World Health Organization

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Final draft 10-7-2020 pending integration to a single publication with other technical specifications

COVID-19 Technical specifications for portable ultrasound

Contents

Abbreviations

B-mode	brightness mode
CDI	colour Doppler imaging
CE	Conformité Européenne
dB	decibels
DICOM	Digital Imaging and Communications in Medicine
FDA	Food and Drug Administration (USA)
FSC	free sales certificate
GB	gigabytes
HD	high definition
HDMI	high-definition multimedia interface
ISO	International Organization for Standardization
LCD	liquid crystal display
MHz	megahertz
M-mode	motion mode
MSK	musculoskeletal
PDI	power Doppler imaging
POC	point-of-care
USB	universal serial bus
WHO	World Health Organization
2D	2-dimensional

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1. Context and considerations

This publication aims to define the basic technical characteristics of ultrasound portable scanners, also called cart-based point-of-care ultrasound scanners or portable ultrasound scanners.[1]

The decision on appropriate clinical use of each of these devices is reserved for medical staff.

Diagnostic ultrasound scanners are medical imaging devices that use high-frequency sound waves to permit users to collect information on normal and pathologic appearances of patients' internal and external organs.

Portable ultrasound scanners are designed for point-of-care (POC) applications. They can be battery operated, are relatively easy to use, and have capabilities and features designed for imaging assessments at the POC. However, since diagnostic ultrasound is a highly operator-dependent imaging modality, proper training is required to make optimum use of the equipment, produce diagnostic quality images, and interpret them correctly to make reliable diagnostic judgements.

Portable ultrasound scanners can speed patient management decision-making, providing more time-efficient and effective patient care. Diagnostic applications include: external imaging (e.g. abdominal, pelvic, lung, cardiovascular, musculoskeletal [MSK] and small parts imaging); intraluminal/intracavitary imaging; obstetrics ultrasound; and trans-fontanelle imaging in neonates/infants, among others. In addition to its diagnostic applications, portable ultrasound is also used to guide interventional procedures such as injection of medications, drainage of collections, and for a range of other applications performed by various health care providers.

2. Definitions and intended use

Laptop-style scanners: These take the shape of a laptop, notebook or tablet computer and often have most of the functionality of a conventional full-size scanner, but in a smaller package. Cart-based portable ultrasound scanners are included in this category.
Handheld scanners: These can be held in one hand, while the attached transducer or probe is held in the other. They lack many of the features of other types of scanners.
USB-powered scanners: This category describes self-contained transducers that can be plugged into the universal serial bus (USB) port of a user-supplied computer-based device (e.g. laptop, tablet, smartphone) either directly or through an adapter.

[1] CND/EMDN nomenclature code Z11040103.

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This document only refers to the laptop style portable scanners category (both touchscreen and/or standard laptop equipment and cart-based), which are also referred to as cart-based point-of-care ultrasound scanners or portable ultrasound scanners.

Regarding the ongoing COVID-19 pandemic and, in particular, COVID-19 related lung damage and associated complications, ultrasound technology offers benefits in imaging pneumonia, assessing pleural complications and evaluating the condition of the heart *(1, 2).*

The portable ultrasound unit will be primarily used in emergency and critical care units, but can also be used in other health care centres and acute respiratory units and treatment centres and will serve for general purposes after the pandemic. The unit will be used for, but not limited to, investigate thoracic, abdominopelvic, obstetrics/gynaecological and vascular diseases and to perform, if needed, interventional procedures.

The infection prevention and control precautions and, in particular, the level of decontamination of the probes should be differently applied depending on procedure, for example, whether the transducers used are in contact with intact skin or body fluids *(3).*

3. Technical specifications for procurement

3.1 Portable ultrasound

		Portable ultrasound
	Naming	**Cart-based point-of-care ultrasound scanners, also called portable ultrasound scanners (both touchscreen and/or standard laptop equipment and cart-based).**
1	General technical requirements	Capable of generating imaging procedures involving lungs, heart, abdomen, pelvis, blood vessels, musculoskeletal and soft tissue. Console: laptop style console design, optional touchscreen combined with conventional user-control panel. Weight of the console: 5–8 kg. Dimensions: 35–45 cm (L); 35–45 cm (H); 5–10 cm (D). Battery duration: minimum 2 hours under normal use conditions. Clear protective control panel cover for infection control. Imaging focusing: adjustable focal depth, synchronization of focal zone to the selected scanning depth. Zooming capability with automated image optimization.

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		Depth range selection: capable of multiple depth range selection. synchronized with automatic focal zone selection. Field of view: deep (> 15 cm). Image orientation: capable of lateral and vertical inversion (in B-mode). Image modes at least: • 2D imaging • M-mode • B/M mode • dual 2D/colour image mode with cine loop • Doppler, colour Doppler imaging (CDI), power Doppler imaging (PDI), duplex, continuous wave Doppler, triple mode (optional). Needle enhancement ability. Software applications that include at least: • Obstetrics/gynaecological measurements and calculations, including gestational sac mean, mean sac diameter, femur length, crown-rump length, biparietal diameter and abdominal circumference, enabling estimation of gestational age • small parts • lung • vascular/basic cardiac quantification • easy selection of callipers • measurements capabilities (distance, area and circumference by ellipse and trace method) • capability to be upgraded with additional software applications. Probe-dependant applications with factory-default presets at least: cardiac, peripheral vascular, abdominal adult, abdominal paediatric, small parts, lung, MSK-general, MSK-superficial, obstetrics/gynaecological Equipment with write-zoom function available. Screen annotations capture patient data, date and time, scanning protocols, probes. Text annotations and body markers and image orientation indicator. Transducer ports: at least two active transducer ports permanently available; capability of electronic switch between probes.
2	Monitor and display	Screen monitor: high-definition (HD) digital black and white and colour liquid crystal display (LCD) monitor of at least 25 cm diagonal (across), equivalent to 10 inches, with reflection filter. Screen monitor protection. Laptop monitor fold-down and lock mechanism of the screen for safe and easy transportation (if applicable). User-friendly control panel: easy to use, logical and orderly control panel: for quick and easy location of most common functions.

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		Back lighting of application knobs/buttons.
3	Communication and storage	Data communication, storage and transfer interface: USB minimum, high-definition multimedia interface (HDMI) preferable. DICOM 3.0 conformance. Digital image storage: Image and cine memory of at least 64 GB of cine memory. Cine loop: freeze and cine-loop functions. Image grey scale: 256 shades of grey and video output of 625 lines/frame 150 dB full time dynamic range. Capability for database of patient images and information.
4	Consumables	Ultrasound transmission gel for 3 months' operation. Disinfectants for 3 months' operation. Compatible printing paper for 3 months' operation.
5	Accessories (included)	Transducers: • Phased-array 1–5 MHz for basic cardiac and lung studies and phased array up to 8 MHz for paediatric patients. • Broadband curvilinear at least 5–2 MHz for general abdominal, lung and obstetrics/gynaecological ultrasound applications. This should have colour, power and spectral Doppler capabilities. M-mode is desirable for obstetrics. • Linear-array high frequency broadband at least 12–5 MHz, with colour, power and spectral Doppler capabilities for vascular and small parts. • Capability to connect endo-cavitary transducers. Matching trolley compact and lightweight, easy to transport. Cables and other connection accessories. Storage security lock/chain and key Wheeled cart (if applicable) with gel bottle holders, drawer or dedicated space for accessories, place for scanner positioning and easy orientation.
6	Power supply (voltage, frequency and plug vary across the countries)	Equipment must be connected to a reliable and continuous source of energy. Operates from AC power electric line: 100–240 V ~, 50/60 Hz. In-built rechargeable battery shall be included. Automatic switch from AC power electric line mode to battery operating mode and vice versa. Power supply: power supply may vary according to countries. Working time in battery mode and standard operations not less than 1 hour. Battery recharging time not more than 4 hours.

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7	Documentation (included, minimum in English language)	Hard and soft copies in English (provision of versions in other UN languages, if available, will be an asset). Certificate of calibration and inspection. User manual with specific protocols for cleaning, disinfection, troubleshooting. Service manual with calibration and routine maintenance. Contact details for after sales service. Contact details of manufacturer, supplier and local service agent.
8	Primary packaging label	Labelling on the primary packaging to include: • Name and/or trademark of the manufacturer. • Model or product's reference. • Information for particular storage conditions (temperature, pressure, light, humidity).
9	Standards, for the manufacturer and the equipment	Certified quality management system for medical devices (e.g. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes). General quality management (e.g. ISO 9001:2015 Quality management systems – Requirements). Application of risk management to medical devices (e.g. ISO 14971:2019 Medical devices – Application of risk management to medical devices).
10	Regulatory approval/certification	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). National local regulatory approval (of recipient country, as applicable)
11	Standards, for product performance	Compliance to the following international standards or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended. • ISO 29821:2018-Condition monitoring and diagnostics of machines – Ultrasound – General guidelines, procedures and validation. • IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. • IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems.

		• IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. • IEC 60601-2-37:2007 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment. • IEC 61157:2007/AMD1:2013 Amendment 1 – Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment. • IEC 60601-1-4 Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: programmable electrical medical systems.
12	Warranty	The system shall be covered by two (2) years of warranty including parts and labour, including the probes, starting as of the date of successful on-site acceptance, as per testing and acceptance. Spare parts availability for the equipment lifespan (not less than 7 years). Warranty shall include all necessary spare parts, shipment to site, cost of replacement work, personnel, disposal of faulty parts, and software (patches, upgrades, and updates).
		Any variation to be indicated in the offer.

3.2 Additional services required

Testing and acceptance

- The system, prior to shipment, shall be tested by designated agents for conformance with manufacturer's performance specifications and the minimum requirements specified.
- The results of the testing of the system shall be documented by the contractor in an acceptance protocol that shall be signed by the end user.

Training and manuals

- User care instructions and protocols (manuals) to be provided, including guidance for replacement of accessories and consumables and safe decontamination of reusable parts (if applicable), indicating if they are generic or brand related.
- Technical maintenance protocols and manuals to be provided.
- Training for users and technical maintenance teams (provided also in online format, if available).

4. Methodology

Technical specifications define the minimum requirements for the product to ensure good quality, safety and efficacy. The process to develop these specifications included:

- Analysis of the technologies required to perform the clinical management of COVID-19 patients: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management
- Analysis of existing products in the market, based on approval from the regulatory agencies.
- Device overviews, specifications and comparative data published by ECRI – an evidence-based practice centre – which is a non-profit, independent organization that conducts independent medical device evaluations: https://www.ecri.org/
- International experts drafted the document (WHO consultants: Laura Alejandra Velez Ruiz Gaitan, Gabriela Jimenez Moyao, Francesco Ribolzi).
- Expert input from the International Atomic Energy Agency (Francesco Giammarile, Enrique Estrada Lobato, Diana Paez, Olivier Pellet, Virginia Tsapaki).
- Expert input from WHO (Tahera Emilie van Deventer, Pryanka Relan, Maria del Rosario Perez) and other clinical and technical ad hoc panel of experts (Jocelyne M Basseal, Vano Eliseo, Michael G Kawooya, Konstantin Yastrebov).
- All members of the panels provided Conflict of Interest documents, which were reviewed by WHO and no conflict of interests were found.
- Development coordinated by Adriana Velazquez, Group Lead Medical Devices and In Vitro Diagnostics, WHO.

References

1. Manna S, Wruble J, Maron S, Toussie D, Voutsinas N, Finkelstein M et al. COVID-19: a multimodality review of radiologic techniques, clinical utility, and imaging features. Radiol Cardiothorac Imaging. 2020;2(3) (https://pubs.rsna.org/doi/10.1148/ryct.2020200210, accessed 26 June 2020).
2. Yasukawa K and Minami T. Point-of-care lung ultrasound findings in patients with COVID-19 pneumonia. Am J Trop Med Hyg. 2020;102(6):1198–1202.
3. WHO (2020). Use of chest imaging in COVID-19: a rapid advice guide. 11 June 2020. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/332336, accessed 26 June 2020).

Resources

ECRI (2015a). Evaluation & Guidance – Point-of-care ultrasound scanners: an introduction. 8 April 2015 (https://www.ecri.org/components/HDJournal/Pages/POC-Ultrasound-Scanners.aspx?tab=1, accessed 26 June 2020).

ECRI (2015b). Evaluation & Guidance – Point-of-care ultrasound scanners: key purchasing considerations. 12 August 2015 (https://www.ecri.org/components/HDJournal/Pages/Guidance-Point-of-Care-Ultrasound-Purchasing.aspx?tab=1, accessed 26 June 2020).

ECRI (2020a). Evaluation & Guidance – Evaluation background: tablet-style point-of-care ultrasound scanners. 26 February 2020 (https://www.ecri.org/components/HDJournal/Pages/Eval-Background-Tablet-Style-POC-US-Scanners.aspx?tab=1, accessed 26 June 2020).

WHO (2018). WHO compendium of innovative health technologies for low-resource settings: 2016–2017 (https://apps.who.int/iris/bitstream/handle/10665/274893/9789241514699-eng.pdf?ua=1, accessed 27 June 2020).

WHO (2020). WHO Technical Specification for Medical Devices [website]. Geneva: World Health Organization; 2020 (https://www.who.int/medical_devices/management_use/mde_tech_spec/en/, accessed 26 June 2020).

[disclaimer in final publication]