WFSA – MINIMUM CAPNOMETER SPECIFICATIONS 2020

1.0 INTRODUCTION

A capnometer is an invaluable piece of equipment for monitoring respiratory and other physiological systems, especially in anaesthesia and intensive care. It is particularly useful in confirming placement of an endotracheal tube into the trachea, identification of circuit disconnection or obstruction and hypoventilation.

Unidentified oesophageal intubation is a cause of mortality or severe morbidity. The availability of a capnometer at the time of intubation increases patient safety by reducing the incidence of unidentified oesophageal intubation.[1]

Continuous capnometry for any anaesthetised patient and for patients in other situations is desirable but the cost of such widespread use needing multiple devices may be prohibitive in locations with limited resources.

The requirements for a monitor used in many Low and Middle Income Countries (LMIC) must include robustness to endure harsh environmental conditions and ease of cleaning, disinfecting and maintenance where biomedical technical back up is limited.[2]

2.0 PURPOSE

These specifications list the **minimum** requirements for capnometry equipment for use in locations with limited resources and harsh environments to primarily identify oesophageal intubation in patients who are intubated and also to identify circuit disconnection and obstruction in all anaesthetised patients.

In addition to essential requirements the specifications include features considered to be desirable.

3.0 SPECIFICATIONS

3.1 Mandatory (essential) features

3.1.1 Compliance with International Standards

The capnometer shall comply with the requirements of ISO 80601-2-55:2018 with the exception of references to nitrous oxide, halogenated anaesthetic gases, main supply (electricity) and functional connectivity (data transmission) and excluding Clause 201.7.9.2.2.101, 'warning to effect that (*the monitor*) shall not be used with gas supplied from oxygen concentrators' i.e. can be used with oxygen concentrators.

The environmental conditions in ISO 80601-2-55 are replaced by those in 3.1.4 below.

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

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[1] Jooste et al. Global Capnography Project: capnography implementation in Malawi. Anaesthesia 2019: 74: 157. doi:10.1111/anae.14426

[2] Lipnick MS et al. The global capnography gap: a call to action. Anaesthesia 2018; 74:147 doi:10.1111/anae.14478

performance requirements of respiratory gas monitors including sensor, display, alarm and accessories.

3.1.2 Target patients

The device shall be suitable for adult, paediatric and neonatal populations.

3.1.3 Power supply

If electrically powered, the power source shall be an internal, rechargeable battery that enables the capnometer to function normally for at least six hours and to continue to function normally when being recharged. The rechargeable battery can be replaced by standard AA sized cells.

An indication of status of the power supply shall be visible on the display if an electrically powered device.

3.1.4 Environmental conditions[3]

a) Transport and storage

The capnometer shall remain operational within its specification after transport or storage in the following environmental range:

- - 40 °C to + 5 °C without relative humidity control;
- + 5 °C to + 35 °C at a relative humidity up to 90 %, non-condensing;
- >35° C to 70 °C at a water vapour pressure up to 50 hPa.

b) Operating conditions

The capnometer shall remain operational within its specification when operated under the following environmental operating conditions:

- a temperature range of 0 °C to + 40 °C;
- a relative humidity range of 15 % to 90 %, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa; and
- an atmospheric pressure range of 620 hPa to 1 060 hPa.

3.1.5 Mechanical strength

The capnometer shall comply with the requirements of IEC 60601-1:2005 + A1:2013 Clauses 15.3.1, 15.3.2, 15.3.3, 15.3.4 and 15.3.5.

3.1.6 Protection against dust and water

The capnometer shall have a rating of at least IP53.[4]

3.1.7 Sensor

The capnometer shall have a mainstream (inline) or side stream (diverting) sensor. The device shall be reusable with the housing easily cleaned and disinfected.

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[3] From IEC 60601-1-12:2014 Medical electrical equipment Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment Clause 4.2

[4] See IEC 60529:1989+A1:1999 Degrees of protection provided by enclosures (IP Code)

3.1.8 Display

The CO_2 value shall be either digital numeric or colourimetric display. The display shall be legible to an operator having visual acuity of 1 i.e. 6/6 vision or 20/20 vision (corrected if necessary), 1 m from the sensor with an illuminance of 215 lx.

3.1.9 Alarms

If the device is electrically powered, the alarms will comply with ISO 80601-2-55:2018.

3.1.10 Labelling information on the unit, for 'instructions for use' & information from the manufacturer shall be in the language relevant to where the device will be used.

3.1.11 Portability

The capnometer shall be handheld or portable. The device shall be supplied with accessory to attach to a pole or bed rail.

3.1.12 Warranty

The device shall have a warranty of at least 2 years

3.2 Optional but very desirable features

3.2.1 Display of the respiratory rate

3.2.2 Capnography trace continuous display

3.2.3 Adaptor for use with facemask or nasal cannulae for monitoring patients spontaneously ventilating

3.2.4 Connectivity and data transfer capacity

3.2.5 Self-calibrating sensor