IEC 60601-2 24

Differences Between IEC 60601-2-24 Edition 1.0 and 2.0 Requirements for Medical Devices (Infusion pumps)

Created by: Liem Lam, MSEE

Certifier - Electro medical & Test and Measurement Products

Scope

IEC 60601-2-24 ED1.0, clause 1.1

- This Particular Standard specifies the requirement for INFUSION PUMPS, INFUSION CONTROLLERS, SYRINGE PUMPS and PUMPS FOR AMBULATORY USE
- These particular requirements do **NOT** apply to devices:
- 1) specifically intended for diagnostic or similar use (e.g. angiography or other pumps permanently controlled or supervised by the OPERATOR),
- 2) enteral infusion,
- 3) extracorporeal circulation of blood,
- 4) implantable or disposable devices,
- 5) EQUIPMENT specifically intended for diagnostic use within urodynamics (measurement of pressure-volume relationship of the urinary bladder when filled through a catheter with water);
- 6) EQUIPMENT specifically intended for diagnostic use within male impotence testing (measurement of amount of liquid infused, necessary to maintain a preset pressure level for maintaining penile erection: cavernosometry, cavernosography).

IEC 60601-2-24 ED2.0, clause 201.1.1

- This particular standard specifies the requirements for ENTERAL NUTRITION PUMPS, INFUSION PUMPS, INFUSION PUMPS FOR AMBULATORY USE, SYRINGE OR CONTAINER PUMPS, VOLUMETRIC INFUSION CONTROLLERS and VOLUMETRIC INFUSION PUMPS
- These particular standard does **NOT** apply to the following:
- a) devices specifically intended for diagnostic or similar use (e.g. angiography or other pumps permanently controlled or supervised by the OPERATOR);
- b) devices for extracorporeal circulation of blood;
- c) implantable devices;
- d) ME EQUIPMENT specifically intended for diagnostic use within urodynamics (measurement of pressure-volume relationship of the urinary bladder when filled through a catheter with water);
- e) ME EQUIPMENT specifically intended for diagnostic use within male impotence testing (measurement of amount of liquid infused, necessary to maintain a preset pressure level for maintaining penile erection: cavernosometry, cavernosography);
- f) devices covered by ISO 28620. (non-electrically driven portable infusion device)

Collateral Standards

In addition to applicable collateral standards that are listed in general standard IEC 60601-1

IEC 60601-2-24 ED1.0, Clause 1.5

- IEC 60601-1-2:1993
- IEC 60601-1-4: 1996 was replaced by IEC 60601-1 3rd Ed. Clause 14 Programmable Electrical Medical Systems (PEMS)
- IEC 60601-1-3:1994 was replaced by IEC 60601-1 3rd Ed. Clause 10 Protection against unwanted and excessive radiation hazards

IEC 60601-2-24 ED2.0, Clause 201.1.3

- IEC 60601-1-2:2007
- IEC 60601-1-6:2010
- IEC 60601-1-8:2006

Terms and definitions

INFUSION PUMP

IEC 60601-2-24 Ed1.0, Clause 2.101

- The INFUSION PUMP may be of:
- type 1: continuous infusion flow only,
- – type 2: non-continuous flow only,
- – type 3: discrete delivery of a BOLUS,
- – type 4: type 1 combined with type 3 and/or type 2 in the same EQUIPMENT,
- – type 5: PROFILE PUMP.

IEC 60601-2-24 Ed2.0, Clause 201.3.206

- The INFUSION PUMP may provide one or more of the following types of flow:
- – type 1: continuous infusion;
- – type 2: non-continuous infusion;
- – type 3: discrete delivery of a bolus;
- – type 4: PROFILE PUMP

Terms and definitions

VOLUMETRIC INFUSION PUMP

IEC 60601-2-24 Ed1.0, Clause 2.102

- INFUSION PUMP in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in volume per unit of time, but excluding SYRINGE PUMPS

IEC 60601-2-24 Ed2.0, Clause 201.3.223

- INFUSION PUMP in which the delivery rate is indicated in volume per unit of time or units related to drug dosage, but excluding SYRINGE OR CONTAINER PUMPS

Terms and definitions

ADMINISTRATION SET and *BOLUS*

IEC 60601-2-24 Ed1.0, Clause 2.112

- ADMINISTRATION SET: device(s) that convey(s) liquid from the supply via the EQUIPMENT to the PATIENT

IEC 60601-2-24 Ed1.0, Clause 2.119

- BOLUS: discrete quantity of liquid which is delivered in a short time

IEC 60601-2-24 Ed2.0, Clause 201.3.201

- ADMINISTRATION SET: accessory that convey(s) liquid from the supply via the ME EQUIPMENT to the PATIENT

IEC 60601-2-24 Ed2.0, Clause 201.3.203

- BOLUS: discrete quantity of liquid which is intended to be delivered by the ME EQUIPMENT

Terms and definitions

INTERMEDIATE RATE – Test Rate

IEC 60601-2-24 Ed1.0, Clause 2.120

- – for volumetric infusion pumps and volumetric infusion controllers, set the rate to 25 ml/h;
- – for drip-rate infusion pumps and drip-rate infusion controllers, set the rate to 20 drops/minute;
- – for syringe pumps, set the rate to 5 ml/h;
- – for special use equipment and infusion pumps for ambulatory use, set the rate specified by the manufacturer as typical for the equipment.

IEC 60601-2-24 Ed2.0, Clause 201.3.208

- – for VOLUMETRIC INFUSION PUMP and VOLUMETRIC INFUSION CONTROLLER, set the rate to 25 ml/h;
- – for SYRINGE OR CONTAINER PUMP, set the rate to 5 ml/h;
- – for INFUSION PUMPS FOR AMBULATORY USE, set the rate specified by the MANUFACTURER as typical for the ME EQUIPMENT.

Terms and definitions

MINIMUM RATE

IEC 60601-2-24 Ed1.0, Clause 2.121

- lowest rate selectable by the OPERATOR, but not less than 1 ml/h
- For INFUSION PUMPS FOR AMBULATORY USE it is the lowest selectable rate.

IEC 60601-2-24 Ed2.0, Clause 201.3.211

- lowest rate selectable by the OPERATOR, but not less than 1 ml/h

Terms and definitions

SELECTABLE RATE

IEC 60601-2-24 Ed1.0

- No MAXIMUM SELECTABLE RATE
- No MINIMUM SELECTABLE RATE

IEC 60601-2-24 Ed2.0, Clause 201.3.212

- MAXIMUM SELECTABLE RATE:

Highest rate selectable by the OPERATOR if higher than the INTERMEDIATE RATE

IEC 60601-2-24 Ed2.0, Clause 201.3.213

- MINIMUM SELECTABLE RATE:

lowest rate selectable by the OPERATOR if lower than the MINIMUM RATE

Terms and definitions

VOLUMETRIC INFUSION CONTROLLER

IEC 60601-2-24 Ed1.0, Clause 2.105

- INFUSION CONTROLLER in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in volume per unit of time

IEC 60601-2-24 Ed2.0, Clause 201.3.222

- ME EQUIPMENT intended to regulate the flow of liquid into the PATIENT under positive pressure generated by gravitational force in which the delivery rate is indicated by the ME EQUIPMENT in volume per unit of time

General requirements

ESSENTIAL PERFORMANCE requirements

IEC 60601-2-24 Ed1.0

- No Table of essential performance

IEC 60601-2-24 Ed2.0, Clause 201.4.3.101

New Table added

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Accuracy tests for VOLUMETRIC INFUSION CONTROLLERS, VOLUMETRIC INFUSION PUMPS and SYRING OR CONTAINER PUMPS	201.12.1.102
Accuracy tests for INFUSION PUMPS FOR AMBULATORY USE type 1	201.12.1.103
Accuracy tests for INFUSION PUMP FOR AMBULATORY USE type 2	201.12.1.104
Accuracy tests for INFUSION PUMP type 3	201.12.1.105
Accuracy tests for INFUSION PUMP type 4	201.12.1.106
Accuracy tests for INFUSION PUMP type 5	201.12.1.107
Protection against UNINTENDED BOLUS volumes and occlusion	201.12.4.4.104
ALARM SIGNALS of HIGH PRIORITY according to Table 208.101 NOTE For ALARM CONDITIONS resulting from ME EQUIPMENT failure no EMC and environmental testing is necessary.	208.6.1.2.101

General requirements

SINGLE FAULT CONDITION for ME EQUIPMENT

IEC 60601-2-24 Ed1.0, Clause 3.6

- SINGLE FAULT CONDITIONS occurring in those protective systems specified in 51.5 and 51.102 shall become obvious to the OPERATOR within the ADMINISTRATION SET CHANGE INTERVAL.
- SINGLE FAULT CONDITIONS occurring in the protective system specified in clause 51.103 shall cause the cessation of delivery and the generation of an alarm within a time interval less than the volume of the ADMINISTRATION SET between the air detector and the venous cannula connected to it divided by the maximum flow rate of the pump.

IEC 60601-2-24 Ed2.0, Clause 201.4.7

- SINGLE FAULT CONDITIONS occurring in those protective systems specified in 201.12.4.4.101, 201.12.4.4.102, 201.12.4.4.105 and 201.12.4.4.107 shall become obvious to the OPERATOR within the ADMINISTRATION SET CHANGE INTERVAL.

General requirements

General requirements for testing of ME EQUIPMENT

IEC 60601-2-24 Ed1.0

- Not required

IEC 60601-2-24 Ed2.0, Clause 201.5.2

- The MANUFACTURER shall define the number of samples of INFUSION PUMP / INFUSION CONTROLLERS and ADMINISTRATION SET(S) with regard to **accuracy** in the technical documentation.

ACCOMPANYING DOCUMENTS

Instructions for use

IEC 60601-2-24 Ed1.0, Clause 6.8.2

- A statement to indicate to the OPERATOR if the EQUIPMENT cannot be used as PORTABLE EQUIPMENT.
- Recommendations on any specific method of cleaning and maintaining the EQUIPMENT.
- The time for which the electronic memory is retained following switch-off.
- Information concerning type(s) of battery to be used and where available.
- A statement of the meaning of claimed IP-classification.

IEC 60601-2-24 Ed2.0, Clause 201.7.9.2.101

- Not required

ACCOMPANYING DOCUMENTS

Instructions for use

IEC 60601-2-24 Ed1.0, Clause 6.8.2

- A statement of the maximum time for activation of the occlusion alarm when the EQUIPMENT is operating at the MINIMUM RATE and the INTERMEDIATE RATE and at the minimum and maximum selectable OCCLUSION ALARM THRESHOLD (PRESSURE)(S)
- The typical operating time when the EQUIPMENT is operating from the INTERNAL ELECTRICAL POWER SOURCE at the INTERMEDIATE RATE.

IEC 60601-2-24 Ed2.0, Clause 201.7.9.2.101

- A statement of the maximum time for activation of the occlusion alarm 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 THRESHOLD. The MANUFACTURER shall also state that temperature and length of ADMINISTRATION SET affect the time, if applicable.
- The typical operating time when the ME EQUIPMENT is operating from the INTERNAL ELECTRICAL POWER SOURCE at the INTERMEDIATE RATE and, for VOLUMETRIC INFUSION PUMPS and VOLUMETRIC INFUSION CONTROLLERS, also at the MAXIMUM SELECTABLE RATE with a new and fully charged battery.

ACCOMPANYING DOCUMENTS

Instructions for use

IEC 60601-2-24 Ed1.0, Clause 6.8.2

- Not required

IEC 60601-2-24 Ed2.0, Clause 201.7.9.2.101

- If changing between different allowed ADMINISTRATION SETS can result in an unacceptable RISK if no changes are made to the ME EQUIPMENT, a statement regarding the procedure to be followed to guarantee the stated accuracy shall be included
- The range of infusion rates and the conditions (e.g. temperature) for which the stated accuracy is valid
- For PROFILE PUMPS the programmed sequence of delivery rates.

ACCOMPANYING DOCUMENTS

Technical description

IEC 60601-2-24 Ed1.0, Clause 6.8.3

- A functional description of the means provided to protect the PATIENT from EQUIPMENT error resulting in overinfusion and, where applicable, in underinfusion
- The manufacturer shall disclose the ADMINISTRATION SET(S) used for all the tests in this standard.

IEC 60601-2-24 Ed2.0, Clause 201.7.9.3.101

- A functional description of the means provided to protect the PATIENT from overinfusion and, where applicable, underinfusion resulting from ME EQUIPMENT error or partial or total blockage of the ADMINISTRATION SET
- The MANUFACTURER shall disclose the identification of ADMINISTRATION SET(S) used for all the tests in this standard
- If the ME EQUIPMENT cannot be programmed in volume per unit time, and does not display the rate in volume per unit time, the formula is provided for calculating volume per unit time

Requirements related to classification of applied part

IEC 60601-2-24 Ed1.0, Clause 14.6

- Below was additional requirement to IEC 60601-1 2nd Ed.
- 14.6 d) EQUIPMENT intended for DIRECT CARDIAC APPLICATION having one or more APPLIED PARTs of TYPE CF may have one or more additional APPLIED PARTS of TYPE BF which may be applied simultaneously if the requirements of 6.1 l) and 19.3 for such EQUIPMENT have been met.

IEC 60601-2-24 Ed2.0, Clause 201.8.3.101

- Not required

Separation

IEC 60601-2-24 Ed1.0, Clause 17

- This clause of the General Standard applies, except Item c) as following is **not** applicable:
- c) An APPLIED PART shall have no CONDUCTIVE CONNECTION to ACCESSIBLE METAL PARTS which are not PROTECTIVELY EARTHED.

IEC 60601-2-24 Ed2.0, Clause 201.8

- The clause 8.5.1.1 of the General Standard applies to separation of F-type applied parts as follows:
- ME EQUIPMENT shall have two MEANS OF PROTECTION to prevent APPLIED PARTS and other ACCESSIBLE PARTS from exceeding the (leakage current) limits specified in clause 8.4.
- The clause 8.5.2.1 of the General Standard applies to separation of F-type applied parts as follows:
- The PATIENT CONNECTION(S) of any F-TYPE APPLIED PART shall be separated from all other parts, including the PATIENT CONNECTION(S) of other APPLIED PARTS, by means equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE and shall comply with the specified limit for PATIENT LEAKAGE CURRENT

Mechanical strength / Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS *Vibration Test*

IEC 60601-2-24 Ed1.0, Clause 21.1

- EQUIPMENT shall not present a safety hazard to the PATIENT as a result of external vibration.
- This requirement applies only to PORTABLE EQUIPMENT.
- Apply vibrations in a vertical direction and consecutively in two other directions perpendicular to each other in a horizontal plane and in accordance with the values given in table 101.

Table 101 – Vibration value

Frequency range Hz	Displacement or acceleration (peak value)	Number of sweep cycles in each direction
3 to 8	7,5 mm	4
8 to 300	2 g	4
Applied with a sweep rate of 1 octave/min.		

IEC 60601-2-24 Ed2.0, Clause 201.9

- The clause 9.6.3 of the General Standard applies to Hand-transmitted vibration. Except for vibrations directly required to carry out the INTENDED USE of the ME EQUIPMENT. Means shall be provided to protect the PATIENT, OPERATOR and other persons if in NORMAL USE the hand-transmitted frequency-weighted r.m.s. acceleration generated by the ME EQUIPMENT exceeds the value 2.5 m/s2 for a cumulative time of 8 hours during a 24 hours period.
- Compliance is checked by measurements at points of equipment in hand contact with PATIENT, OPERATOR or other persons. Measurements are made in accordance with ISO 5349-1.

Mechanical strength / Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS *Drop Test*

IEC 60601-2-24 Ed1.0, Clause 21.4

- Remote parts including MAINS OPERATED adapters and parts not specified in 21.5 shall not present a safety hazard. Subsequent to the fall of the remote part, when the EQUIPMENT is turned on for use, it shall either function normally, or cease delivery and activate an alarm.
- After drop test, no LIVE parts shall become accessible. Cracks not visible to the naked eye and surface cracks in fibre reinforced mouldings and the like shall be ignored. If the EQUIPMENT is operational after the test a dielectric strength test and LEAKAGE CURRENT tests according to clauses 19 and 20 and FUNCTIONAL TESTS at the INTERMEDIATE RATE shall be carried out.

IEC 60601-2-24 Ed2.0, Clause 201.9

- The clause 15.3.4 of the General Standard applies to:
- HAND-HELD ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts that are HAND-HELD shall not result in an unacceptable RISK as a result of a free fall.
- After the test, the HAND-HELD ME EQUIPMENT and, ACCESSORY or ME EQUIPMENT parts that are HAND-HELD shall not result in an unacceptable RISK.

Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

Spillage on ME EQUIPMENT and ME SYSTEMS

IEC 60601-2-24 Ed1.0, Clause 21.4

- In the event of spillage (accidental wetting) no liquid is retained within the EQUIPMENT ENCLOSURE and the EQUIPMENT shall either continue to function normally or cease delivery and activate an alarm. If an IPX1-classification or better is not claimed, use the test in accordance with IEC 60529 with a test apparatus for DRIP-PROOF EQUIPMENT. Subject the EQUIPMENT to an artificial rainfall of 3 mm/min for 30 s, falling vertically from a height of 0,5 m above the top of the EQUIPMENT. Carry out the test using tap water.
- Immediately after spillage test inspecting for water entered. If water has entered the EQUIPMENT, repeat the test using saline solution (0,9 % NaCl). Carry out a functional test at the INTERMEDIATE RATE for a period of 1 h. Carry out the dielectric strength tests specified in 20.4.

IEC 60601-2-24 Ed2.0, Clause 201.11.6.3

- ME EQUIPMENT and ME SYSTEMS requiring the handling of liquids in NORMAL USE shall be so constructed that spillage does not wet parts that could result in a HAZARDOUS SITUATION.
- Compliance is checked by the test according to IEC 60529 IPX1 (1 mm/min for 10 min) or better:
- After these PROCEDURES, the ME EQUIPMENT is to pass the appropriate dielectric strength and LEAKAGE CURRENT tests and is to show no signs of wetting of uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION and is to maintain BASIC SAFETY and ESSENTIAL PERFORMANCE

Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

Ingress of liquids – IEC 60529

IEC 60601-2-24 Ed1.0, Clause 44.6

- IPX1-classification is minimum requirement.
- EQUIPMENT shall withstand the dielectric strength test specified in clause 20 of IEC 60601-1 2 Ed2. Inspection shall show that water which may have entered EQUIPMENT can have no harmful effect; in particular, there shall be no trace of water on insulation for which CREEPAGE DISTANCES are specified in subclause 57.10 of IEC 60601-1 Ed2.

IEC 60601-2-24 Ed2.0, Clause 201.11.6.5

- ME EQUIPMENT shall be appropriate to the environment of use and at least IPX2.
- ME EQUIPMENT is to show no signs of bridging of insulation or electrical components that could result in a HAZARDOUS SITUATION in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests. Verify that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained.

Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility
Leakage

IEC 60601-2-24 Ed1.0, Clause 44.4

- Set up the EQUIPMENT in NORMAL USE and according to the manufacturer's instructions for use.

IEC 60601-2-24 Ed2.0, Clause 201.13.2.6

- Set up the ME EQUIPMENT in the least favourable orientation of NORMAL USE and according to the MANUFACTURER'S instructions for use.

Interruption of the power supply

IEC 60601-2-24 Ed1.0, Clause 49

- EQUIPMENT powered from the SUPPLY MAINS only shall give an audible alarm in the event of an accidental disconnection or a SUPPLY MAINS failure. Under such conditions, the audible alarm shall be maintained for at least 3 min or until power is restored, whichever is the less.

IEC 60601-2-24 Ed2.0, Clause 201.11.8.101.1

- 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.

Interruption of the power supply

IEC 60601-2-24 Ed1.0, Clause 49

- EQUIPMENT which utilizes an INTERNAL ELECTRICAL POWER SOURCE either as a primary or standby supply shall give an audible and visible warning 30 min before delivery ceases due to battery exhaustion.
- During this period, the EQUIPMENT shall give a continuous visible and an intermittent audible warning at least 3 min before the end of the battery life the EQUIPMENT shall give an audible and visible alarm and cease delivery. The alarm shall be maintained for the duration of the remaining battery lifetime.

IEC 60601-2-24 Ed2.0, Clause 201.11.8.101.1

- 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.
- 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 shall be maintained for the duration of at least 3 min.

Protection against hazardous output

Incorrect output - Protection against overinfusion

IEC 60601-2-24 Ed1.0, Clause 51.5

- Means shall be provided to prevent overinfusion under SINGLE FAULT CONDITIONS. An audible alarm shall be initiated in the event of overinfusion and the EQUIPMENT shall either cease delivery of infusion liquid or reduce the delivery rate to the KEEP OPEN RATE or less.

IEC 60601-2-24 Ed2.0, Clause 201.12.4.4.101

- Means shall be provided in the ME EQUIPMENT to protect against overinfusion under SINGLE FAULT CONDITIONS. An ALARM SIGNAL (high priority audio and visual alarm) 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.

Protection against hazardous output

Incorrect output - Protection against BOLUS volumes and occlusion

IEC 60601-2-24 Ed1.0, Clause 51.5

- Means shall be provided to protect the PATIENT from BOLUS and underinfusion resulting from occlusion following activation of the occlusion alarm.
- An acceptable method of complying with this requirement is to activate an audible alarm and terminate the infusion liquid flow at the OCCLUSION ALARM THRESHOLD (PRESSURE).

IEC 60601-2-24 Ed2.0, Clause 201.12.4.4.104

- Means shall be provided in the ME EQUIPMENT to protect the PATIENT from underinfusion resulting from occlusion.
- 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.

Protection against hazardous output

Incorrect output - Protection against BOLUS volumes and occlusion

IEC 60601-2-24 Ed1.0, Clause 51.5

- Select the INTERMEDIATE RATE and the OCCLUSION ALARM THRESHOLD (PRESSURE) specified by the manufacturer.
- If the OCCLUSION ALARM THRESHOLD (PRESSURE) can be selected, set it to minimum.

IEC 60601-2-24 Ed2.0, Clause 201.12.4.4.104

- Select the INTERMEDIATE RATE and the minimum OCCLUSION ALARM THRESHOLD.

The followings are additional requirement:

- If an automatic bolus reduction feature is available, allow this function to complete.
- If an automatic bolus reduction feature can be disabled repeat the test with this feature disabled.

Protection against hazardous output

Reverse delivery - Protection against air infusion

IEC 60601-2-24 Ed1.0, Clause 51.104

- This requirement does not apply to SYRINGE PUMPS.
- The EQUIPMENT shall protect the PATIENT from air infusion which may cause a SAFETY HAZARD (Potentially detrimental effect on the PATIENT, other persons, animals, or the surroundings, arising directly from EQUIPMENT) due to air embolism.

IEC 60601-2-24 Ed2.0, Clause 201.12.4.4.107

- 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 (defined in RMF by manufacturer) due to air embolism.

Protection against hazardous output

Reverse delivery - Protection against air infusion

IEC 60601-2-24 Ed1.0, Clause 51.104

- After the initiation of an air detection alarm it shall not be possible to recommence liquid delivery by a single action.

IEC 60601-2-24 Ed2.0, Clause 201.12.4.4.107

- After the initiation of an ALARM SIGNAL for air detection alarm it shall not be possible to recommence liquid delivery by a single action.
- The generation of an ALARM SIGNAL according to Table 208.101 (High priority audio and visual alarm) within a time interval less than the volume of the ADMINISTRATION SET between the air detector and the venous cannula connected to it divided by the maximum flow rate of the pump.

Protection against hazardous output

Reverse delivery - Protection against underinfusion

IEC 60601-2-24 Ed1.0

- None

IEC 60601-2-24 Ed2.0, Clause 201.12.4.4.109

- The MANUFACTURER shall address in the RISK MANAGEMENT PROCESS RISKS associated with underinfusion due to any cause including blockage of the ADMINISTRATION SET.
- Compliance is checked by inspection of the risk management file

Audible and visual alarms

Volume of auditory ALARM SIGNALS

IEC 60601-2-24 Ed1.0, Clause 51.107

- The audible alarm shall be able to produce a sound-pressure level (or, if adjustable a maximum level) of at least 65 dB(A) at 1 m, and shall not be by the OPERATOR externally adjustable below 45 dB(A) at 1m

IEC 60601-2-24 Ed2.0, Clause 208.6.3.3.2.101

- The volume of auditory ALARM SIGNALS shall generate a sound-pressure level of at least 45 dBA at 1 m, and shall not be adjustable by the OPERATOR without the use of a TOOL below 45 dBA at 1 m.

Audible and visual alarms

Volume of auditory ALARM SIGNALS - AUDIO PAUSED period

IEC 60601-2-24 Ed1.0, Clause 51.108 and 51.109

- For INFUSION PUMPS FOR AMBULATORY USE shall additionally include an alarm, if the EQUIPMENT is switched to a standby mode of operation for more than 1 h.
- The audible alarm silence period of the EQUIPMENT in stand-alone operation shall not exceed 2 min.
- The visual alarm shall continue to operate during the audible alarm silence period.

IEC 60601-2-24 Ed2.0, Clause 208.6.3.3.2.102

- For INFUSION PUMPS For AMBULATORY USE the maximum time for AUDIO PAUSED is specified according to the RISK ASSESSMENT of the MANUFACTURER
- 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.
- The AUDIO PAUSED shall be indicated visually during the AUDIO PAUSED period.

Audible and visual alarms

ALARM CONDITION priorities and related situations-End of infusion

IEC 60601-2-24 Ed1.0, Clause 51.110

- Audible means shall be provided to indicate to the OPERATOR the end of infusion. This requirement does not apply to INFUSION PUMPS FOR AMBULATORY USE.

IEC 60601-2-24 Ed2.0, Clause 208.6.1.2.101

- Audible means (High priority audio and visual alarm) shall be provided to indicate to the OPERATOR the end of infusion. This requirement applies only to PROFILE PUMP, SYRINGE OR CONTAINER, VOLUMETRIC INFUSION CONTROLLER, VOLUMETRIC INFUSION PUMP.

Audible and visual alarms

ALARM CONDITION priorities and related situations

IEC 60601-2-24 Ed1.0, Clause 51.111

- An audible warning shall be provided prior to the end of the infusion alarm.
- This requirement applies only to SYRINGE PUMPS.

IEC 60601-2-24 Ed2.0, Clause 208.6.1.2.101

- An audible warning (Low priority audio and visual alarm) shall be provided prior to the end of the infusion alarm.
- This requirement applies only to PROFILE PUMP, SYRINGE OR CONTAINER PUMP.

Audible and visual alarms

Characteristics of auditory ALARM SIGNALS

IEC 60601-2-24 Ed1.0

- Table 4 of IEC 60601-1-8:2006

Table 4 – * Characteristics of the PULSE of auditory ALARM SIGNALS

Characteristic	Value
PULSE FREQUENCY (f_o)	150 Hz to 1 000 Hz
Number of harmonic components in the range 300 Hz to 4 000 Hz	Minimum of 4
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.	

IEC 60601-2-24 Ed2.0, Clause 208.6.3.3.1

- Modification of the first and second rows of Table 4 of IEC 60601-1-8:2006 for INFUSION PUMPS FOR AMBULATORY USE only, as shown in Table 208.102.

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.	

Construction of ME EQUIPMENT

Fitting of syringe

IEC 60601-2-24 Ed1.0, Clause 54.101

- In the event of incorrect location of the plunger the SYRINGE PUMP shall not start. Means shall be provided to prevent syphoning under SINGLE FAULT CONDITIONS.
- An alarm shall be activated, if an attempt is made to remove the syringe while the SYRINGE PUMP is running.

IEC 60601-2-24 Ed2.0, Clause 201.15.101

- 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, High Priority, according to Table 208.101, shall be activated.
- An ALARM SIGNAL, High Priority (according to Table 208.101 shall be activated, if an attempt is made to remove the syringe/container while the INFUSION PUMP is running.

Construction of ME EQUIPMENT

Fitting of the administration set

IEC 60601-2-24 Ed1.0, Clause 54.102

- Alarm shall be activated, if the administration set is removed while the infusion pump is delivering fluid.

IEC 60601-2-24 Ed2.0, Clause 201.15.102

- High priority alarm according to Table 208.101 shall be activated, if the administration set is removed while the infusion pump is delivering fluid.
- Test is performed with a force of 15 N and for 15 s in worst case condition. There is no unacceptable risk to the patient due to pulling force on patient line and supply line.

Usability

IEC 60601-2-24 Ed1.0

- Not mandated

IEC 60601-2-24 Ed2.0, Clause 206.101

- PRIMARY OPERATING FUNCTIONS

As a minimum, the following shall be considered.

– power on;

– load ADMINISTRATION SET or syringe/container;

– select infusion parameters;

– infusion start;

– alarm notification and operator action(s) to resolve the alarm situation;

– changing infusion parameters;

Usability

IEC 60601-2-24 Ed1.0

- Not mandated

IEC 60601-2-24 Ed2.0, Clause 206.101

- PRIMARY OPERATING FUNCTIONS

– infusion stop;

– remove ADMINISTRATION SET or syringe/container;

– power off.

– The MANUFACTURER shall determine the complete list of PRIMARY OPERATING FUNCTIONS for the ME EQUIPMENT.