

The World Federation of Societies of Anaesthesiologists Minimum Capnometer Specifications 2021—A Guide for Health Care Decision Makers

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Capnometry, the measurement of respiratory carbon dioxide, is regarded as a highly recommended safety technology in intubated and nonintubated sedated and/or anesthetized patients. Its utility includes confirmation of initial and ongoing placement of an airway device as well as in detecting gas exchange, bronchospasm, airway obstruction, reduced cardiac output, and metabolic changes. The utility applies prehospital and throughout all phases of in-hospital care. Unfortunately, capnometry devices are not readily available in many countries, especially those that are resource-limited. Constraining factors include cost, durability of devices, availability of consumables, lack of dependable power supply, difficulty with cleaning, and maintenance. There is, thus, an urgent need for all stakeholders to come together to develop, market, and distribute appropriate devices that address costs and other requirements. To foster this process, the World Federation of Societies of Anaesthesiologists (WFSA) has developed the “WFSA—Minimum Capnometer Specifications 2021.” The intent of the specifications is to set the minimum that would be acceptable from industry in their attempts to reduce costs while meeting other needs in resource-constrained regions. The document also includes very desirable and preferred options. The intent is to stimulate interest and engagement among industry, clinical providers, professional associations, and ministries of health to address this important patient safety need. The WFSA—Minimum Capnometer Specifications 2021 is based on the International Organization for Standardization (ISO) capnometer specifications. While industry is familiar with such specifications and their presentation format, most clinicians are not; therefore, this article serves to more clearly explain the requirements. In addition, the specifications as described can be used as a purchasing guide by clinicians. (Anesth Analg XXX;XXX:00–00)

GLOSSARY

CD = compact disc; **CO₂** = carbon dioxide; **IEC** = International Electrotechnical Commission; **IP** = ingress protection; **ISO** = International Organization for Standardization; **LMICs** = low- and middle-income countries; **USB** = universal serial bus; **WFSA** = World Federation of Societies of Anaesthesiologists; **WHO** = World Health Organization

Measurement of respiratory carbon dioxide (CO₂) is invaluable in the clinical care of patients including those who are intubated or nonintubated, anesthetized, or sedated, independent of the location in which care is provided. The values of inspired and expired CO₂ can provide confirmation

of correct placement and functioning of airway devices as well as information about gas exchange and the physiological state of a patient including presence of bronchospasm, hypoventilation, airway obstruction, and altered cardiac and metabolic functions. These situations, if untreated, result in hypoxia and/or hypercapnia, causing morbidity or mortality; thus, a capnometer is an important device in anesthesia and critical care for improving patient safety.¹ A cardinal example is esophageal intubation. If undetected, it is likely to result in severe neurological damage or death. This applies not only at the time of intubation but also throughout the period in which the endotracheal tube remains in place, as inadvertent dislodgement from the trachea carries the same risk. Most professional anesthesia bodies require that CO₂ monitoring is used for any patient undergoing general anesthesia and for patients undergoing moderate-deep sedation.^{2–4} In resource-variable settings, sedation and anesthesia are frequently administered by providers with limited

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training or support such that such respiratory complications are quite common.¹

To implement existing standards for perioperative patient safety worldwide, CO₂ monitoring must be available alongside other essential monitors such as pulse oximetry, pulse rate, and blood pressure.³ This will require a shared effort from industry, ministries of health, professional associations, funders, and stakeholders from multiple health care worker cadres to make CO₂ monitoring an achievable requirement rather than an illusory option available only to the privileged few.

Equipment for monitoring CO₂ is not widely available in many parts of the world, particularly in low- and middle-income countries (LMICs). Common barriers to access include cost, durability of available devices, availability of consumables, lack of dependable power supply, difficulty with cleaning, and availability of maintenance. The World Health Organization (WHO)–World Federation of Societies of Anaesthesiologists (WFSA) International Standards for a Safe Practice of Anesthesia deliberately listed CO₂ monitoring at 1 level below essential or mandatory due to these factors that limit access and availability, but, as an incentive, state that “this form of monitoring will be HIGHLY RECOMMENDED (the WHO’s highest level of recommendation and equivalent to mandatory) when appropriately robust and suitably priced devices are available. Equipment manufacturers are encouraged to urgently address this deficiency.”³

The WHO convened an international consultation on pulse oximetry, the Global Pulse Oximetry Project, and published the report of the meeting in October

2008.⁵ The report noted that monitoring of CO₂ was another modality recommended by most anesthesia societies. However, as a first step to improving patient safety through monitoring equipment in resource-variable settings, increased access to pulse oximetry was considered more beneficial to overall clinical care, because tissue hypoxia occurs from many more mechanisms than hypoventilation and/or apnea and is thought to be a common cause of morbidity and mortality. In addition, it is cheaper than CO₂ monitoring and does not require any or as many disposables. Pulse oximetry is indeed a sensitive and quick monitor for hypoxemia but is not the earliest means of detecting potentially fatal airway misadventures. In the past decade, the Global Pulse Oximetry Project, subsequently called Lifebox, has made significant inroads in improving the availability of pulse oximetry. The WFSA now seeks to promote CO₂ detection as a globally available mandatory monitor to save lives and reduce complications.⁶

The WFSA has developed a set of specifications, “WFSA—Minimum Capnometer Specifications 2021” (<https://wfsahq.org/our-work/safety-quality/international-standards/>) (Tables 1 and 2). These specifications are intended to promote interest from designers and manufacturers. It will serve as a standard tender document for contracts to build, distribute, and price appropriate devices for use in LMICs. The primary function is to detect initial and ongoing esophageal intubation with some other features being viewed as “very desirable but optional,” depending on added cost.

Table 1. WFSA—Minimum Capnometer Specifications 2021 Overarching Principles

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

Unidentified esophageal intubation is a cause of mortality or severe morbidity. The availability of a capnometer from the time of intubation onward increases patient safety by reducing the incidence of unrecognized esophageal intubation.^a The requirements for a monitor used in many LMICs must include robustness to endure harsh environmental conditions and ease of cleaning, disinfecting, and maintenance where biomedical technical backup is limited.^b

Purpose

These specifications list the minimum requirements for capnometry equipment for use in locations with limited resources and harsh environments to primarily identify esophageal intubation and also identify circuit disconnection and obstruction in all anesthetized patients. In addition to essential requirements, the specifications include features considered to be desirable.

Mandatory (essential) features

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 anesthetic 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,” ie, 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—Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors) specifies the basic safety and essential performance requirements of respiratory gas monitors including sensor, display, alarm, and accessories.

Target patients

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

Abbreviations: ISO, International Organization for Standardization; LMICs, low- and middle-income countries; WFSA, World Federation of Societies of Anaesthesiologists.

^aFrom Jooste et al.⁹

^bFrom Lipnick et al.⁶

Table 2. WFSA—Minimum Capnometer Specifications 2021 Specific and Desirable Features

Power supply	If electrically powered, the power source shall be an internal, rechargeable battery that enables the capnometer to function normally for at least 6 h 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 of an electrically powered device.
Environmental conditions^a	
Transport and storage	The capnometer shall remain operational within its specification after transport or storage in the following environmental range: –40 to +5 °C without relative humidity control +5 to +35 °C at a relative humidity up to 90%, noncondensing >35 to 70 °C at a water vapor pressure up to 50 hPa
Operating conditions	The capnometer shall remain operational within its specification when operated under the following environmental operating conditions: A temperature range of 0 to +40 °C A relative humidity range of 15% to 90%, noncondensing, but not requiring a water vapor partial pressure >50 hPa An atmospheric pressure range of 620 to 1 060 hPa
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.
Protection against dust and water	The capnometer shall have a rating of at least IP53. ^b
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.
Display	The CO ₂ value shall be either digital numeric or colorimetric display. The display shall be legible to an operator having visual acuity of 1, ie, 6/6 vision or 20/20 vision (corrected if necessary), 1 m from the sensor with an illuminance of 215 lx.
Alarms	If the device is electrically powered, the alarms will comply with ISO 80601-2-55:2018.
Labeling	Information on the unit, for “instructions for use” and information from the manufacturer shall be in the language relevant to where the device will be used.
Portability	The capnometer shall be handheld or portable. The device shall be supplied with an accessory to attach to a pole or bed rail.
Warranty	The device shall have a warranty of at least 2 y
Desirable but optional features, if resulting in substantial cost savings	<ul style="list-style-type: none"> Display of the respiratory rate Capnography trace continuous display Adaptor for use with facemask or nasal cannulae for monitoring patients spontaneously ventilating Connectivity and data transfer capacity Solar-powered battery charging Self-calibrating sensor

Abbreviations: CO₂, carbon dioxide; IEC, International Electrotechnical Commission; ISO, International Organization for Standardization; WFSA, World Federation of Societies of Anaesthesiologists.

^aFrom 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 used in the emergency medical services environment), clause 4.2.

^bSee IEC 60529:1989+A1:1999 (Degrees of protection provided by enclosures [IP code]).

These specifications were developed by the WFSA Ad Hoc Capnometry Workgroup that has multinational representation of clinicians and an engineer, all listed as authors. The workgroup was made up of individuals who were on the WFSA Board, Council, or Committees, plus an engineer, all with substantial experience with anesthesia and anesthetic equipment for resource-variable settings. The representation is from high-, middle-, and low-income countries—Africa (Congo, Nigeria), Australia, Latin America (Colombia, Honduras), Middle East (Lebanon), the United Kingdom, and the United States. The reviewed material included those listed as references for this article and many of the references within those documents. The international standard that applies to CO₂-monitoring devices, International Organization for Standardization (ISO) 80601-2-55:2018 (Medical

electrical equipment—Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors), was used as the template for the specifications.⁷ Consensus was achieved over a period of 18 months of regular correspondence and teleconferences.

Capnometry and capnography are frequently used interchangeably. However, they are not the same, and distinguishing them is important in relation to these specifications and to product usage. For the current purposes, a capnometer is a device that can repeatedly measure the presence of CO₂ and present the result in some clinically useful format, usually numerically or colorimetrically. Capnometers may be qualitative or quantitative. Colorimetric devices are qualitative, indicating either simply the presence or absence of CO₂ or the ranges of CO₂, for example, 1% to 2% and 3% to 5%.

Quantitative devices measure the CO₂ concentration more accurately breath by breath and may display the result numerically, graphically, or both. Capnography displays the CO₂ measurement as a continuous time-based waveform, thus yielding more clinically useful information. Qualitative colorimetric devices for continuous use are included in the WFSA specifications, despite not being the optimal for operating room and non-operating room use. Increased complexity of equipment usually results in increased cost. The requirements of the proposed WFSA CO₂ monitor are the minimum necessary for an affordable device that can detect initial and ongoing esophageal intubation. Only meeting the minimum should be viewed by both industry and providers as an interim step toward more optimal devices while still enhancing greater use of CO₂ monitoring and patient safety. The minimum specifications, together with the desirable but optional components, represent a preferred ultimate market product.

GLOBAL STANDARDS FOR CAPNOMETRY

As the WFSA—Minimum Capnometer Specifications 2021 were written with manufacturers in mind who are familiar with the various international standards, governing bodies, and their documents, the WFSA specifications, therefore, may not be as easily understood by clinicians. We provide in the following section a description of the standard-setting agencies and their requirements mentioned in the specifications.

The ISO is an independent, nongovernmental international organization with a membership of 164 national standards bodies that develop and publish international standards. Experts are brought together to share knowledge and develop voluntary, consensus-based, market-relevant international standards that support innovation and provide solutions to global challenges.⁸ The international standard that applies to CO₂ monitoring devices is ISO 80601-2-55:2018 (Medical electrical equipment—Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors).⁷

KEY FEATURES OF THE WFSA MINIMUM CAPNOMETER SPECIFICATIONS

The WFSA Specifications (Tables 1 and 2) have included features that are mandatory to ensure that the capnometer is appropriate for use in all environments including LMICs. In some instances, these desired features vary from the ISO International Standard 80601-2-55:2018. For example, it states that the “capnometer shall comply with the requirements of ISO 80601-2-55:2018 with the exception of references to nitrous oxide, halogenated anesthetic 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.” As the WFSA Specifications do not include measurement of other inhaled gases and vapors, all references to them in the ISO document can be ignored. Given the common need for and use of an oxygen concentrator in resource-variable settings, they can be in use with the capnometer.

The WHO-WFSA International Standards for a Safe Practice of Anesthesia call for the development of appropriately robust devices that should also be able to operate in a wide variety of environmental conditions including at the extremes of temperature, humidity, and altitude.³ The mechanical strength, dust, and water protection should therefore comply with the ISO International Standards. A 2-year warranty helps to foster such compliance. Ideally, the expected life of the capnometer and probes device should be specified.

The sensor may be side stream (diverting) or inline and should preferably be reusable, easily cleaned, and disinfected. However, the disposables required for a diverting device such as connectors, tubing, and water traps increase the ongoing costs and may pose additional challenges where supply chains are not in place. Generic, rather than proprietary, disposables are therefore much preferred. Not specified in the specifications are the dead space of connectors, sampling tubing, and sampling rates. These may be particularly important for neonates and young children and, therefore, a consideration in decisions about what device to buy.

The specifications do not mandate that the device be electrically powered. Qualitative colorimetric devices are usually not electrically powered and therefore have a limited duration of use, 2 to 24 hours. However, if it is electrically powered, the source of power needs to include an internal rechargeable battery that can be recharged while in use. The running time of the battery when not connected to a mains supply should be specified and should be at least 6 hours, that is, encompassing a major component of a working operating room day and likely compatible with reasonable battery price and size. The battery recharging cycle time should be specified. Both the device and the battery-charging process need to be compatible with local electricity specification (voltage, hertz) and protected from the substantial fluctuations that are common in resource-variable settings. The device should also be able to function on AA batteries as these are relatively easily obtainable globally.

Alarms can be visual, audible, or both, with both being the preference. Qualitative colorimetric devices could have a color alarm indicating no CO₂ but usually depend on a negative alarm, that is, the absence of a color change. Both audible and visual alarms must be available with electrically powered devices. The ISO includes battery powered under the term “electrically powered.” When the power falls below the values for normal operation, an

alarm needs to be triggered. An apnea alarm must be triggered if >30 seconds of no breathing activity is detected, following a breathing phase. In most in-hospital clinical situations, patients will have been preoxygenated and breathing detected, so that an alarm will be triggered when CO₂ is not detected after intubation. The high- and low-alarm limits should be preprogrammed, and, if adjustable, the default limits should automatically reset each time the device is switched on.

Other important power considerations specified include that when the supply mains are interrupted for <30 seconds or there is an automatic switchover to an internal power source that all settings and patient data shall be maintained. If there is a reserve power source, then it needs to provide at least 30 minutes of normal operation. Devices that are intended for patient transport must be capable of supporting at least 2 hours of normal operation.

The following features substantially enhance the utility of the device but may possibly add to the cost and are therefore described as “desirable but optional”: a display of respiratory rate, a continuous display of capnography trace, an adaptor for use with facemask or nasal cannula, Wi-Fi or Bluetooth connectivity, data transfer capacity, and solar-powered charging. As the primary lifesaving aim of the WFSA specifications is to detect esophageal intubation and/or dislodgement out of the trachea, these optional items were not deemed mandatory. However, capnography, respiratory rate, and adaptors for noninvasive airway techniques are very strongly encouraged. Data transfer, Wi-Fi, and Bluetooth are desirable as one looks to enhance quality assurance initiatives, metric collection, and adoption of electronic medical records.

Monitoring equipment is available with >1 parameter, for example, pulse oximetry and CO₂ monitoring combined in a single device. The utility of this equipment in the LMIC environment is dependent on several considerations. These include the cost of 2 individual monitors versus the cost of a combined or multimodal unit, duration of battery capacity, loss of both monitors if the device is out of service, and complexity of the device for maintenance, disposables, and consumables.

The device should be easy and intuitive to use and available with multiple configurable language choices for countries where the device will be used. Electronic and hard copies of user and service manuals should be provided in a variety of appropriate languages for where the device will be used. Instructions for maintenance should also be provided, including the contact details of relevant suppliers, the basis of support such as whether the device is returned to the supplier and loan units provided, anticipated turnaround times for servicing and parts acquisition, and any limitations on maintenance under warranty. An extended warranty

or maintenance package is highly desirable including how much stock of spare parts will be maintained to help with repair/replacement.

PURCHASING CONSIDERATIONS

Table 3 is intended as a checklist to help purchasers determine their needs and to facilitate the evaluation of products. There are likely local considerations that may need to be added to the list of considerations.

IMPLEMENTATION

Technology is only as useful as the ability of the provider to use it. Therefore, appropriate, tailored education and implementation is crucial. It is important that an education program be developed for the introduction of the capnometer, covering both technical aspects of capnometry, physiology of gas exchange, and clinical use of the device. The education program should be made available in a number of languages including the local or most appropriate language, as well as across a variety of platforms, that is, paper, compact disc (CD), website, and downloads to smartphones. Webinars by the manufacturer specially to cover technical aspects of device usage should be encouraged. Clinically focused webinars by organizations such as the WFSA, Lifebox, academia, and others will be an important component of training inexperienced clinicians in the utility and appropriate clinical use, interpretation, and patient management options. These too should be in appropriate languages. A potentially useful approach is a train-the-trainer model, which will allow rapid expansion of education by creating an expanding group of local experts and educators. A study of the impact of provision of CO₂ monitoring in Malawi demonstrated the feasibility of introducing this device, the recognition of critical airway events, and the positive impact on patient safety.⁹

In conclusion, the specifications developed by the WFSA provide sufficient guidance and set a clinically suitable threshold for equipment manufacturers to develop devices appropriate for use in LMICs. Capnometry saves lives, yet a huge availability gap is apparent largely due to unacceptable pricing, poor access to consumables, and lack of sufficiently robust equipment. It is hoped that by setting minimum specifications, manufacturers will rise to the challenge and begin development and sales of suitable devices at a more appropriate price point for resource-limited settings. ■

DISCLOSURES

Name: Adrian W. Gelb, MBChB.

Contribution: This author helped conceive, write, and edit the manuscript.

Conflicts of Interest: A. W. Gelb is a consultant to Masimo Inc and Haisco Pharma.

Table 3. Purchasing Checklist WFSA—Minimum Capnometer Specifications

The aim of this checklist is to help you understand your needs and to facilitate review of available products.

Device meets ISO 80601-2-55 requirements as stated in the WFSA Minimum Specifications for CO₂ +/- other anesthetic gasses and vapors including environmental operating ranges, transport, storage, strength, dust and water protection

Documentation of above available for review

Intended uses

- Neonatal patients
- Pediatric patients
- Adults
- Esophageal intubation and/or dislodgement into esophagus detection
- Identify circuit disconnection
- Detect obstruction and bronchospasm
- Assess cardiac and metabolic physiology
- Use with mask and/or nasal prongs
- Carbon dioxide only
- Anesthetic gasses and vapors

Measurement and display

- Qualitative
 - Colorimetric
 - One-time measurement
 - Continuous measure
 - Continuous measures for <2 h, 2–6 h, > 6 h
- Quantitative
 - Numerical
 - Wave form (capnography)
 - Numerical plus wave form
 - Display easily visible from 1 m away
 - Language and symbols easily understood by intended users

Alarms

- Shows power status
- Apnea alarm when no CO₂ for 30 s

Sensor

- Mainstream (inline)
- Side stream (diverting)
- Reusable sensor (colorimetric usually single-use only)
- Self-calibrating
- Easy cleaning
- Generic disposables
- Proprietary disposables
- Dependable supply chain

Power supply

- Battery powered
- Rechargeable batteries
- Rechargeable while device running
- Battery lasts ≈6 h
- Can run on standard AA batteries
- Electricity
- You have access to dependable electricity
- Device runs on the available volts and frequency
- Portability
 - Handheld
 - Portable
 - Can attach to a pole or bed rail

Warranty

- 2-year warranty
- In-country repairs

Connectivity

- USB
- Bluetooth
- Wi-Fi
- Allows easy data transfer

Abbreviations: CO₂, carbon dioxide; IEC, International Electrotechnical Commission; IP, ingress protection; ISO, International Organization for Standardization; USB, universal serial bus; WFSA, World Federation of Societies of Anaesthesiologists.

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