RWANDA FDA
Rwanda Food and Drugs Authority

RWANDA FDA GUIDELINES ON REQUIREMENTS AND SPECIFICATIONS OF VENTILATORS

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Foreword

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018 to regulate matters related to quality, safety and performance of medical devices including ventilators in order to protect public health.

These guidelines provide guidance on the manufacturing, use and performance requirements of ventilators. Ventilators are most likely to confer therapeutic benefits on patients requiring ventilation because of respiratory failure caused by COVID-19, used in the initial care of patients requiring urgent ventilation, in the current health emergency whereby, there is an urgent need of those medical devices to treat symptomatically those with respiratory failure.

These guidelines intend to guide manufacturers in the process of complying to the requirements of a Rapidly Manufactured Ventilation System (RMVS) and these guidelines do not provide a comprehensive list of requirements as the manufacturer is expected to be familiar with the concepts and basic mechanics of mechanical ventilation devices. Whilst the key operating parameters are subject to change, they are not expected to differ significantly from those set in these guidelines.

Adherence to these guidelines will ensure the quality of ventilators on the market during this emergency situation.

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Table of Contents

ABBREVIATIONS AND ACRONYMS

BIPAP	Bilevel Positive Airway Pressure
BTPS	Body Temperature and Pressure Saturated
CMV	Continuous Mandatory Ventilation
COVID-19	CoronaVirus Disease 19
HME	Heat and Moisture Exchangers
I:E	Inspiratory: Expiratory
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
PCV	Pressure Controlled Ventilation
PEEP	Positive End Expiratory Pressure
PRVC	Pressure Regulated Volume Controlled
SIMV-PC	Synchronized Intermittent Mandatory Ventilation - Pressure Controlled
STPD	Standard Temperature Pressure Dry

1. Scope

These guidelines prescribe the minimum requirements for performance and safety of the ventilators manufactured locally and used in Rwanda during the COVID-19 pandemic or any other emergencies. These guidelines apply to the basic safety and essential performance of a ventilator in combination with its accessories.

2. Normative references

The following referenced documents are indispensable for the application of these guidelines some are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited and latest edition of the referenced document (including any amendments) applies.

-ISO 7396-1:2016**:** Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum

-ISO 15223-1:2016: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

-ISO 5359:2014: Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases

-ISO 32:1977: Gas cylinders for medical use — Marking for identification of content

-ISO 7000: Graphical symbols for use on equipment

-IEC 62570 :2014: Standard practice for marking medical Devices and other items for safety in the magnetic resonance environment

-ISO 10651-4:2002: Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators

-ISO 19223:2019: Lung ventilators and related equipment — Vocabulary and semantics

-ISO 5356-1:2015: Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets

-ISO 80369-1:2018: Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirement

-ISO 80601-2-74: Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

-ISO 80601-2-13: Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

-ISO 80601-1-2-7:2017: Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

-ISO 5367:2014: Anaesthetic and respiratory equipment — Breathing sets and connectors

-ISO 9360-1:2000: Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml

-ISO 9360-2:2001: Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml

-ISO 23328-1:2003: Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance

-ISO 23328-2:2002: Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects

-ISO 80601-2-55:2018: Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

-ISO 4871:1996: Acoustics — Declaration and verification of noise emission values of machinery and equipment

-ISO 3744:2010: Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane

-IEC 60539:1989+AMD1:1999+AMD2:2013: Degrees of protection provided by enclosures (IP Code)

-IEC 62366–1:2015: Medical devices — Part 1: Application of usability engineering to medical devices

-IEC 60601-1:2005+AMD1:2012: Amendment 1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

-ISO 14159:2002: Safety of machinery — Hygiene requirements for the design of machinery

-ISO 17664:2017: Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices

-ISO 14937:2009: Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

-KS IEC 60601: Medical electrical equipment

-KS ISO 80601: Medical electrical equipment

3. Definitions

For the purposes of these guidelines, the following definitions shall apply:

Ventilator:

An active medical device that provides temporary ventilation support or respiratory assistance to patients who cannot breathe on their own or who require assistance to maintain adequate ventilation because of illness, trauma, congenital defects, or drugs (e.g., anesthetics).

Breathing system:

Gas pathways in direct connection with the patient through which intermittent or reciprocating gas flow occurs and into which a mixture of controlled composition may be dispensed.

End-expiratory pressure:

Pressure in the breathing system at the end of the expiratory phase time, prior to the beginning of the inspiratory phase time.

Expiratory phase time, (TE):

Interval from the start of expiratory flow to the start of inspiratory flow.

Inspiratory phase time, (TI):

Interval from the start of inspiratory flow to the start of expiratory flow.

Maximum limited pressure, (PL max):

Highest gage pressure that can be attained in the patient system during malfunction of the ventilator, but with functioning safety mechanisms.

Maximum working pressure, (Pw max):

Highest gage pressure that can be attained in the patient system during the inspiratory phase when the ventilator is functioning normally.

Patient connection port:

That opening at the patient end of an expiratory valve unit; a Y-piece fitting or a unidirectional valve to which may be connected either a tracheal tube adaptor or a face mask angle piece.

Inspiratory: Expiratory ratio (I:E):

Proportion of each breathing cycle that is spent breathing in comparison to breathing out

FiO_2: Fraction of inspired oxygen

Concentration of oxygen in the gas mixture that the patient inhales

BIPAP - Bilevel Positive Airway Pressure

non-invasive ventilation mode that provides different levels of pressure when the patient inhales and exhales

Patient system:

That part of the gas system of a ventilator through which respired gas travels at appropriate respiratory pressures.

Peak pressure:

The maximum gage pressure achieved during the inspiratory phase time, with all pressure limiting mechanisms functioning.

Positive End Expiratory Pressure (PEEP)

Pressure maintained in the breathing system during expiration

PRVC – Pressure Regulated Volume Controlled

Mode of ventilation where a set tidal volume is delivered to the patient while maintaining the lowest pressure possible in the airway, to avoid trauma

Respiratory Rate

Number of breathing cycles every minute

SIMV-PC - Synchronized Intermittent Mandatory Ventilation - Pressure Controlled

Mode of ventilation where the patient is allowed to take spontaneous breaths, the machine will assist the patients breathing when a spontaneous breath is taken. If the patient does not make a pre-set number of breaths a minute (i.e. 10) the machine provides mechanical ventilation to provide the set number.

4. Requirements

4.1. General

4.1.1. All manufacturers shall have a risk management system in place related to:

a. Manufacturer's policy on risk.
b. Risk management file of the Medical Equipment (ME).
c. Risk management plan.

4.1.2. The ventilator shall:

i. Be reliable. It shall work continuously without failure (100% duty cycle) for blocks of 14 days - 24 h a day.

NOTE Interruption by the user for purposes of replacing consumables that require replacing within the duty cycle (e.g. resuscitation bags) shall not be deemed as a failure of the ventilator.

ii. Have the capability for patient circuit to remain pressurized at up to 20 cm H2O during operation.

iii. Have the elements of gas pathway built from oxygen safe components to minimize the risk of fire, introduction of foreign matter, contamination of patient airway and demonstrate avoidance of hot spots

iv. have support connections for hospital oxygen supplies – whether driven by piped or cylinder infrastructure compatible with the specifications for pipeline systems for compressed medical gases and vacuum;

v. Be compatible with standard Commercial-Off-the-Shelf (COTS) catheter mount fittings (15 mm Male 22 mm Female);

vi. be capable of being easily cleaned/disinfected and parts easily sterilized using readily available materials; and

vii. have a power backup rechargeable battery with a minimum life of five (5) hours.

4.2. Ventilation requirements

4.2.1. The ventilator shall have at least 1, optionally 2 modes of ventilation:

a. Shall have Continuous Mandatory Ventilation (CMV).

b. The CMV mode shall either be;

i. (ideally) Pressure Regulated Volume Control (PRVC) or

ii. pressure controlled ventilation (PCV) or

iii. minimally a volume controlled ventilation (VCV).

c. PRVC/Pressure Controlled: a set pressure is delivered for the period of inspiration and the volume achieved is measured and displayed. Ideally PRVC, an adaptive mode where the tidal volume is set and the lowest possible pressure is delivered to achieve this volume. PCV where the user has to provide the adaptive control to achieve tidal volume is only acceptable if the tidal volume delivered is clearly displayed and the user can set patient specific upper and lower tidal volume alarms to alert to the need to adjust the pressure.

d. Volume Control Ventilation: the user sets a tidal volume and respiratory rate. The tidal volume is delivered during the inspiratory period. Acceptable only if additional pressure limiting controls are available, see Inspiratory Pressure section.

e. Should have a spontaneous breathing pressure support mode for those patients breathing to some extent themselves, e.g. BIPAP or SIMV-PC. The user sets an inspiratory pressure and an expiratory pressure. The ventilator can sense when a patient starts to breathe in and apply the inspiratory pressure, then sense when the patient starts to breathe out and apply the expiratory pressure (this pressure is still positive but lower than the inspiratory pressure).

4.2.2. If a pressure support mode is provided, the ventilator shall failsafe automatically onto mandatory ventilation if the patient stops breathing in this mode.

4.2.3. Inspiratory airway pressure

The higher pressure setting that is applied to make the patient breathe in:

a. Plateau pressure should be adjusted to achieve volume and shall be limited to 35 cm H2O by default. It is acceptable if an option to increase this to 60 cm H2O in exceptional circumstances is provided. This shall require a positive decision and action by the user
b. Peak pressure should be no more than 2 cm H2O greater than plateau pressure.
c. If volume control ventilation is used, the user shall be able to set inspiratory airway pressure limit in the range at least 15 – 40 cmH_2O in at increments of 5 cm H_2O.
d. There shall be a mechanical failsafe valve that opens at >60 cm H_2O.

4.2.4. Positive End Expiratory Pressure (PEEP)

a. PEEP shall be maintained during expiration.
b. The ventilator shall provide a range 5 – 20 cm H_2O adjustable in 5 cm H_2O increments.

4.2.5. Inspiratory: Expiratory ratio (I:E)

a. The ventilator shall provide 1:2 (i.e. expiration lasts twice as long as inspiration) as the default setting.
b. The ventilator shall have adjustable I:E in the range 1:1 – 1:4 in steps of 0.5.

4.2.6. Respiratory Rate

The ventilator shall provide a range 10 – 30 breaths per minute in increments of 2 (only in mandatory mode) that can be set by the user.

4.2.7. Tidal Volume (Vt) setting, if provided

The volume of gas flowing into the lungs during one inspiratory cycle

a. shall have at least one setting of 400 ml +/- 10 ml in no more than 1.5 s

b. shall have a range 200 – 800 ml in steps of 50 ml.

4.3. Overpressure requirement

4.3.1. A ventilator with a pressurized gas input shall:

a. Operate within the rated range of input pressure.

b. Not cause unacceptable risk under the single-fault condition of 1000 kPa.

4.3.2. A ventilator with a maximum rated input pressure in excess of 600 kPa shall not cause an unacceptable risk under the single-fault condition of twice the maximum rated input pressure.

4.4. Compatibility requirement

If the ventilator is intended to be connected to a medical gas pipeline system, then:

a. The rated range of input pressure shall cover the range in the pipeline, and

b. Under normal condition,

i. The maximum input flowrate required by the ventilator for each gas shall not exceed 60 l/min averaged over 10 s at a pressure of 280 kPa measured at the gas intake port; and

ii. any transient input flowrate shall not exceed 200 l/min averaged over 3 s. or

iii. The accompanying documents shall disclose:

- the maximum input flowrate required by the ventilator for each gas at a pressure of 280 kPa averaged over 10 s measured at the gas intake port;
- the maximum transient input flowrate averaged over 3 s required by the ventilator for each gas at a pressure of 280 kPa measured at the gas intake port; and
- warning to the effect that this ventilator is a high flow device and should only be connected to a pipeline installation designed using a diversity factor that allows the indicated high flow at a specified number of terminal outlets in order to avoid exceeding the pipeline design flow, thereby minimizing the risk that the ventilator interferes with the operation of adjacent equipment.

4.5. Protection against hazardous output

4.5.1. Oxygen monitor

The ventilator shall either;

a. Be equipped with oxygen monitoring equipment for the measurement of the inspiratory oxygen concentration (e.g. in the inspiratory limb or at the patient-connection port) that is integral to the ventilator; or

   The instructions for use shall contain a statement to the effect that the ventilator is to be equipped with oxygen monitoring equipment for the measurement of the inspiratory oxygen concentration (e.g. in the inspiratory limb or at the patient-connection port) before being put into service.

b. Where the oxygen monitoring equipment is not an integral part of the ventilator, the instructions for use shall include the following:
   i. A statement to the effect that the ventilator is to be provided with oxygen monitoring equipment before being put into service; and
   ii. Information on where to connect the oxygen monitoring equipment.

c. The oxygen monitoring equipment shall in addition be equipped with an alarm system that includes a low/high oxygen level alarm condition;

d. The low/high oxygen level alarm condition
   i. shall be at least medium priority unless the intelligent alarm system, based on additional information determines that the low/high oxygen level alarm condition is suppressed or its priority is changed.

4.5.2. Airway pressure

a. The ventilator shall be equipped with monitoring equipment to measure airway pressure.

b. The site of actual measurement
   i. Maybe anywhere in the ventilator breathing system; but
   ii. The indicated value shall be referenced to the patient-connection port.

c. Under steady- state conditions, the indicated airway pressure shall be accurate to within ± (2 + (4% of the actual reading)) cm H2O.

The ventilator shall be equipped with monitoring equipment with an alarm system to indicate when the high- pressure limit for airway pressure is reached.

4.6. Calibration

The ventilator shall have an option for calibration and shall be regularly calibrated as determined by the competent institution for the accuracy of controlled and displayed parameters.

5. General requirements for testing

Usability testing at both prototype and final production stages will be required. This should be done as a short Formative Usability Test along the lines of IEC 62366 in a realistic environment if possible. The user will be wearing complex protective clothing which includes: Eye goggles (in addition to spectacles if worn), Face shield, Plastic apron, Surgical gown, two layers of gloves, usually nitrile non-handed small, medium, large variants, Gloves are donned in layers and sticky taped onto sleeves of gown in between layers.

The user shall be able to instantly see the settings selected and be able to easily operate all controls while dressed in protective gear. They may be required to remain so clothed and operating the ventilator for a number of hours without breaks.

5.1. Ventilator test conditions

1) For testing, the ventilator

a. Shall be connected to gas supplies as specified for normal use,

b. Except that industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.

2) When using substitute gases, care should be taken to ensure that the test gases are oil-free and appropriate, dry.

5.2. Gas flowrate and leakage specifications

All requirements for gas flowrate, volume and leakage in this document,

a. Are expressed at Standard Temperature Pressure Dry (STPD),

b. except for those associated with the VBS,Which are expressed at Body Temperature and Pressure Saturated (BTPS).

Correct all test measurements to STPD or BTPS, as appropriate.

5.3. Ventilator testing errors

1) For the purposes of these guidelines, declared tolerances shall be adjusted by the measurement uncertainty.
2) The manufacturer shall disclose the measurement uncertainty for each disclosed tolerance is the technical description.

Check conformity by inspection of the instructions for use and the technical description.

The compliance with essential safety standards shall be demonstrated for patient safety and the user shall be able to instantly see the settings selected and be able to easily operate all controls while dressed in full protective gear.

6. Monitoring and alarms

Since alarms, alarm limits, and priorities are complex areas to optimize for human usability, the key requirement is to get enough alarms but not too many and for alarms to be clearly ranked so that more urgent patient safety problems are highlighted than others. Early attention to this area is important, and should be built in from the start.

6.1. Shall alarm at:

a. Gas or electricity supply failure.

b. Machine switched off while in mandatory ventilation mode.

c. Inspiratory airway pressure exceeded.

d. Inspiratory and PEEP pressure not achieved (equivalent to disconnection alarm).

e. Tidal volume not achieved or exceeded.

f. Upon switching to the power backup mode.

g. Low battery with a time of an hour before exhaustion.

6.2. Monitoring displayed continuously so the user can verify:

a. the current settings of tidal volume, frequency, PEEP, FiO_2, ventilation mode.
b. the actual current airway pressure.
c. the achieved tidal volume measured at the patient airway, breathing rate, PEEP, and FiO_2.
d. if pressure support mode is provided there shall be real time confirmation of each patient breath and an alarm if below acceptable range.
e. CO_2 monitoring (optional).
f. a log displaying the previous 72 h of alarm events.

7. Programmable electronic subsystems

For systems incorporating programmable electronic subsystems the software shall be developed under satisfactory control and tested for safety and effective before use. At least the following artefacts should be produced to aid this review:

a. Software development plan.
b. System and software requirements specifications.
c. Appropriate software architecture and software design documents.
d. A risk management plan and report.
e. Software verification and validation plans and reports.
f. A software release note.
g. 14 days reliability duty cycle.
h. Size, mounting and robustness of the software able to withstand drop test.
i. Clear labelling of all critical functions and controls using standard terms, pictograms and colours that will be readily recognized by healthcare staff.

8. Biocompatibility evaluation of breathing pathways

8.1. The manufacturer of ventilators shall establish a structured programme for biocompatibility evaluation of breathing pathways within a risk management process.

8.2. The biocompatibility evaluation shall be planned, carried out and documented by knowledgeable and experienced personnel. At least the following parameters should be evaluated to establish safety:

a. Cytoxicity assessment of materials used on breathing pathways.
b. Toxic elements (Lead, Arsenic, Cadmium and Mercury).
c. Particulate matter (2.5-10µm).
d. Volatile organic Carbons (VoCs).

9. Equipment identification, marking and documents

9.1. Medical equipment shall be legibly and indelibly marked with the following information:

a. Name and trade mark of manufacturer;
b. Model;
c. Serial number;
d. Control switches;
e. Operating altitude range
f. Safety signs and symbols;
g. Nature of supply;
h. Rated inputs;
i. The rated range of gas pressure;
j. The gas name or chemical symbol;
k. For oxygen gas inputs, the rated range of oxygen concentration; and
l. Contact information of manufacturer.
m. ME equipment, parts or accessories shall have clearly legible markings including
    1) any special storage, handling or operating instructions.
    2) any warnings or precautions relevant to the immediate operation of the ventilator.
    3) an arrow indicating the intended direction of gas flow:
n. If applicable, operator-accessible ME equipment, parts or accessories shall have clearly legible markings of the following
    1) for a ventilator intended to be used in the magnetic resonance(MR) environment,
    2) an arrow indicating the direction of the flow for flow-direction-sensitive components that are operator-removable without the use of a tool.
    3) an indication of the date after which ME equipment, part or accessory should not be used, expressed as the year and month.

4) a warning not to obstruct the gas intake port.

9.2. “Single-use” or “do not reuse” for any material, component, accessory or equipment intended for single- use.

9.3. User and service instructions not limited to operation, maintenance and disinfection procedure.

9.4. Requirements for physiological effects

a) All natural rubber latex- containing components in the gas pathways or accessories shall be marked as containing latex,
b) Such marking shall be clearly legible.
c) The instructions for use shall disclose all natural rubber latex- containing components.

9.5. Requirements for protective packaging

Packages containing breathing attachments intended for single use or for reuse shall have clearly legible markings of the following

1) A description of the contents
2) An identification reference to the batch, type or serial numbers

9.6. External gas source

a) The gas name or chemical symbols in accordance with ISO 5359:2014;
b) the rated range of gas pressure;
c) for oxygen gas inputs, the rated range of oxygen concentration;
d) gas-specific colour coding in accordance with ISO 32:1977, if colour coding is used.

Annex 1

(normative)

Electrical safety tests

Standard	Clause	Parameter	Test	Requirement	Test method
IEC 60601-1	Clause 15	Construction of medical equipment	Arrangement of controls	The manufacturer shall address in the risk management process the risks associated with the arrangement of controls and indicators of medical equipment as specified in clause 15.1	Inspection of risk management file
			Mains supply transformers	Shall meet requirements specified in clause 15.5	Short circuit , overload, and dielectric tests as per 15.5
			ME Equipment components	Shall meet requirements specified in clause 15.4 regarding connectors, temperature and overload control, batteries, indicators	Inspection and risk management file
			Mechanical strength	Shall have adequate mechanical strength to withstand mechanical stress caused by pushing, impact, dropping, and rough handling as specified in clause 15.3	Mechanical strength tests in clause 15.3
			Serviceability	Shall meet requirements specified in clause 15.2	Inspection of parts
			Batteries	Shall meet requirements specified in clause 15.4	Inspection of parts
	Clause 8	Protection against electrical hazards	Protection against electrical hazards	Shall meet requirements specified in clause 8	Inspection of parts
	Clause 8.7	Leakage and Patient Auxiliary Currents	Earth leakage current: Normal	Shall meet requirements specified in clause 8.7	Electrical testing as per 8.7
			Earth leakage current: Permanent installation	A higher value of leakage current is allowed for permanently installed ME equipment connected to a supply circuit supplying only the ME equipment	
			Earth leakage current: Single fault	Shall meet requirements specified in clause 8.7	
			Touch current: Normal	Shall meet requirements specified in clause 8.7	
			Touch current: Single fault		

	clause 9	Protection against Mechanical Hazards	Emergency stopping devices	Where it is considered necessary to have one or more emergency stopping device(s), the device shall comply to the requirements of clause 9.2.4 items a) to k)	Clause 9
			Force for propulsion	The force required for moving mobile ME equipment on a hard flat horizontal floor shall not exceed 200N unless the instructions for use state that more than one person is needed	

Standard	Clause	Parameter	Test	Requirement	Test method
			Grips and other handling devices	ME equipment other than portable ME equipment or its parts with a mass of more than 20kg that needs to be lifted in normal use or transport shall meet the requirements of clause 9.4.4	
			Instability excluding transport position	ME equipment or its parts shall not overbalance when placed in any position of normal use, excluding any transport positions, on a plane inclined at an angle of 5º from the horizontal plane	
			Instability excluding transport position: lateral	Mobile ME equipment shall be provided with wheel locks or with a braking system to prevent unwanted movement from lateral forces	
			Instability from horizontal and vertical forces	ME equipment or its parts having a mass of 25kg or more other than fixed ME equipment that is intended to be used on the floor shall be permanently marked with a clearly legible warning of this risk	

			Instability in transport position	ME equipment or its parts shall not overbalance when placed in any transport position of normal use on a plane inclined at an angle of 10º from the horizontal plane	
			Surfaces, corners and edges	Mechanical hazards associated with rough surfaces, sharp corners and edges that could cause injury or damage shall be avoided or covered	
	Clause 13	Hazardous situations and fault conditions	Specific hazardous situations Single fault conditions	Shall meet requirements of clause 13	Clause 13
	Clause 11	Protection against excessive temperatures	Protection against excessive temperatures	Equipment shall not exceed allowable temperature limits on parts that are likely to be touched as per clause 11	Clause 11
	Clause 16	ME systems	ME systems	Shall meet the requirements of Clause 16 as applicable	Clause 16