

USER GUIDE:

WHO technical specification for medical devices

Version 1.1 , 2014

IMPORTANT NOTES

Please note the following points before using WHO technical specifications:

1) Technical specifications should be tailored appropriately by users according to the specific situation, especially:

Local standards and legislation; local regulations and conditions; languages; installation conditions, technological levels, electrical range, capacities, utility environment, clinical procedures, personnel (users) experience and other local specific conditions.

2) Technical characteristics of WHO technical specifications indicate basic, appropriate, standard equipment for low- and middle- income countries. If you are interested in purchasing more advanced equipment, you should consider optional functions depending on your needs.

3) The number of accessories, consumables, spare parts and other components indicates usual and/or ideal number and is not a mandatory quantity. The user can determine this quantity according to a product's characteristics and frequency of use in your hospital.

4) For tender purposes, you should consider not only medical equipment itself, but also related services in order to be able to use the equipment. Please see Annex 5 for services associated with purchasing medical equipment.

Useful information

1. WHO medical devices technical series/ Management and use:

http://www.who.int/medical_devices/management_use/en/ accessed June 2014.

2. UNOPS UN webbuy:

<https://www.unwebbuy.org> accessed December 2014.

3. UNICEF supply catalogue:

<https://supply.unicef.org> accessed June 2014.

4. UNFPA AccessRH:

<http://www.myaccessrh.org> accessed June 2014.

Complements

1. Who are the TS intended for?

Technical health workers in a hospital such as biomedical engineers, hospital managers, planning officers, procurement officers, and other health related stakeholders such as ministry of health, regulators, manufacturers, NGOs, and UN agencies

2. How to use WHO technical specifications (WHO TS)?

For tendering, procurement, and purchasing of medical equipment, you can search for appropriate equipment according to “technical characteristics, physical characteristics, utility requirement, warranty and maintenance, documentation” of WHO TS.

For planning maintenance, you can search for technical information of medical equipment in your hospital according to “accessories, consumables, spare parts, other components; warranty and maintenance” of WHO TS.

For arranging a training session for health workers in your hospital, you can review “training, installation and utilization” of WHO TS. You can also make requests to manufacturers for training materials and tools.

For searching technical information, you can review “purpose of use, definition, technical characteristics”, and you can search according to “generic name, GMDN name, GMDN code, GMDN category, UMDNS name, UMDNS code, alternative names and others” of WHO TS.

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The advisory expert group included: Kamel Abdul Rahim, Jordan; Firas Mustafa Abu-Dalou, Biomedical Engineering Directorate, Ministry of Health, Jordan; Roberto Ayala Perdomo, Centro Nacional de Excelencia Tecnologica en Salud (CENETEC), Mexico; Andrew Gammie, United Kingdom; Niranjana Khambete, Sree Chitra Tirunal Institute for Medical Sciences and Technology, India; Nicolas Pallikarakis, University of Patras, Greece; and Didier Vallens, France.

The technical specifications of 13 devices related to United Nations Commission on Life Saving Commodities (UNCoLSC) were reviewed by the technical consultation group of UNCoLSC, including the following individuals: Alusine B. Kabia, Sierra Leone; Rehema Mariki, United Republic of Tanzania; Lovemore Mkukuma, Malawi; Valentino Mvanga, United Republic of Tanzania; Youssou Ndao, Senegal; Sam. S. B. Wanda, Uganda; Indira Narayanan, USAID; Nagarajan Kartik Nagesh, India; Keith Neroutsos, PATH; Steve Wall, Save the Children; Bidia Deperthes, UNFPA; Helene Moller, UNICEF; Hayley Traeger, UNFPA; Jean Bosco Ndiokubayo, WHO regional office for Africa; Rajiv Bahl, WHO; Mario Festin, WHO; Bernadette Daelmans, WHO; Selma Khamassi, WHO; Frederik Kristensen, WHO; Denis Maire, WHO; Shamim Ahmad Qazi, WHO; Krisantha Weerasuriya, WHO.

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Disclaimer

Eligibility for inclusion in WHO technical specifications has been developed by WHO, WHO technical advisory group, and UN agencies listed in the Acknowledgements. However, the development and review has been solely based on limited data, information, were existing WHO publications or publicly available information. There has been no rigorous review for safety, efficacy, quality, applicability, or cost acceptability of any of the technologies. Therefore, inclusion in WHO technical specifications does not imply that a device is suitable for a particular purpose. The responsibility for the quality, safety, and efficacy of each technology remains with the developer and/or manufacturer.

WHO does not endorse or recommend any technology included in WHO technical specifications. Inclusion in WHO technical specifications solely aims to provide useful information to technicians in hospitals and/or health managers in healthcare facilities concerning procurement, maintenance, safe-use, waste management, and other technical issues.

Furthermore, WHO does not claim the following statements:

1. WHO technical specification is exhaustive or error free; and/or that
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3. the use of the technologies listed is, or will be, in accordance with the national laws and regulations of any country, including but not limited to patent laws; and/or that
4. any product that may be developed from the listed technologies will be successfully commercialized in target countries or that WHO will finance or otherwise support the development or commercialization of any such product.

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INTRODUCTION

Background

As outlined in the World Health Assembly resolution on health technologies, WHA 60.29, “Medical devices are essential for safe and effective prevention, diagnosis, treatment and rehabilitation of illness and disease. The achievement of health-related development goals, including the Millennium Development Goals, depends upon proper manufacturing, regulation, planning, assessment, acquisition, management, and use of medical devices which are of good quality, safe, and compatible with the settings in which they are used”.

The WHO Department of Essential Medicines and Health Products (EMP), particularly the Diagnostic Imaging and Medical Devices Unit (DIM), aims to ensure improved access, quality and use of safe and appropriate medical devices. Specifically, in paragraph 2.6 it requests that the secretariat, WHO, “establish and update regularly an evidence and web-based health technology database to serve as a clearing house which will provide guidance on appropriate medical devices according to level of care, setting, environment, and intended health intervention, tailored to the specific needs of the country or region”.*(WHA60.29) www.who.int/healthsystems/WHA60_29.pdf

One of the important elements of this health technology database is the Technical Specifications (TS) for medical devices. Technical specifications are required for the procurement and acquisition process of medical devices.

There is a growing need, especially for health care professionals, administrators, and planners involved in procurement, to have access to a high quality technical library which contains searchable, downloadable, and editable specifications of medical devices as part of a larger Medical Devices Database. However, there is currently a lack of relevant, reliable, and impartial information.

It is essential to mention that in the health literature, clinical practice guidelines do not usually include the specific profile of medical devices required for care. Thus, having a harmonized database might provide valuable information on the specific type of medical devices required for the interventions in the guidelines.

As can be found in the baseline country survey of medical devices, (http://www.who.int/medical_devices/countries/en/), various countries have published national technical specifications, and some have these data available in public websites.

In order to have a public database of TS, a rigorous methodology is required to compile best practices, integrate the information, approve the contents, disseminate in a public website, and update regularly.

The need to have a set of TS for specific medical devices required for priority clinical interventions has been important in WHO; therefore, different departments develop their own TS according to their needs, and these TS become a complete monograph of the medical device. One recent example of those monographs is the guidelines published in 2012 on “Cryosurgical equipment for the treatment of precancerous cervical lesions and prevention of cervical cancer”

(<http://www.who.int/reproductivehealth/publications/cancers/9789241504560/en/>); Additional examples include the technical specifications for a blood pressure meter and for a pulse oximeter developed in 2008.

Furthermore, a proposal to develop technical specifications for medical devices was initiated in 2011.

Development of WHO technical specifications

WHO technical advisory group meeting (Annex 1) took place in Geneva, Switzerland on 30th April to 2nd May in 2013 with the following objectives:

- To reach a consensus on a methodology for developing technical specifications (TS) endorsed by WHO, generated within a proposed time frame;
- To define the key elements of a TS WHO format, where stakeholders can organize the information they would provide to WHO to make the compendium of TS;
- To define a global collaboration strategy based on the time frame.

The discussion of the advisory group for developing technical specifications was based on the global overview on technical specifications for medical devices (Table 1) and the usability analysis for technical specifications (Table 2).

Table 1 Global overview on technical specifications for medical devices

• 65% of 145 countries have an authority responsible for implementing and enforcing medical device specific product regulations • 63% of 166 countries carry out the procurement of medical devices at national level • 45% of 166 countries have a national list of approved medical devices for procurement or reimbursement • 37% of 161 countries do not have national standards or recommended lists of medical devices for different types of healthcare facilities or specific procedures • 37% of 161 countries have available TS of medical devices to support procurement or donations
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Source: Baseline Country Survey on Medical Devices, 2010:
http://www.who.int/gho/health_technologies/medical_devices/en/

Table 2 Usability analysis for technical specifications

<u>User</u>	<u>What required from TS?</u>	<u>How to increase usability?</u>
Planner	Guide on options available	Fit well with intervention Simplicity of access Different levels of technology
Medical staff	Understandable Guide as to what is appropriate	Simple language Local names Searchable Linked with intervention Different levels of technology
Biomedical Engineer	Reference for internal TS development	Simple to cross reference with other formats

		Clear, consistent format
Procurement Department	Copy and use for bids	Not too many options to choose
	Adaptable for local use	Simple contents
Maintainer of database	Easy to keep up	Manageable quantity of devices Simple, relational database
Industry	Benchmarking of products	Open access
	Marketing	Facility to comment and object

The advisory group also discussed how to establish a format of WHO technical specifications that allows it to cover all areas of medical devices including consumables, equipment, single-use devices, implantable devices, and others. In this context, some elements of the previous WHO format were merged with other related elements so that it can be adapted to all areas of medical devices.

Finally, the advisory group agreed on the basic framework for developing WHO technical specifications and further work to solidify and elaborate on the WHO technical specifications continuously managed by WHO medical devices.

After the meeting, the group reviewed the contents of WHO technical specifications for 61 medical devices in order to fit them into the agreed WHO format.

United Nations Commission on Life Saving Commodities

The consultation for United Nations Commission Life on Saving Commodities (UNCoLSC) took place in Geneva, Switzerland from 10-12 June 2013 to improve access to medical devices recommended by the UN commission in 2012.

(<http://www.everywomaneverychild.org/resources/un-commission-on-life-savingcommodities/about>).

This recommendation consisted of 10 guidelines aiming to increase access to 13 essential commodities. The 13 commodities involve 3 specific types of medical devices: female condoms, neonatal resuscitation equipment (mask, valve and bag, suction bulb or aspirator) and supportive medical devices for injectable antibiotics (syringes, needles) that are part of the commodities defined by the UNCoLSC.

Focal points from Africa, NGOs, UNICEF, UNFPA and WHO related staff participated in this meeting (Annex 2) to define medical devices concretely and share experiences on effective procedures and appropriate devices. As a part of this initiative, WHO also developed the WHO technical specifications of 13 medical devices, which were defined during the consultation in June 2013 (Table 3). The 13 technical specifications were also based on the same WHO format as the WHO technical specifications agreed upon by the advisory group.

Table 3 13 medical devices for UNCoLSC

Reproductive health commodities	
1	Female condom
Injectable antibiotics for newborn sepsis	
2	Syringe 2 mL with needle 23 G 25mm (with re-use prevention feature)
3	Syringe 2 mL with needle 23 G 25mm (without re-use prevention feature)
4	Sharps container, for used syringes/needles
5	Infant scale less than 20 kg
6	Clinical thermometer, non-mercury
Resuscitation devices for newborn asphyxia	
7	Self-inflating neonatal resuscitation bag with masks for pre-term and term babies
8	Electric or foot operated suction machine/pump, negative pressure less than 100mmHg, with 1 bottle
9	Suction catheter , length 50 cm, single use, conical tip, Fr# 8
10	Single use suction bulb
11	Multi-use suction bulb that can be opened, cleaned and sterilized
12	Training manikin/simulator for neonatal resuscitation
13	Infant stethoscope

Finally, WHO incorporated 13 technical specifications into the WHO technical specifications as a part of the project concerning clearinghouse of technical information in order to improve access to those essential commodities in developing countries.

Further development

After several meetings, the technical advisory group agreed in August 2013 on an initial version of the format for WHO technical specifications and contents (Annex 3).

To consolidate the first draft of WHO technical specifications, WHO consulted with the Trade associations (Global Medical Technology Alliance, Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association) and UN agencies (UNICEF, UNFPA and UNOPS) involved in the procurement of medical devices.

Following the consultation, comments were taken into account regarding equipment for radiotherapy, related information for tendering, and adaptable modifications for local requirements.

In collaboration with these agencies and technical advisors, this first version of WHO technical specifications for 70 medical devices (Annex 4) was consolidated for public consultation.

This first version of WHO technical specifications still has areas to be improved. However, due to the increasing need for WHO technical specifications from countries, we would like to make this first version of WHO technical specifications publicly available in order to collect comments from different stakeholders and users in various countries.

If you have any comments for us, please kindly find the format on the website https://extranet.who.int/datacol/survey.asp?survey_id=3009. Please input the name as 'techspec', password as 'techspec' and Domain as 'Datacol', and feel free to fill in your information, add your comments and then click "submit" at the end.

In the future, WHO will be updating WHO technical specifications periodically based on your comments and needs. Additionally, WHO will publish a guide for developers and manufacturers on the application process for WHO technical specifications for a new product.

ANNEX 1 Participants for the technical advisory group meeting for WHO technical specifications

Mr Kamel ABDUL RAHIM

Medical Devices Consultant
LEBANON
Email: kamelar70@gmail.com

Mr Firas Mustafa ABU-DALOU

Directorate of Biomedical Engineering
Ministry of Health
Amman
JORDAN
Email: dfiras70@yahoo.com

Mr Roberto AYALA PERDOMO

CENETEC
Ministry of Health
MEXICO
Email: Rap6701@gmail.com

Mr Andrew GAMMIE

UNITED KINGDOM
Email: agammie@fishtail.biz

Mr Niranjan KHAMBETE

Sree Chitra Tirunal Institute for Medical Sciences and
Technology
INDIA
Email: niranjan.d.khambete@gmail.com

Mr Nicolas PALLIKARAKIS

University of Patras
GREECE
Email: nipa@upatras.gr

Mr Mladen POLUTA

SOUTH AFRICA
Email: mladen.poluta@uct.ac.za

Mr Didier VALLENS

FRANCE
Email: Didier.vallens@invivo.edu

Ms Alejandra VELEZ RUIZ GAITAN

MEXICO
Email: la.velezrg@gmail.com

WHO HEADQUARTERS

Dr Yukiko NAKATANI

Technical Officer, Diagnostic Imaging and Medical
Devices Unit
Email: nakataniy@who.int

Ms Adriana VELAZQUEZ BERUMEN

Coordinator, Diagnostic Imaging and Medical Devices
Unit
Email: velazquezberumena@who.int

ANNEX 2 Participants for ‘Consultation for technical specifications of medical devices determined by the United Nations Commission on life saving commodities’

HEALTH TECHNOLOGY FOCAL POINTS FROM PATH FINDER COUNTRIES FOR UNCoLSC:

Mr Alusine B. KABIA

Bio Medical Consultant, Ministry of Health and Sanitation, SIERRA LEONE
Email: alusinebk@yahoo.com

Ms Rehema MARIKI

Tanzania Food & Drugs Authorities, UNITED REPUBLIC OF TANZANIA
Email: remariki@yahoo.com

Mr Lovemore MKUKUMA

Ministry of Health, MALAWI
Email: mkukuma@yahoo.co.uk

Mr Valentino MVANGA

Ministry of Health, UNITED REPUBLIC OF TANZANIA
Email: vmvanga@yahoo.com

Dr Youssou NDAO

Pharmacien Inspecteur de sante publique, Ministry of Health, SENEGAL
Email: youisn@yahoo.fr

Mr Sam. S.B. WANDA

Ministry of Health, UGANDA
Email: ssbwanda@gmail.com

NGOs:

Ms Indira NARAYANAN

Neonatal resuscitator main consultant from USAID (lead convener), UNITED STATES
Email: inarayanan6@gmail.com

Dr Nagarajan Kartik NAGESH

Consultant in Neonatology, INDIA
Email: karthiknagesh@yahoo.co.in

Mr Keith NEROUTSOS

Director of Procurement at PATH, UNITED STATES
Email: kneroutsos@path.org

Mr Steve WALL

Save the Children (lead convener for injectable antibiotics)
Email: swall@savechildren.org

OTHER UN ORGANIZATIONS:

Ms Bidia Deperthes

UNFPA (lead convener for female condoms), UNITED STATES
Email: deperthes@unfpa.org

Dr Helene MOLLER

UNICEF Supply division, DENMARK
Email: hmoller@unicef.org

Ms Hayley TRAEGER

UNFPA Procurement Services Branch, DENMARK
Email: traeger@unfpa.org

OBSERVERS:

Ms Tatjana R. SACHSE

Sidley Austin LLP, SWITZERLAND
Email: tsachse@sidley.com

WHO REGIONAL OFFICE FOR AFRICA:

Dr Jean Bosco NDIHOKUBAYO

Regional Advisor for Health Technologies
Email: ndihokubwayoj@who.int

WHO HEADQUARTERS:

Dr Benedetta ALLEGRANZI

Technical Officer, Patient Safety Programme, PSP
Email: allegranzib@who.int

Dr Rajiv BAHL

Medical officer, Research and development, MCA/FWC
Email: bahlr@who.int

Dr Mario FESTIN

Lead specialist Family Planning, FWC
Email: festinma@who.int

Dr Selma KHAMASSI

Technical officer, Injection safety, PSP
Email: khamassis@who.int

Dr Frederik KRISTENSEN

Office of the Assistant DG for Family, Women's and Children's Health (FWC)
Email: kristensenf@who.int

Dr Denis MAIRE

Scientist, Vaccines, EMP
Email: maired@who.int

Dr Shamim Ahmad QAZI

Research and Development, MCA/FWC
Email: gazis@who.int

Dr Krisantha WEERASURIYA

Medicines Access and Rational Use, EMP
Email: weerasuriyak@who.int

WHO Essential Medicines and Health Products Department (EMP)/Medical Devices Unit:

Ms Jennifer BARRAGAN

Consultant
Email: j.barragan.biz@gmail.com

Dr Yukiko NAKATANI

Technical Officer, Diagnostic Imaging and Medical Devices
Email: nakataniy@who.int

Mr Amir SABET SARVESTANI

Technical Officer, Diagnostic Imaging and Medical Devices
Email: sabetsarvestania@who.int

Ms Laura Alejandra VELEZ RUIZ GAITAN

Consultant
Email: la.velezrg@gmail.com

Ms Adriana VELAZQUEZ BERUMEN

Coordinator, Diagnostic Imaging and Medical Devices
Email: velazquezberumena@who.int

ANNEX 3 Medical devices listed in WHO technical specifications

- 1 Abortion suction system
- 2 Anaesthesia ventilator
- 3 Bilirubinometer
- 4 Capillary patient thermometer
- 5 Cardiovascular ultrasound
- 6 CPAP unit
- 7 Cryosurgical unit
- 8 Darkroom automatic x-ray film processor
- 9 Daylight automatic x-ray film processor
- 10 Diagnostic spirometer
- 11 Electrocardiographic monitor
- 12 Examination treatment light
- 13 Floor scale electronic
- 14 Floor scale mechanical
- 15 Foetal cardiac monitor
- 16 Foetal vacuum extraction
- 17 General purpose electrosurgical diathermy
- 18 General purpose tabletop centrifuge
- 19 General purpose ultrasound
- 20 Incubator infant stationary
- 21 Infant warmer
- 22 Infrared thermometer, ear
- 23 Infrared thermometer, skin
- 24 Neonatal/adult intensive-care ventilator
- 25 Laboratory urine analyser IVD
- 26 Laboratory water bath
- 27 Rigid intubation laryngoscope
- 28 Manual emergency suction system
- 29 Microscope light
- 30 Mobile basic diagnostic x-ray system, analogue
- 31 Mobile basic diagnostic x-ray system, digital
- 32 Mobile flourosopic x-ray system, analogue
- 33 Mobile flourosopic x-ray system, digital
- 34 Neonatal physiologic monitoring systems
- 35 Non-rechargeable professional semi-automated external defibrillator
- 36 Obstetrical table, line-powered
- 37 Obstetrical table, manual
- 38 Operating light (fixed)
- 39 Direct ophthalmoscope, battery-powered
- 40 Outer ear otoscope
- 41 Overhead infant phototherapy unit
- 42 Peak flow meter
- 43 Physiologic monitoring system
- 44 Portable ventilator electric
- 45 Pulseoximeter line powered
- 46 Pulseoximeter battery powered

- 47 Scale patient Infant
- 48 Single channel electrocardiograph
- 49 Sphygmomanometer
- 50 Stationary basic diagnostic x-ray system analogue
- 51 Stationary basic diagnostic x-ray system digital
- 52 Mechanical stethoscope
- 53 General-purpose suction system, line-powered
- 54 Syringe pump
- 55 Laboratory thermometer
- 56 Transport infant incubator
- 57 Universal operating table electrohydraulic
- 58 Universal operating table electromechanic
- 59 Universal operating table hydraulic
- 60 Unwrapped steam sterilizer
- 61 Radiographic film view box, non-powered

(UNCoLSC)

- 62 Female condom
- 63 Syringe 2 mL with needle 23 G 25mm (with re-use prevention feature)
- 64 Syringe 2 mL with needle 23 G 25mm (without re-use prevention feature)
- 65 Sharps container, for used syringes/needles
- 66 Infant scale less than 20 kg (See also 47)
- 67 Clinical thermometer, non-mercury (See also 23)
- 68 Self-inflating neonatal resuscitation bag with masks for pre-term and term babies
- 69 Electric or foot operated suction machine/pump, negative pressure less than 100mm Hg, with 1 bottle (See also 53)
- 70 Suction catheter , length 50 cm, single use, conical tip, Fr# 8
- 71 Single use suction bulb
- 72 Multi-use suction bulb that can be opened, cleaned and sterilized
- 73 Training manikin/simulator for neonatal resuscitation
- 74 Infant stethoscope (See also 52)

ANNEX 4 Format of WHO technical specification

Medical devices specification

(including information on the following where relevant/appropriate, but not limited to)

		Instructions and examples
i	Version No.	(Rows i - v and 1 are completed and managed by WHO)
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	
v	Completed / submitted by	Usually name of Institution / Organization / UN agency
NAME, CATEGORY AND CODING		
1	WHO Category / Code	
2	Generic name	Name of the medical device as commonly used (e.g. anaesthesia machine).
3	Specific type or variation (optional)	Characteristics of the device that distinguish it from other similar devices or devices of the same generic name (e.g. handheld, bench-top, portable, digital, adult/paediatric/neonatal, consumable/disposable, single-use, etc.).
4	GMDN name	Name as produced and maintained by the Global Medical Devices Nomenclature (GMDN) Agency, e.g. <i>Anaesthesia unit, mobile</i> . (NB: Access to GMDN Agency nomenclature system may be restricted - see http://www.gmdnagency.com/ for further information).
5	GMDN code	Comments as for [9]; GMDN code for 'Anaesthesia unit, mobile' is 47769 (all GMDN device codes have 5 digits)
6	GMDN category	Comments as for [9]; GMDN category for 'Anaesthesia unit, mobile' is '02 Anaesthetic and respiratory devices'.
7	UMDNS name	Name as produced and maintained by the ECRI institute, e.g. <i>Anaesthesia Units</i> (NB: Access to ECRI nomenclature system may be restricted - see https://www.ecri.org/Products/Pages/UMDNS.aspx for further information).
8	UMDNS code	Comments as for [12]; ECRI code for 'Anaesthesia Units' is 10134 (all ECRI device codes have 5 digits).
9	UNSPSC code (optional)	United Nations Standard Products and Services Code [see http://www.unspsc.org/]. This coding system uses a hierarchy of Family-Class-Commodity. For an anaesthesia unit, which comprises a number of functional modules, there are a number of corresponding Commodity codes and titles listed under more than Class; e.g. Commodities 42272501 'Gas anaesthesia apparatus' and 42272502 'Absorber units for gas anaesthesia apparatus' are included under Class 42272500 'Anaesthesia apparatus and accessories and supplies' in the Family 42270000 'Respiratory and anaesthesia and resuscitation products'.
10	Alternative name/s (optional)	Name/s set by a regional or national authority, local names (e.g. Boyle's machine) or synonyms of formal nomenclature (e.g. anaesthesia apparatus or system).
11	Alternative code/s (optional)	Corresponding code/s set by a regional or national authority.
12	Keywords (optional)	Specific area / disease related to the device (e.g. anaesthesia, intra-operative care, etc.).
13	GMDN/UMDNS definition (optional)	Definitions produced and maintained by the GMDN Agency and ECRI Institute, respectively.
PURPOSE OF USE		
14	Clinical or other purpose	A description of the essential clinical or other objective/s associated with the device's utilisation, e.g. anaesthesia units (allow the anaesthetist to) dispense a mixture of gases and vapours and vary the proportions thereof to control a patient's level of consciousness and/or analgesia during surgical procedures.
15	Level of use (if relevant)	The level of healthcare service delivery at which the device is to be used, or is typically used. [NB: Since the level of skill/s required of the device user/s should also be considered, and the levels of service delivery are not globally standardised, this level may vary from country to country.] Home use should also be considered as a level of care. For our example, the anaesthesia unit would typically be used at district, regional and tertiary hospitals.
16	Clinical department/ward (if relevant)	The usual service area / functional department in which the device would be used, e.g. Operating room, Intensive Care Unit, Paediatric ward, Outpatient department). Home use should also be considered as a level of care.

17	Overview of functional requirements	General description of the device's function, e.g. for anaesthesia unit this would include gas/vapour delivery platform; ventilator with patient breathing circuit; scavenging system to capture and exhaust waste gases; physiological and multi-gas monitors, etc.
TECHNICAL CHARACTERISTICS		
18	Detailed requirements	The required characteristics and specific/critical functional requirements. e.g. modules, components, measured and/or delivered parameters and associated values and ranges, compatibility / inter-operability requirements, etc.
19	Display parameters (if relevant)	User interface information requirements (e.g. display of pressure, volume, flow, status indicators, inspiration and expiration times, etc.) and format (continuous waveform display, digital, trends, etc.).
20	User adjustable settings (if relevant)	Device functional parameters, alarms, language, etc. that should be adjustable at the discretion of the user/s.
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Dimensions, configuration of complex equipment, etc.
22	Mobility, portability (if relevant)	Requirements for non-fixed/installed devices, e.g. weight, handles, on castor wheels of specified diameter, etc.
23	Raw materials (if relevant)	Applies mainly to surgical instruments and /or implants. e.g. stainless steel (linked to bio-compatibility/patient safety, corrosion resistance, etc.).
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Electrical supply: e.g. nominal mains voltage with frequency and permitted fluctuations, battery operation (if relevant); Water and gas supply: quality and flow rate requirements.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Accessories needed (type, number, functional requirements, etc.) for full and proper functioning of the device.
26	Sterilization process for accessories (if relevant)	Preferred method to be specified, if appropriate; otherwise to be clearly indicated by manufacturer/supplier.
27	Consumables / reagents (if relevant)	Consumables (renewables) and disposables (including single-use accessories) to be used with the medical device. Where appropriate, quantity required, shelf life, etc. should be specified.
28	Spare parts (if relevant)	It would be very useful to know what parts are likely to be needed in the first year of operation (based on average usage and experience elsewhere) and/or in the year after expiry of the warranty period.
29	Other components (if relevant)	Complementary equipment (e.g. printers, stands, wall mounts, etc.).
PACKAGING		
30	Sterility status on delivery (if relevant)	To be specified - applies to implantables or single-use devices that are delivered sterile
31	Shelf life (if relevant)	Shelf life and number of uses of the device to be specified
32	Transportation and storage (if relevant)	Specific considerations for transportation and storage
33	Labelling (if relevant)	Specific labelling requirements
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Storage and operating temperatures (specify ranges), resistance to high humidity and/or dust levels (specify requirements) - in accordance with local/anticipated conditions.
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements (if relevant)	Construction / structural changes, utility requirements, etc.
36	Requirements for commissioning/sign-off (if relevant)	Manufacturer/supplier to perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel (if relevant) also to be specified and provided.
38	User care (if relevant)	Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices).
WARRANTY AND MAINTENANCE		
39	Warranty	Date of commencement, duration of warranty period, exclusions/inclusions and other conditions such as maintenance support during warranty must be specified.

40	Maintenance tasks	Specific equipment for needed for calibration or testing purposes must be specified. Advanced maintenance tasks required shall be documented, with details of maintenance support from manufacturer/supplier.
41	Type of service contract	Non Comprehensive or Comprehensive Contract
42	Spare parts availability post-warranty	Usually at least 5 years after device acquisition.
43	Software / hardware upgrade availability	To be specified.
DOCUMENTATION		
44	Documentation requirements	Operating and service manuals (language/s to be specified) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community.
DECOMMISSIONING		
45	Estimated Life Span	Predictable average life span, if it is assumed the average frequency of utilization, maintenance and failure. The device would be better to be assessed on the replacement concerning this span. (see 'How to Plan and Budget for your Healthcare Technology' http://www.who.int/management/plan_budget_healthcare.pdf)
SAFETY AND STANDARDS		
46	Risk Classification	To be provided by manufacturer/supplier (typically verified by regional or national regulatory agencies). There is increasing international harmonisation, facilitated by the International Medical Device Regulators Forum (see http://www.imdrf.org/) with at least four systems in use: Class A to D (IMDRF/GHTF); Class I, IIa, IIb, III (EU, Australia); Class I, II, III (USA); Class I to IV (Japan, Canada), with low-risk devices in Classes A or I and high-risk devices in Classes D or III (or IV for Japan and Canada).
47	Regulatory Approval / Certification	e.g. FDA approval (USA), CE mark (EU)
48	International Standards	Specified for compliance by manufacturers in global marketplace, notably ISO 13485: Quality Management System and ISO 14971: Risk Management System. Apply to categories of devices, e.g. for electromedical devices IEC 60601-1 (General requirements for basic safety and essential performance), IEC 60601-1-1-1 (Collateral standard: safety requirements for medical electrical systems) and IEC 60601-1-2 (Collateral standard: Electromagnetic compatibility - Requirements and tests). Apply to specific devices, e.g. IEC 60601-2-19 (Particular requirements for the basic safety and essential performance of infant incubators), ISO 10079-1 (Medical suction equipment), etc.
49	Regional / Local Standards	Related standards for device in relevant regulatory jurisdiction (region or country)
50	Regulations	Related regulations for device in relevant regulatory jurisdiction (region or country)

ANNEX 5 Related services to be considered for tender, purchasing technology and local conditions purposes

Note: we advise that the adaptation shall be carry out by a specialized engineer or team of engineers according to the complexity of the purchase.

1. Delivery at Place

- a) Specify required certifications for Supplier and Manufacturer (ISO 9001 and ISO13485 suggested) to be included in the Bidding documents.
- b) Specify Delivery Incoterms and Delivery Place.
- c) Specify if there is the possibility for a temporary storage.
- d) The Supplier shall deliver the original software license, in the name of the final Beneficiary, where applicable, together with the equipment.
- e) The Supplier shall make available to the Purchaser all the consumables, measurement and calibration instruments used during commissioning operations.
- f) The Supplier shall provide together with the goods the didactic material for maintenance and user training courses. The didactic material will be in specify language without any exception. The didactic material shall be approved by the Purchaser.
- g) The Supplier shall deliver together with the equipment one hard or one CD/DVD copy of the operation manual and maintenance manual in specify language with each unit provided. If the above required language version of the manual is not available the English shall be delivered along with a translation into the above required language signed by the technical manager of the Supplier.
- h) All the labels and indications on the equipment as well as the software included with the equipment shall be in specify language and exceptionally some English label may be used providing the translation in the above mentioned language during training.

2. Preliminary acceptance

- a) The Purchaser will inspect the delivered good checking their quantities and their integrity.
- b) In case that the installation is not included in the contract the Purchaser will install, directly or by a third part, and check the quality of the goods in this phase and will preliminary accept the goods according with the result of the check.
- c) The Supplier can be present to the above mentioned phases. If the Supplier is not present he will accept any decision taken by the Purchaser.
- d) The Supplier shall supply to the Purchaser all the consumables, measurement and calibration instruments used during official commissioning operations. All the expenses necessary for the official testing and commissioning procedure shall be responsibility of the Contractor.
- e) The Purchaser shall evaluate, item by item, the consistency of the goods and the services supplied respecting the contract conditions and the technical specifications.
- f) The Supplier shall be invited by the Purchaser to assist with the measurement operations during official commissioning for provisional acceptance. At the end of the operations the Purchaser shall prepare minutes of the results and make it available to the Supplier.
- g) Each item shall be declared as compliant, not-compliant or revisable.

- h) The official testing and commissioning is declared successful when all the items of a Lot are declared compliant.
- i) The Supplier shall substitute all not-compliant items with compliant ones at its own cost.
- j) An item is declared revisable only if it has minor defects or is not perfectly compliant. In these cases, only when the Supplier has substituted the item or has solved the defects, he can ask for a new official testing and commissioning.
- k) The not-compliant or revisable items shall be substituted or modified without any break of safety and Manufacturer rules, any cost for the Purchaser or any extension to the contractual deadlines. Any delay due to not-compliant or revisable items is responsibility of the Supplier, thus liquidated damages are applicable.

3. Installation

- a) Specify installation requirements in terms of civil works, data network, electricity, hot and cold water, special treated water, drainage medical gases, steam, air conditioning etc. required to the Supplier.
- b) Specify availability of installations in terms of data network, electricity, hot and cold water, special treated water, drainage, medical gases, steam, air conditioning, etc.: technical characteristics and position.
- c) The Supplier/Installer shall transport the equipment inside the hospital to the installation site, open the packages and install it according with the installation requirements.
- d) The Supplier/Installer shall clean up the site of any packaging/shipping material after installation and after requesting the Purchaser whether or not the original boxes must be left with the Purchaser;
- e) The Supplier/Installer shall install the equipment taking into consideration the construction characteristics of the hospital receiving the equipment.
- f) The Supplier/Installer is responsible to install the equipment "ready to start" for testing and commissioning.
- g) Any damage to hospital structures or finishing caused by the supplier personnel during the installation will be repaired by the supplier within 2 weeks using the same construction materials of the damaged areas.

4. Supplier testing and commissioning

- a) The Supplier/Installer shall test, calibrate and commission the goods as appropriate in a way that that, on installation completion, they are fully operational and can be used. The Purchaser reserves the right to witness the Supplier/Installer's testing and commissioning without thereby relieving the Supplier/Installer of his obligation to provide goods in a fully operable condition.
- b) A complete set of commissioning forms with the entire set of tests run and the results obtained will be given to the Purchaser after the final reception of the equipment.
- c) When the Purchaser will proceed with the commissioning, the successful Bidder will make available to Final beneficiary the use of all consumables, measurement and calibration instruments used during the commissioning.

5. Training to the maintenance personnel

- a) The Supplier/Installer shall train technicians made available by the Purchaser/final Beneficiary in the most frequent problems that could occur during equipment utilization and that are under maintenance technicians' competencies.

- b) The training course for maintenance technicians shall be theoretical and practical, using the equipment in the configuration offered and simulators. The Supplier must supply simulators where and when it is needed. The simulator is a property of the Supplier who will keep it after the course is completed.
- c) The Supplier shall provide the didactic material. The didactic material will be in Specify language without any exception.
- d) The training course for maintenance technicians shall be organized to for a minimum of 1 person to a maximum of 5 persons.
- e) The location of the training course delivery for maintenance technicians shall the place where the equipment is delivered and installed.
- f) The trainers shall be qualified experts belonging to the Manufacturer Company and/or representatives in the country/region of the Supplier/Installer and/or by qualified experts certified by the Manufacturer. The course will be held in Specify language.
- g) The training course for maintenance technicians shall focus at least on the following topics:
 - presentation and contacts of the reference technicians;
 - general equipment functions, specific technical characteristics and alarm signals;
 - main electrical and functional schemes;
 - calibrations (if requested) and daily maintenance in order to assure the longest equipment life;
 - preventive maintenance and its regular recurrence;
 - corrective maintenance (to solve the most frequent problems);
 - equipment safety controls.
- h) The average duration of the training course will be not less than 2 hours per each item.
- i) A final test administered by the trainees shall be organized at the end of the training course in order to verify the know-how acquired. The results shall be delivered to the Purchaser before commissioning.

6. Training to the equipment users

- a) The Supplier/Installer shall train the users in the equipment maintenance and correct utilization.
- b) The training course for users shall be theoretical and practical, using the equipment in the offered configuration and planning simulations of all possible mistakes occurring during equipment utilization.
- c) The Supplier shall provide the didactic material. The didactic material will be in Specify language without any exception.
- d) The training course shall be organized for at least 2 users for each equipment item installed.
- e) The location of the training course delivery shall the place where the equipment is delivered and installed.
- f) The trainers shall be qualified experts belonging to the Manufacturer Company and/or representatives in the country of the Supplier/Installer and/or by qualified experts certified by the Manufacturer. The training will be held in Specify language.
- g) The training course for users shall focus on least on the following topics:
 - presentation and contacts of the reference technicians;

- general equipment functions in the offered configuration, alarm signals and error signals showing all the possible equipment functionalities;
 - calibrations (if requested), daily cleaning and maintenance operations in order to assure the longest equipment life;
 - correct equipment utilization and related possible risks for users and patients;
- h) The average duration of the course shall be not less than 2 hours for each item.
- i) The evaluation of the know-how acquired will be done through two tests: one entrance test at the beginning of the course and one final test at the end. The trainees shall certify that the received training is satisfactory.

7. Provisional equipment handing over

- a) Official testing and commissioning will be carried out by Lot when all items and services of the Lot have been supplied.
- b) The Supplier/Installer shall apply by written notice to the Purchaser for an Official Testing and Commissioning not earlier than 10 days before the date when, in the Supplier/Installer's opinion, the delivery of the goods and services of one Lot will be complete and ready for Provisional Taking Over.
- c) Upon receipt of the above mentioned note and within 15 days after the receipt of the goods and the Services according to the specified requirements, the Purchaser shall conclude the Official Testing and Commissioning procedure.
- d) If the Purchaser fails to conclude the Official Testing and Commissioning procedure within the aforementioned term he shall be deemed to have issued the preliminary Taking-Over Certificate on the last day of that period.
- e) The Purchaser shall evaluate, item by item, the consistency of the goods and the services supplied respecting the contract conditions and the technical specifications after the installation phase.
- f) The Supplier shall be invited by the Purchaser to assist with the measurement operations. At the end of the operations the Purchaser shall prepare minutes of the results and make it available to the Supplier.
- g) Each item shall be declared as compliant, not-compliant or revisable.
- h) The official testing and commissioning is declared successful when all the items of a Lot are declared compliant.
- i) The Supplier shall substitute all not-compliant items with compliant ones at its own cost.
- j) An item is declared revisable only if it has minor defects or is not perfectly compliant. In these cases, only when the Supplier has substituted the item or has solved the defects, he can ask for a new official testing and commissioning.
- k) The not-compliant or revisable items shall be substituted or modified without any break of safety and Manufacturer rules, any cost for the Purchaser or any extension to the contractual deadlines. Any delay due to not-compliant or revisable items is responsibility of the Supplier, thus liquidated damages are applicable.
- l) The Goods are taken over by the Purchaser once they have been supplied together with the services in accordance with the Contract. Within two weeks after successful official testing and commissioning of all the items of one Lot and of one Hospital the Purchaser shall deliver to the Supplier the Preliminary Taking Over Certification. This Certificate shall be deemed to signify the Purchaser's satisfaction with the supplied Goods and Services and therefore the completion of the Supplier's obligations under Contract for the said Hospital.
- m) The warranty period shall commence on the date of Preliminary Taking Over stated in the Preliminary Taking-Over Certificate.

8. Manufacturer Warranty

- a) The manufacturer warranty certificate will be in the name of the final Beneficiary.
- b) The warranty period will be not less than **specify manufacturer warranty duration** starting from the date of issuance of the preliminary acceptance (before installation).
- c) The warranty will cover the entire machine including any and all component parts, spare parts, software modules, accessories and consumables thereof. The warranty coverage will be applied fully and without any cost to Beneficiary and to the users whatsoever, including but not limited to the cost of visits, labor, spare parts, and shall be valid for unlimited consultations within the warranty period save in cases of proven misuse, intentional damage, or force majeure.
- d) If in the opinion of the Supplier, Goods were subject to misuse, intentional damage or force majeure; therefore, not covered by warranty, the Supplier should present indubitable proof of such misuse, intentional damage or force majeure.
- e) The Manufacturer warranty will be carried out at manufacturer premise, being all the travel and transport cost covered by the Supplier.

9. Supplier/installer additional Warranty

- a) The supplier warranty integrates the manufacturer warranty both for coverage and duration.
- b) The supplier warranty certificate will be in the name of the final Beneficiary.
- c) The warranty period will be not less **specify supplier warranty duration** starting from the date of provisional taking over (after installation and commissioning).
- d) The Supplier/Installer additional warranty will be at delivery place, being any cost of equipment transport or technician travelling at Supplier/Installer charge and included in the offered price.
- e) At least 95% of one single year of full functioning, i.e. 347 days out of 365/366 days, will be guaranteed by the Supplier within the warranty period. In the event that the equipment supplied has been malfunctioning for more than five percent (5%) of one single year of the warranty period, i.e. more than 18 natural days in one single year, the Supplier shall extend the warranty period for a duration of six times of the time duration when the equipment was malfunctioning.
- f) The time elapsed between the communication about the broken equipment and the intervention on site will be, inside the warranty period, not longer than 5 business days.
- g) During the warranty validity period the programmed on-site maintenance and calibration visits will be at least 2 per year. The schedule of the visit will be presented before the taking preliminary taking over certification. During the visits a concise additional training will be provided to the users and to the maintenance personnel.
- h) During on-site maintenance and calibration visits a short user training update will be carried out by the Supplier/Installer.

10. Final Taking Over Certificate

- a) Within one month after expiration of the Warranty Period for the Goods or any part and in case the Supplier has fulfilled all his obligations under Contract, the Purchaser's shall issue and send to the Supplier a Final Taking-Over Certificate.
- b) Before issuing the Final Taking-Over Certificate, the Purchaser shall receive from the Supplier a written warranty that the manufacturer will continue to grant the availability spare parts and Support Services for the Goods for **Specify duration for spare parts availability**.

11. After warranty services

- a) The sole availability (not the provision) of the maintenance services and equipment spare parts shall be guaranteed for Specify duration for spare parts availability since the date of issuance of the final equipment taking over certificate. A written warranty from the manufacturer shall confirm the availability (not the provision) of spare parts for 5 years and the letter must be presented before the Final Taking Over Certificate.
- b) The maintenance services and equipment spare parts shall be available directly in the Specify the country or region for maintenance and spare parts availability.

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