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# **Critical care ventilators — Specification**

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Association of Medical Engineers of Kenya (AMEK)  
Christian Health Association of Kenya (CHAK)  
Diverse Management Consultancy Ltd.  
Equra Health Kenya  
Gertrude's Children's Hospital  
Jads Diagnostics EA Ltd.  
Kenya Accreditation Service (KENAS)  
Kenya Medical Supplies Agency (KEMSA)  
Kenya National Chamber of Commerce and Industry (KNCCI)  
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# Critical care ventilators — Specification

Kenya Bureau of Standards, Popo Road, Off Mombasa Road,  
P.O. Box 54974 - 00200, Nairobi, Kenya



+254 020 6948000, + 254 722202137, + 254 734600471



info@kebs.org



@KEBS\_ke



kenya bureau of standards (kebs)

## Foreword

This Kenya Publicly Available Specification was prepared by the Medical Devices, Tools and Equipment Technical Committee under the guidance of the Standards Projects Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards.

This document gives the minimum specifications of a clinically acceptable ventilator to be used in health care premises during the current COVID-19 pandemic caused by SARS-CoV-2 virus or any other emergency declared by the Cabinet Secretary for Health. It sets out the clinical requirements of what is 'minimally acceptable' performance in the emergency situation. It is for devices, which are most likely to confer therapeutic benefit on a patient requiring invasive ventilation because of respiratory failure caused by SARS-CoV-2, used in the initial care of patients requiring urgent ventilation. A ventilator with lower specifications than this is likely to provide no clinical benefit and might lead to increased harm, which would be unacceptable for clinicians.

This document is intended to guide manufacturers in the process of meeting the key requirements of a Rapidly Manufactured Ventilation System (RMVS) and does not attempt to 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 this document.

Intensive care medicine is a whole system of care and ventilators cannot be safely used on any patient without trained staff and other equipment and medicines.

It is accepted that full demonstration of compliance with ISO 80601-2-12:2020 is unrealistic in the time frame required for development. Nevertheless, compliance with the essential safety standards shall be demonstrated for patient safety.

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.

In the process of preparing this standard, clinical acceptance of functionality, safety and performance by relevant stakeholders and their consensus was sought.

During the preparation of this standard, reference was made to the following documents:

KS IEC 60601-1:2015, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

ISO 80601-2-12:2020, Particular requirements for basic safety and essential performance of critical care ventilators.

RMVS001\_v4, Rapidly Manufactured Ventilator System (RMVS).

Specification for RMVS Challenge, Indicative specification for a Rapidly Manufactured Ventilator System (RMVS).

Pharmacy and Poisons Board Kenya, Guidelines on submission of documentation for registration of medical devices, First Edition, 2011.

Kenya Society of Anaesthesiologists (safe anaesthesia), Ventilator prototype desirables.

Acknowledgement is hereby made for the assistance derived from these sources.

## Critical care ventilators — Specification

### 1 Scope

This Kenya Publicly Available Specification prescribes the minimum requirements for performance and safety of the ventilators manufactured locally and to be used in Kenyan health care facilities during the COVID-19 pandemic or any other emergency declared by the cabinet secretary for health.

### 2 Normative references

The following referenced documents 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 applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

KS IEC 60601, *Medical electrical equipment*

KS ISO 80601, *Medical electrical equipment*

### 3 Terms and definitions

For the purpose of this document, the terms and definitions given in KS IEC 60601 and KS ISO 80601 and the following apply.

#### 3.1

##### **BIPAP – Bilevel Positive Airway Pressure**

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

#### 3.2

##### **FiO<sub>2</sub> – Fraction of inspired oxygen**

concentration of oxygen in the gas mixture that the patient inhales

#### 3.3

##### **Inspiratory:Expiratory ratio (I:E)**

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

#### 3.4

##### **Positive End Expiratory Pressure (PEEP)**

pressure maintained in the breathing system during expiration

#### 3.5

##### **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

#### 3.6

##### **Respiratory Rate**

number of breathing cycles every minute

#### 3.7

##### **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.

## 3.8

### user

trained, qualified medical personnel authorized to use the ventilator

## 3.9

### ventilator

a machine that provides mechanical ventilation by moving breathable air into and out of the lungs to deliver breath to a patient who is physically unable to breath or breathing insufficiently developed for use in health care facilities in Kenya during the COVID-19 pandemic or any other emergency declared by the cabinet secretary for health at the time

## 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:

- a) 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.

- b) Have the capability for patient circuit to remain pressurised at up to 20 cm H<sub>2</sub>O during operation.
- c) 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
- d) 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;
- e) Be compatible with standard Commercial-Off-the-Shelf (COTS) catheter mount fittings (15 mm Male 22 mm Female);
- f) be capable of being easily cleaned/disinfected and parts easily sterilized using readily available materials; and
- g) have a power backup rechargeable battery with a minimum life of 4 h.

### 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 H<sub>2</sub>O by default. It is acceptable if an option to increase this to 60 cm H<sub>2</sub>O 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 H<sub>2</sub>O 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<sub>2</sub>O in at increments of 5 cm H<sub>2</sub>O.
- d) There shall be a mechanical failsafe valve that opens at >60 cm H<sub>2</sub>O.

#### **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<sub>2</sub>O adjustable in 5 cm H<sub>2</sub>O 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 (V<sub>t</sub>) 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  $\pm (2 + (4\% \text{ of the actual reading}))$  cm H<sub>2</sub>O.

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 be calibrated for the accuracy of controlled and displayed parameters.

### 5 Testing and electrical safety

5.1 Compliance with essential safety standards shall be demonstrated for patient safety

5.2 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

5.3 The ventilator shall conform to the electrical safety tests as outlined in Annex A

### 6 Monitoring and alarms

Since alarms, alarm limits, and priorities are complex areas to optimise 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<sub>2</sub>, ventilation mode.
- b) the actual current airway pressure.
- c) the achieved tidal volume measured at the patient airway, breathing rate, PEEP, and FiO<sub>2</sub>.
- 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<sub>2</sub> 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) Cytotoxicity assessment of materials used on breathing pathways.
- b) Toxic elements (Lead, Arsenic, Cadmium and Mercury).
- c) Particulate matter (2.5-10 $\mu$ m).
- 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.

- 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.

**Annex A**  
(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	

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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 5° 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 10° 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	Shall meet requirements of clause 13	Clause 13
			Single fault conditions		
	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

## Bibliography

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

ISO 80801-2-12:2020, *Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

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