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Eurofins MET Labs

CERTIFYING MEDICAL PRODUCTS TO IEC 60601-1

Your industry, our focus

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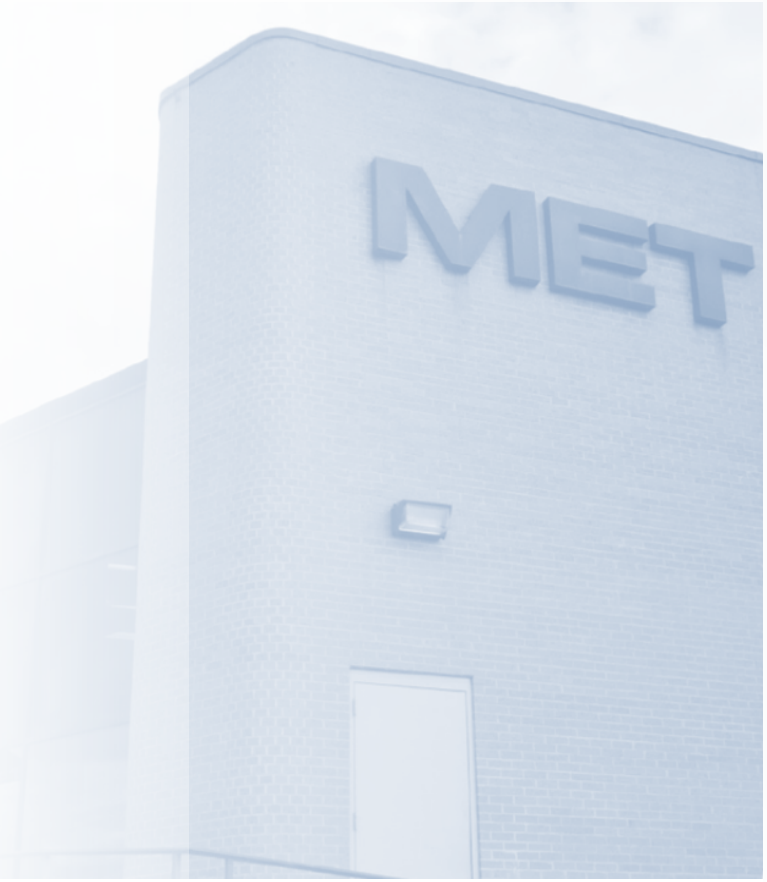
What We'll Cover Today

- **Patient – the Concept**
- **Essential Performance**
- **60601-1 Testing**
- **Risk Management File – ISO 14971**
- **PEMS – Clause 14**
- **Usability File – IEC 60601-1-6**
- **Alarms – IEC 60601-1-8**
- **Home Healthcare Products 60601-1-11**
- **Questions**



Patient – The Concept

What Makes a Patient Different

A patient is a living being (person or animal) undergoing a medical, surgical or dental procedure.

What Makes a Patient Different

A patient is a living being (person or animal) undergoing a medical, surgical or dental procedure

1.) A patient may have open skin – lower electrical resistance, more susceptible to electric shock

What Makes a Patient Different

A patient is a living being (person or animal) undergoing a medical, surgical or dental procedure

2.) A patient may be unconscious – unable to react to pain.

What Makes a Patient Different

A patient is a living being (person or animal) undergoing a medical, surgical or dental procedure

3.) A patient may be bedridden – unable to move away from pain.

What Makes a Patient Different

A patient is a living being (person or animal) undergoing a medical, surgical or dental procedure

4.) A patient may have a depressed immune system, more susceptible to germs and allergic reactions.

What Makes a Patient Different

Susceptibility to Leakage Current – the current that can travel from the surface of equipment to ground.

What Makes a Patient Different

Currents of low frequency flowing directly into or through the heart considerably increase the danger of ventricular fibrillation.

The patient is more susceptible, can't call for help and can't move away.

What Makes a Patient Different

Currents of low frequency flowing directly into or through the heart considerably increase the danger of ventricular fibrillation.

- **Any amount of current over 10 milliamps (0.01 amp) is capable of producing painful to severe shock, muscular contractions are so strong that the victim cannot let go of the wire that is shocking him.**

The patient is more susceptible, can't call for help and can't move away.

What Makes a Patient Different

Currents of low frequency flowing directly into or through the heart considerably increase the danger of ventricular fibrillation.

- **At values as low as 20 milliamps, breathing becomes labored, finally ceasing completely even at values below 75 milliamps.**

The patient is more susceptible, can't call for help and can't move away.

What Makes a Patient Different

Currents of low frequency flowing directly into or through the heart considerably increase the danger of ventricular fibrillation.

- **As the current approaches 100 milliamps, ventricular fibrillation of the heart occurs - an uncoordinated twitching of the walls of the heart's ventricles which results in death.**

The patient is more susceptible, can't call for help and can't move away.

What Makes a Patient Different Susceptibility to Burns/Skin Damage

The patient is more susceptible, can't call for help and can't move away.

What Makes a Patient Different

Burns/Skin Damage

Water temperature coming out of a faucet causes pain at 110 degrees. When temperature is 120 degrees (49C), a five minute exposure could result in third-degree burns.

The patient is more susceptible, can't call for help and can't move away.

What Makes a Patient Different

Burns/Skin Damage

Burns will also occur with a thirty second exposure to 130 degree water (55C), and with a six-second exposure to 140 degree water (60C). Most adults will suffer third-degree burns if exposed to 150 degree water (65C) for two seconds.

The patient is more susceptible, can't call for help and can't move away.

What Makes a Patient Different

Biocompatibility

BIOCOMPATIBILITY is "the quality of being compatible with living tissue or a living system by not being toxic or injurious and not causing immunological rejection".

The patient is more susceptible, with a depressed immune system.

What Makes a Patient Different

Biocompatibility

Systemic toxicity impairs an entire biological system such as the nervous or immune system.

A systemic reaction is generally distant from the point of contact of the medical device. Therefore, the patient or doctor may not realize that a medical device is the source of a toxic reaction.

A toxic reaction may cause death.

The patient is more susceptible, with a depressed immune system.

What Makes a Patient Different

The IEC 60601-1 Applied Part Concept

What Makes a Patient Different

The IEC 60601-1 Applied Part Concept

The part of the medical equipment, which is designed to come into physical contact with the patient to perform its function. It can include a blood pressure cuff, an operating table, the sensor of a multi-parameter monitor, the leads of a defibrillator.

What Makes a Patient Different

The IEC 60601-1 Applied Part Concept

- Type CF  suitable for direct cardiac application
- Type BF  delivers electrical energy or an electrophysiological signal to or from the patient
- Type B  basic applied parts, often grounded.

Each can be defibrillation proof. 

What Makes a Patient Different

The IEC 60601-1 Applied Part Concept

- Applied parts have lower permissible leakage current limits based on type.
- All applied parts have lower temperature requirements.
- All applied parts have biocompatibility requirements.

Essential Performance

What is 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

UNACCEPTABLE RISK – Something so severe that you would never want it to happen. Or something mild that happens too often. Or anything in between.

What is Essential Performance

Examples of an essential performance failure:

- Failure of a defibrillator to deliver adequate electrical shock.
- Failure of a respiratory monitor to alarm when respiratory rate goes below a set threshold.
- Failure of an Insulin pump to deliver correct doses.
- Failure of a heart monitor to recover after a defibrillator has been applied.

In order to comply with IEC 60601-1, a medical product must not only demonstrate basic safety – it must also continue to meet its essential performance after testing.

Testing to 60601-1

Some Tests in 60601-1 that are Familiar

- **Power Input (same as 60950-1 and 61010-1)**
- **Marking Durability (similar to 60950-1 and 61010-1 but all chemicals: isopropyl alcohol, hexane and water)**
- **Accessible Parts (similar to 61010-1 and 60950-1: jointed test finger, also “test hook”)**
- **Cap Discharge – (similar to 61010-1 but 1s instead of 5 s, and can pass with stored charge under 45µC.)**
- **Pressure Vessels (same as 61010-1)**

Some Tests in 60601-1 that are Familiar

- Ground Impedance (similar to 60950-1 and 61010-1: 0.1Ω, 25A or 1.5x rated current)
- Cord Anchorage (same as 60950-1 with additional torque test)
- Cord Guard (same as 60950-1)
- Stability (same as 61010-1)
- Push/Impact/Mold Stress (same as 60950-1)
- Ball pressure (similar to 61010-1)
- Cleaning/overflow/spillage (similar to 61010-1)

Some Tests in 60601-1 with Additions

Temperature:

- **An applied part that exceeds 41C (105F) has to be documented**
- **An applied part that touches the patient for long periods of time (>10 minutes) should never exceed 43 C (110F) either in normal condition or in fault condition unless its purpose is to heat.**
- **Touchable parts by the operator have defined temperature limits based on how long they may be touched.**

Some Tests in 60601-1 with Additions

Leakage

- **Patient leakage is the current that can pass from an applied part through the patient to ground.**

Some Tests in 60601-1 with Additions

Leakage

- **A type F (BF or CF) applied part "floats" and is supposed to be electrically isolated from everything else in the equipment, including ground, other low voltage parts, and IT connections.**

Some Tests in 60601-1 with Additions

Leakage

- **Part of safety testing is to verify that no excessive current can get to the patient.**

Some Tests in 60601-1 with Additions

Leakage Testing Includes:

- **A test to see how much current is going through the ground pin. (Earth Leakage)**
- **A test to see how much current the operator is exposed to (Touch Current)**
- **A test to see how much current the patient is exposed to from the surface of the applied part (Patient Leakage Current)**

Some Tests in 60601-1 with Additions

Leakage Testing Includes:

- **A test done on F-type parts to demonstrate that the electricity from second piece of equipment cannot go through the patient to the first piece of equipment**
- **A test done on unearthed metal to demonstrate that if a live part contacts the unearthed metal, there is no path to the patient.**

Some Tests in 60601-1 with Additions

Leakage Testing Includes:

- **A test done on all signal ports (Ethernet, USB, HDMI, etc.) to demonstrate that if a live part contacts the signal port, there is no path to the patient.**
- **A test done between two applied parts to see how much current flows.**

Entirely New Tests in IEC 60601-1

- **Castors and Wheels – mobile equipment is tested for the force needed to move it and to make sure it doesn't slide or tip over**
- **Rough Handling –mobile equipment must be able to move safely over bumps and thresholds**
- **Support – equipment must be able to bear the weight of a patient, on purpose or by accident.**

Entirely New Tests in IEC 60601-1

- **Legibility – all markings should be visible in the dark or bright light from 1m unless they are intended for use at a closer range.**
- **Interruption of the Power Supply - equipment should come on in a safe state, when power is restored after a power event.**

Entirely New Tests in IEC 60601-1

- **Defibrillation Protection – a 5000V shock cannot affect the applied part or any other part of the equipment**
- **Hazardous output – it cannot be possible to accidentally increase the output to a hazardous level**

Entirely New Tests in IEC 60601-1

- **Safety in an oxygen rich environment – equipment cannot start a fire, when it is in a room with oxygen or when oxygen is piped through it**
- **Biocompatibility – contact with the material of the applied part does not cause harm**

The Risk Management File

The Risk Management Process

Why is there a risk management process?

The Risk Management Process
Why is there a risk management process:

- **A standard cannot capture all of the safety and essential performance aspects of a medical product.**

The Risk Management Process
Why is there a risk management process:

- **A standard cannot determine whether the risk, i.e. the combination of severity (injury, death) and likelihood (never, sometimes, often) is acceptable.**

The Risk Management Process
Why is there a risk management process:

- **A standard cannot identify all of the tests which are appropriate for determining whether a product meets essential performance**

The Risk Management Process

Why is there a risk management process:

- There needs to be a systematic method for walking through the steps necessary to ensure that there is no unacceptable risk with a new medical product

ISO 14971 - Application of risk management to medical devices

The Risk Management Process

The Risk Management Plan is the high level process of:

- **Establishing the personnel necessary to design, develop and test a new product**
- **Providing the resources necessary for the project**
- **Determining unacceptable risk.**
- **Planning how risk analysis will be implemented throughout design and development of the product.**

The Risk Management Process

Unacceptable risk is a combination of how bad and how often.

The Risk Management Process

Unacceptable Risk – severity

Table D.3 — Example of five qualitative severity levels

Common terms	Possible description
Catastrophic	Results in patient death
Critical	Results in permanent impairment or life-threatening injury
Serious	Results in injury or impairment requiring professional medical intervention
Minor	Results in temporary injury or impairment not requiring professional medical intervention
Negligible	Inconvenience or temporary discomfort

The Risk Management Process

Unacceptable Risk –probability

Table D.4 — Example of semi-quantitative probability levels

Common terms	Examples of probability range
Frequent	$\geqslant 10^{-3}$
Probable	$< 10^{-3}$ and $\geqslant 10^{-4}$
Occasional	$< 10^{-4}$ and $\geqslant 10^{-5}$
Remote	$< 10^{-5}$ and $\geqslant 10^{-6}$
Improbable	$< 10^{-6}$

The Risk Management Process

Unacceptable Risk – probability and severity

Semi-quantitative probability levels	Qualitative severity levels: Negligible	Minor	Serious	Critical	Catastrophic
Frequent					
Probable	R_1	R_2			
Occasional		R_4		R_5	R_6
Remote					
Improbable			R_3		

Key

unacceptable risk

acceptable risk

The Risk Management Process

Unacceptable Risk – severity and probability:

Semi-quantitative probability levels	Qualitative severity levels: Negligible	Minor	Serious	Critical	Catastrophic
Frequent					
Probable	R_1	R_2			
Occasional		R_4		R_5	R_6
Remote					
Improbable			R_3		

Key

	unacceptable risk
	investigate further risk reduction
	insignificant risk

The Risk Management Process – Risk Analysis

1. **Define the intended use, characteristics and essential performance of the product.**
2. **Identify the safety hazards inherent in the product, at the concept stage,**
3. **Identify faults (hardware, software, physical design, component selection) that could cause a compromise of the basic safety or essential performance**

The Risk Management Process – Risk Control

4. **Estimate the risk, and determine if it is acceptable. If not…**
5. **Implement risk control: design, protective measures, information for safety**
6. **Review the design for residual risk. If there is residual risk, go back to Step 4.**
7. **Risk/benefit analysis.**

The Risk Analysis Process – Examples of Characteristics

Annex C of ISO 14971

- **How is the product used – does it take measurements, does it deliver or extract energy**
- **Does the product touch a patient, can it be implanted. What part of the product touches the patent and what is it made of. Must it be sterile.**

The Risk Analysis Process – Examples of Characteristics

Annex C of ISO 14971

- **Is it sensitive to the environment, can it alter the environment.**
- **Does the product have accessories or detachable parts**
- **Does the product have critical software**
- **Is training required to operate the product**

The Risk Control Process – Examples of Safety Hazards

Annex D of ISO 14971

Product/ process	Example devices	Hazard
Single use medical device	Catheter	Bio-(cross)-contamination
Active implant	Pacemaker	Electric fields
IVD medical device	Blood analyser	Incorrect result due to method bias
Software	Patient data management	Erroneous data
Steam sterilization	Biopsy device, operation forceps	High temperature (material degradation)

The Risk Control Process – Examples of Safety Hazards and Risk Control

Annex D of ISO 14971

Product/ process	Example devices	Hazard	Inherent safe design
Single use medical device	Catheter	Bio-(cross)-contamination	Self-destruction after use
Active implant	Pacemaker	Electric fields	Use of non-electric drives and controls
IVD medical device	Blood analyser	Incorrect result due to method bias	Implement traceable calibrators
Software	Patient data management	Erroneous data	High integrity software
Steam sterilization	Biopsy device, operation forceps	High temperature (material degradation)	Use of material that is compatible with high temperatures

The Risk Control Process – Examples of Safety Hazards and Risk Control

Annex D of ISO 14971

Product/ process	Example devices	Hazard	Inherent safe design	Protective measure
Single use medical device	Catheter	Bio-(cross)-contamination	Self-destruction after use	Obvious indication after first use
Active implant	Pacemaker	Electric fields	Use of non-electric drives and controls	Use of differential amplifiers and additional filter algorithms
IVD medical device	Blood analyser	Incorrect result due to method bias	Implement traceable calibrators	Provide traceable trueness controls
Software	Patient data management	Erroneous data	High integrity software	Use of checksums
Steam sterilization	Biopsy device, operation forceps	High temperature (material degradation)	Use of material that is compatible with high temperatures	Pressure and temperature monitoring and recording

The Risk Control Process – Examples of Safety Hazards and Risk Control

Annex D of ISO 14971

Product/ process	Example devices	Hazard	Inherent safe design	Protective measure	Information for safety
Single use medical device	Catheter	Bio-(cross)-contamination	Self-destruction after use	Obvious indication after first use	Warning against re-use and of the adverse consequence(s) that could arise from any such re-use
Active implant	Pacemaker	Electric fields	Use of non-electric drives and controls	Use of differential amplifiers and additional filter algorithms	Warning for commonly encountered hazardous situations
IVD medical device	Blood analyser	Incorrect result due to method bias	Implement traceable calibrators	Provide traceable trueness controls	Inform users of unacceptable deviation from assigned values
Software	Patient data management	Erroneous data	High integrity software	Use of checksums	Warnings on screen for user
Steam sterilization	Biopsy device, operation forceps	High temperature (material degradation)	Use of material that is compatible with high temperatures	Pressure and temperature monitoring and recording	Packaging and loading instructions

The Risk Management Process – Examples of Risk/benefit analysis

- **Burns from high frequency surgical devices are tolerated because the surgical technique has great benefit compared to other treatments.**

- **X-rays are known to produce harmful radiation, but x-radiation is an excellent form of internal imaging.**

- **Implantable devices which are intended to last for decades cannot be completely tested by accelerated means. There is risk in using such devices before several years worth of data has been compiled.**

The Contents of the Risk Management File

1. The Management Plan
2. The Risk Acceptability Matrix
3. The Intended Use and Characteristics
4. The Essential Performance Evaluation
5. The Risk Analysis Matrix
6. The Test Matrix

This is the file that is presented to the safety agency, along with an index of where the necessary information is in the file.

Programmable Electrical Medical Systems (PEMS)

Programmable Electrical Medical Systems

If the software provides functionality necessary for basic safety OR essential performance, or if failure of the software can cause harm, the software development process must be reviewed.

Programmable Electrical Medical Systems

Examples of critical software:

- Code that prevents an excessive hazardous output (lasers, ultrasound, radiation)
- Code that prevents an element from getting too hot
- Code that controls motor/pump activation and speed
- Code that controls alarms

Programmable Electrical Medical Systems

The safety agency is not an expert in software design. We apply the guidelines of the standard to make sure that the software was developed, verified and validated with consideration for risk control.

Risk control: process of taking measures to reduce or eliminate the potential for harm to the patient, operator or environment through design changes or protective measures

Programmable Electrical Medical Systems

Development of the software must follow a lifecycle process, outlined in IEC 62304. The life cycle process is for planning software requirements, architectural design, unit implementation, integration and testing.

Programmable Electrical Medical Systems

Development of the software must also follow a risk management process, outlined in ISO 14971. The risk management process is for identification of known or foreseeable hazards, verification of risk control measures, and control of changes.

Programmable Electrical Medical Systems

Software testing requirements are outlined in IEC 60601-1 Clauses 14.10 and 14.11 and IEC 62304 Clause 5.7. Tests cover verification and validation of the subsystems and integrated software and are carried out independent of the designers.

Programmable Electrical Medical Systems

The PEMS section also considers the hazards of connecting to outside IT equipment – in terms of security and patient leakage.

60601-1-6: Usability

60601-1-6: Usability

Use errors caused by inadequate medical device design are some of the largest triggers of hazardous events in the healthcare sector.

60601-1-6: Usability

-Medical products are complicated

-Medical products require training to use

-Medical products can injure if misused

- From safety perspective
- From essential performance perspective

-Sometimes, the only mitigations are training, labels and the manual.

60601-1-6: Usability

The Usability Engineering Process is intended to achieve reasonable Usability, which in turn is intended to minimize use errors and use associated risks

60601-1-6: Usability

The outcome of the usability engineering process is a product that meets the usability specification, as demonstrated by validation.

Usability specification: a way of detailing the design requirements of the equipment such that user can interact with it without error, even under adverse conditions

60601-1-6: Usability

The purpose of the validation is to make sure that ALL aspects of the user interface intuitive or easy for the user with proper training

User Interface: how the user interacts with the product. Reading, seeing hearing, touching, typing, smelling, tasting.

60601-1-6: Usability

Let's work backwards.

A usable product

Is assured by validation ***(testing)***

Because the product has been tested based on a validation plan ***(how the test is conducted)***

Because the product has been designed from a usability specification ***(what must the user be able to do and how fast and how well, under unfavorable conditions)***

Which is based on primary functions ***(every major step in using the product)***

and known or foreseeable hazards ***(every mistake that could cause harm)***

Which comes from frequently used functions

Based on the application specification. ***(what the product is intended to do, to whom, by whom, on what and where)***

Let's Look at The Process with an Example – A Thermometer

Intended use: Electronic thermometer that gives an audible information signal when it detects that a stable reading has been achieved.

Application Specification Includes:

- **Medical Purpose**
- **Patient Population: age, weight, consciousness, health, nationality**
- **Applied Part: skin, tissue, orifices**
- **Intended User: education, knowledge, experience, possible impairments**
- **Environment: location, visibility, temperature**
- **Frequency of use: daily, hourly**

Let's Look at The Process with an Example – A Thermometer

Primary Operating Functions - Frequently Used Functions

a) removing protective cover
b) placing the device at the correct location in mouth or rectum
c) detecting measurement completed - information signal
d) reading display
e) cleaning
f) gripping / holding the device
g) removing the device
h) switching on
i) switching off
j) replacing protective cover
k) storing

Let's Look at The Process with an Example – A Thermometer

HAZARDOUS SITUATIONS and HARMS

a) No reading ⇒ delayed treatment

b) Incorrect reading ⇒ delayed or improper treatment

c) Puncturing tissue ⇒ trauma, bleeding, infection, etc.

d) Ingesting toxic material from the display ⇒ poisoning

e) Introducing contaminants into the body ⇒ infection

Let's Look at The Process with an Example – A Thermometer

Usability Specification includes:

- **Use Scenarios to be Tested (dark room, user is a child)**
- **User Interface Requirements (cover removal, on/off button design, display design, surface material, thermometer shape, reading-complete auditory signal characteristics, contents of the user manual)**

Let's Look at The Process with an Example – A Thermometer

User Actions Related to Primary Operating Functions

b) Switching on the device (on/off button):

– easy tactile identification of location of button
– recessed location to prevent unintentional operation
– no gaps around button for ease of cleaning
– auto power off
– depressing button for more than 3 s is necessary to avoid unintentional switch off during measurement

60601-1-6 Usability

The usability process is comprehensive and orderly. If done correctly, it produces a document that allows for meaningful attributes of user interface design, based on data on the most prevalent user errors in the industry, as well as the basics of sound ergonomic design.

60601-1-8: Alarms Highlights

60601-1-8: Alarms - Highlights

The object of this collateral standard is to specify basic safety and essential performance requirements and tests for alarm systems in ME equipment and ME systems and to provide guidance for their application. This is accomplished by defining alarm categories (priorities) by degree of urgency, consistent alarm signals and consistent control states and their marking for all alarm systems.

This collateral standard does not specify:

– Whether any particular ME equipment or ME system is required to be provided with alarm

60601-1-8: Alarms - Highlights

ALARM CONDITION – when an alarm is activated

- PHYSIOLOGICAL ALARM CONDITIONS: arising from a monitored patient-related variable
- TECHNICAL ALARM CONDITIONS: arising from a monitored equipment-related or alarm system-related variable
- INFORMATIONAL SIGNAL: indicating functionality

60601-1-8: Alarms - Highlights

ALARM CONDITION PRIORITY – immediate response, prompt response or "awareness"

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 ALARM CONDITION [e]	HIGH PRIORITY ALARM CONDITION	MEDIUM PRIORITY ALARM CONDITION
Reversible injury	HIGH PRIORITY ALARM CONDITION	MEDIUM PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION
Discomfort or reversible minor injury	MEDIUM PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION, NO ALARM CONDITION or INFORMATION SIGNAL

60601-1-8: Alarms - Highlights

Generation of Alarm Signals

- **Visual Characteristics**

Alarm category	Indicator colour	Flashing frequency	Duty cycle
HIGH PRIORITY	Red	1,4 Hz to 2,8 Hz	20 % to 60 % on
MEDIUM PRIORITY	Yellow	0,4 Hz to 0,8 Hz	20 % to 60 % on
LOW PRIORITY	Cyan or yellow	Constant (on)	100 % on

60601-1-8: Alarms - Highlights

Generation of Alarm Signals

- **Audible Alarm Characteristics**

Characteristic	HIGH PRIORITY ALARM SIGNAL	MEDIUM PRIORITY ALARM SIGNAL	LOW PRIORITY ALARM SIGNAL[d]
Number of PULSES in BURST [a, e]	10	3	1 or 2
PULSE spacing (t_s) (see Figure 1)			
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 or no repeat

60601-1-8: Alarms - Highlights

Other concerns:

Latching – when the alarm turns off

Presets – who determines the alarm trigger limit

Inactivation – can the alarm be silenced temporarily

60601-1-11: Home Health Care Highlights

60601-1-11: Home Healthcare Highlights

This international standard applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems for use in the home healthcare environment:

- The dwelling place in which a patient lives;
- Other places where patients are present both indoors and outdoors, excluding professional healthcare facility environments where operators with medical training are continually available when patients are present.

Key Points - 60601-1-11: Home Healthcare

What is so special about the home healthcare environment:

- **Poor or non-existent earthing (ground) connections**
- **Possible interaction with uncertified equipment**
- **Possible interaction with unprotected networks**

Key Points - 60601-1-11: Home Healthcare

What is so special about the home healthcare environment:

- **Untrained, possibly uneducated users**
- **Possible use without reading the instructions**

Key Points - 60601-1-11: Home Healthcare

What is so special about the home healthcare environment:

- **Higher incidence of spillage (eating/drinking during use of equipment)**
- **Uncontrolled temperature, humidity and altitude including outdoors**

Key Points - 60601-1-11: Home Healthcare

Mitigating the risks

- **Risk: Poor or non-existent earthing (ground) connections, use of uncertified equipment and unprotected networks**
- **Mitigation:– Type F (floating) applied parts and Class II (unearthed) or battery operated equipment**

Key Points - 60601-1-11: Home Healthcare

Mitigating the risks

- **Risk: Untrained, possibly uneducated users**
- **Mitigation: 8th grade reading level instructions**

- **Risk: Possible use without reading the instructions**
- **Mitigation: extensive usability studies**

Key Points - 60601-1-11: Home Healthcare

Mitigating the risks

- **Risk: Higher incidence of spillage**
- **Mitigation: IP21 water ingress protection**

- **Risk: Uncontrolled temperature, humidity and altitude**
- **Mitigation: testing over a broad range of conditions to ensure operation, safety and essential performance are met.**

Questions?