.

SOUND PRESSURE LEVEL, SPL, L_p – Functionally, the Volume of the EUT; Ten times the logarithm to the base 10 of the ratio of the square of the sound pressure, P, to the square of a reference value, Po, expressed in decibels
$L_p = 10\ \mathrm{lg}(p^2 / p_o^2)$ dB where the reference value, p_o, is 20 µPa
NOTE 1: If specific frequency and time weightings as specified in lEG 61672-1 and/or specific frequency bands are applied, this is indicated by appropriate subscripts; e.g. LpA denotes the A-weighted sound pressure level
NOTE 2: This definition is technically in accordance with ISO 80000-8:2007[21 1, 8-22]

SPECIFICITY– Amount of detail which an Alarm System may use to determine an Alarm Condition

STATE OF AWARENESS – Perceived amount of attention required in order to align with its associated Level of Urgency

START POINT – Beginning of segment of time to be measured, E.g. beginning time of Pulse Duration

SUB-HARMONIC – Any Partial, lower in Frequency (Hz) than, and not including f_o

SUSTAIN♪ - The S segment of the ADSR Envelope which is comprised of the plateau volume reached at the end of the Decay segment, leading to the Release segment. Equivalent to Pulse Duration

TECHNICAL ALARM CONDITION - Alarm Condition arising from a monitored equipment-related or Alarm System-related variable, which may or may not require action from caregivers; An Alarm Condition that is not a Physiological Alarm Condition

Example 1: An electrical, mechanical or other failure
Example 2: A failure of a sensor or component (unsafe voltage, high impedance, signal impedance, artifact, noisy signal, disconnection, calibration error, tubing obstruction, etc.)
Example 3: An algorithm that cannot classify or resolve the available data

TIME TO ALARM – The sum of Alarm Condition Delay and Alarm Signal Generation Delay

TIMED ACKNOWLEDGED – An Acknowledged which shall terminate after a defined duration. An indefinite Acknowledged shall not terminate after a defined duration

TRF – Test Report Form

TRUE ALARM – An Alarm Condition or Alarm Signal detected by an Alarm System and has been determined to have been properly assigned or implemented, See True Positive, True Negative, True Alarm Signal

TRUE ALARM CONDITION - An Alarm Condition, propagated by an Alarm System, which has been determined to have been properly assigned, See True Alarm

TRUE ALARM SIGNAL - An Alarm Signal, propagated by an Alarm System, which has been determined to have been properly implemented, See True Alarm

TRUE NEGATIVE – An absence of an Alarm Condition or Alarm Signal in an Alarm System when no true triggering event has occurred

TRUE POSITIVE – True Alarm Condition or Alarm Signal, propagated by an Alarm System, which has been determined to have been properly assigned

USABILITY - Characteristic that establishes Effectiveness, Efficiency and Operator learnability and satisfaction, See 60601-1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability

USABILITY ENGINEERING - Application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of tools, machines, ME Equipment, devices, systems, tasks, jobs, and environments to achieve adequate Usability

USE ERRORS – Also “Operator Use Error”, Act or omission of an act that has a different ME Equipment response than intended by the Manufacturer or expected by the Operator; E.g. An Operator fails to detect a dangerous increase in heart rate because the Alarm Limit is mistakenly set too high and Operator is over-reliant on Alarm System

USERS - Persons who use, or operate, medical equipment. In some older standards, the term “User” was reserved for the owner or lessor of the equipment, e.g. the hospital, clinic, home-care equipment operator (which could be the patient), etc.; and the term “Operator” was used for the person who actually controlled the device. The human factors literature has long referred to the “User” as the person who operates a device, and we shall follow that usage here. In more recent standards, what was previously called “User” is now called the “Responsible Organization” or “Responsible Party.”

UUT – Unit Under Test

VISUAL INDICATOR - The light-generating means by which a Visual Alarm Signal is seen
Example – LED or Monitor Screen

WAVE FILE – There are many types of audio recording files. These with extension ".wav" are very common.

WAVEFORM – Audio files which are converted into images which are analyzed to determine the properties of the Alarm Signal

x – Variable for Pulse Spacing of High Priority Alarm Signals

y – Variable for Pulse Spacing of Medium and / or Low Priority Alarm Signals