



# COVID-19 Technical specifications for infusion devices

## Contents

### Abbreviations

1. Context and considerations
  2. Definitions and intended use
  3. Technical specifications for procurement
    - 3.1 Infusion pump
    - 3.2 Syringe pump
    - 3.3 Drop counter
  4. Methodology
- References and resources

## Abbreviations

CE	Conformité Européenne
dB	decibels
FDA	Food and Drug Administration (USA)
FSC	free sales certificate
ISO	International Organization for Standardization
IV	intravenous
KVO	keep vein open
LCD	liquid crystal display
psi	pounds per square inch
USB	universal serial bus
VTBI	volume to be infused selector
WHO	World Health Organization



# COVID-19 Technical specifications for infusion devices

## 1. Context and considerations

This publication aims to define the basic technical characteristics of infusion devices – infusion pump, syringe pump and drop counters – for accurate administration of medicines to patients. The decision on appropriate clinical use of each of these devices is reserved for medical staff.

In many contexts technical-mechanical performance will no longer be the main focus when selecting this type of device but the interoperability with other devices and hospital systems/servers, the access to drug libraries, and log events record and editor access. However, for all contexts basic criteria in all cases should be considered:

- Consumable costs, availability and compatibility (administration sets/infusion sets used to connect the drug supply and the patient) and licence fees. Buying a pump generally involves establishing a long-term relationship with the pump supplier.
- User training required – ease of use.
- Calibration and maintenance requirements.

## 2. Definitions and intended use

**Infusion pump:** Infusion pumps are devices used to accurately deliver liquids through intravenous (IV) or epidural routes for therapeutic or diagnostic purposes. They provide greater accuracy than gravity administration sets, and higher pressures. They are calibrated in flow settings of mL per hour ranging from 0.1 to 3600 mL/hr. Most pumps have a drug dose calculator that permits programming of the flow according to the physician dose order.

It should be noted that infusion pumps are of high risk to patients and special care should be taken in the delivery of the medication or IV solution. Mistakes when setting the infusion rate or volume can damage the patient. All infusion devices should be used under close monitoring of patients.

Special considerations for COVID-19 or other highly infectious patients is the length of the infusion IV tubing, which can cause higher resistance in the delivery of the infusion solution, and alarms that will pause the infusion.



# COVID-19 Technical specifications for infusion devices

## Box 1. Use of extension sets to position infusion pumps outside COVID-19 patients' rooms

At high flow rates (e.g. 300 mL/hour), increasing resistance to fluid flow because of the microbore tubing extensions can result in frequent occlusion alarms, making the pump unusable.

For more information:

Institute for Safe Medication practices: <https://ismp.org>

ECRI Institute: <https://assets.ecri.org/PDF/COVID-19-Resource-Center/COVID-19-Clinical-Care/COVID-Alert-Large-Vol-Infusion-Pumps-3.pdf>

**Syringe pump:** Syringe pumps administer highly concentrated drugs or antibiotics from a syringe. They are designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency. They are commonly used for neonatal and paediatric patients because of the mentioned characteristics and for management of small volumes ( $\leq 60$  mL). A syringe containing medication is securely mounted on the drive arm. The drive arm infuses the medication at a steady, programmed rate.

**Drop counter:** This device counts the number of drops according to the number of drops previously memorized and selected by the operator. This device is rarely used today because of its poor accuracy and limited or non-existent market availability.

## 3. Technical specifications for procurement

### 3.1. Infusion pump

		Infusion pump
	Naming	<b>EMDN nomenclature: infusion pumps (code: Z12030301).</b> <b>Alternative names: infusion multi-therapy pumps; injection pumps.</b>
1	General technical requirements	One channel (at least). Capable of accepting any kind of fluids (solutions and medications preferable). Pump capabilities: <ul style="list-style-type: none"> <li>• flow range 0.1 to <math>\geq 999</math> mL/hr</li> <li>• increments 0.1–100 mL/hr</li> <li>• keep vein open (KVO) rate 1–5 mL/hr</li> <li>• volume to be infused selector (VTBI) 1–9999 mL</li> <li>• flow rate accuracy of <math>\pm 5\%</math> or better</li> <li>• when multiple channel automatic piggybacking.</li> </ul>



## COVID-19 Technical specifications for infusion devices

		<p>Ingress protection not less than IPX2.  Front panel lockout.  Self-check carried out on powering on.  Events stored system – log book.  Pause infusion facility required.  Anti-bolus system to reduce pressure on sudden release of occlusion.  IV set:</p> <ul style="list-style-type: none"> <li>• free-flow protection</li> <li>• air trapping capability</li> <li>• needleless IV connection.</li> </ul> <p>“Dose error” reduction system (preferable).  Drug library software available, including updates (free during warranty).  Air bubble detector with single and cumulative functions (preferable).  Clearly visible optical alarms.  Acoustic alarms not less than 45dB.  Easy set up and operation.  Large easy to read display.  Real-time display.  Availability of a nurse call system connectable to a staff alerting system, 24 V/0.2 A; static or dynamic (preferable).  Compatibility with standard infusion sets commonly distributed in the market (desirable at least by the leading brands).  Equipment provided “ready to use”.  Continuous operation within specification in ambient temperature of at least 5–40 °C, relative humidity of at least 10–90% non-condensing. A limit of 85% relative humidity will be possibly considered as “acceptable” in the current COVID-19 pandemic context.  Any accessory or dedicated device necessary to the proper functioning and utilization of the equipment is included.  Shock-fall protection.</p>
2	Monitored and displayed parameters (colour and graphic preferable)	<p>Flow.  Pressure.  Dose.  Availability of software to monitor the delivery of drugs (preferable).</p>
3	Alarms	<p>Audible alarm required with volume control.  Momentary silence less than 2 min.  Occlusion upstream.  Occlusion downstream.  Air in line.  System malfunction.  Set loaded improperly.  Door open.</p>



## COVID-19 Technical specifications for infusion devices

		<p>Infusion complete. Loss of mains power. Low battery. Depleted battery (preferable). Clinical advisory messages.</p>
4	<p>Consumables, <b>labelled</b> "single use", (included and mentioned in a disaggregated list)</p>	<p>Compatible administration sets: 100. Compatible administration sets microbore and macrobore: 100. Compatible long administration sets both microbore/small and macrobore or long extension sets: 100.</p>
5	<p>Accessories, reusable (included and mentioned in a disaggregated list)</p>	<p>Clamp for mounting pump on IV stand. Clamp for external transportation (preferable) (if applicable).</p>
6	<p>Spare parts (included and mentioned in a disaggregated list)</p>	<p>As per manufacturer. Include calibration software and hardware (kit). Include list of spare parts with their part numbers and costs.</p>
7	<p>Portability</p>	<p>Data port required, at least RS232 and/or USB interface. Log analysis software and updates provided for free during warranty period. Wireless connectivity (preferable). Event log required and recording, 1 week at least of operations. Software upgrade required. Software to diagnose and calibrate the equipment with access to calibration settings.</p>
8	<p>Power supply (voltage, frequency and plug vary across the countries)</p>	<p>Operates from AC mains power: 100–240 V~/50–60 Hz. In-built rechargeable battery. Battery with operating time at least 4 hours at 25 mL/hr. Automatic switch from AC mains power mode to battery operating mode and vice versa. Total re-charging time not greater than 6 hours. Appropriate external device to protect the equipment against over-voltage and over-current line conditions (between plug and socket). 12 V DC socket for recharging during outside transportation (preferable). <b>Equipment must be connected to a reliable and continuous source of energy.</b></p>
9	<p>Documentation (included)</p>	<p>Instruction for use; service manual and product information to be provided in English, at least. Certification of calibration. List of procedures for calibration and routine maintenance.</p>
10	<p>Primary packaging label</p>	<p>Name and/or trademark of the manufacturer. Model or product reference.</p>



## COVID-19 Technical specifications for infusion devices

		Information for particular storage conditions (temperature, pressure, light, humidity).
11	Standards, for the manufacturer	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
12	Regulatory approval/certification	Free sales certificate (FSC) and 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).
13	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) for:  Standards specific for infusion equipment: ISO 8536-8:2004 Infusion equipment for medical use – Part 8: Infusion equipment for use with pressure infusion apparatus. ISO 8536-9:2004 Infusion equipment for medical use – Part 9: Fluid lines for use with pressure infusion equipment. ISO 8536-10:2004 Infusion equipment for medical use – Part 10: Accessories for fluid lines for use with pressure infusion equipment. ISO 8536-11:2004 Infusion equipment for medical use – Part 11: Infusion filters for use with pressure infusion equipment. ISO 8536-12:2007 Infusion equipment for medical use – Part 12: Check valves. IEC 60601-2-24 Ed. 2.0:2012 (b) Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers.  Other general standards for medical equipment: IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1:2000 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
14	Warranty	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 5 years.
		<i>Any variation to be indicated in the offer.</i>



# COVID-19 Technical specifications for infusion devices

## 3.2 Syringe pump

		<b>Syringe pump</b>
	Naming	<b>EMDN nomenclature: syringe pumps (code: Z12030302).</b> <b>Alternative names: infusion pumps, syringe; syringe drivers; drivers, syringe.</b>
1	General technical requirements	<p>Capable of accepting any kind of fluids (as solutions and medicines).</p> <p>Capable of working with the commonly available 20, 50 and 60 mL syringes (with at least the leading brands of syringes).</p> <p>Volumetric flow rate accuracy with dedicated syringes better than +/- 2%, and +/- 5% with common syringes.</p> <p>Maximum pressure generated ≤ 20 psi.</p> <p>Automatic detection of syringe size and proper fixing.</p> <p>Must provide alarm for incorrect loading of syringe.</p> <p>Clearly visible optical alarms.</p> <p>Acoustic alarms not less than 45dB.</p> <p>Anti-bolus system to reduce pressure on sudden release of occlusion.</p> <p>Pause infusion facility required.</p> <p>Self-check carried out on powering on.</p> <p>Event logging system.</p> <p>Capability of recording of dose units, default values, bolus settings, technical values.</p> <p>KVO rate configurable; deactivation possible.</p> <p>Pump based priming feature available to reduce lag time (preferable).</p> <p>“Dose error” reduction system. Allow the user to enter dose rate rather than volume rate.</p> <p>Availability of a medications database with at least 250 medications selectable for download to pump.</p> <p>Easy to clean equipment.</p> <p>Large and easy to read display.</p> <p>Ingress protection not less than IPX2.</p> <p>Nurse call: connectable to a staff alerting system, 24 V/0.2 A.</p> <p>Continuous operation within specification in ambient temperature of at least 5–40 °C, relative humidity of at least 10–85% non-condensing. 90% RH relative humidity (is preferable).</p> <p>Equipment provided “ready to use”.</p> <p>Any accessory or dedicated device necessary to the proper functioning and utilization of the equipment is included.</p> <p>Shock-fall protection.</p>
2	Monitored and controlled parameters (by user)	<p>Control panel.</p> <p>Flow rate programmable range at least from 0.1–200 mL/hr, in steps of 0.1 mL/hr; and at least from 100–1200 mL/hr in steps of 1 mL/hr.</p>



## COVID-19 Technical specifications for infusion devices

	Displayed parameters (colour and graphic preferable)	Flow rate or volume limit to administer at least from 0.1–999.9 mL. Saves last infusion rate even when the AC power is switched off. Bolus rate should be programmable at least in the range from 0.1–1000 mL/hr, with infused volume display. Selectable occlusion pressure trigger levels selectable at least from 300, 500 and 900 mmHg. Availability of software to monitor the delivery of drugs (preferable).
3	Alarms	Comprehensive alarm package required, including at least: <ul style="list-style-type: none"> <li>• occlusion alarm</li> <li>• plunger disengaged</li> <li>• syringe loading error</li> <li>• flow error</li> <li>• syringe unlocked</li> <li>• infusion complete</li> <li>• near/end of infusion pre-alarm/alarm</li> <li>• volume limit pre-alarm and alarm</li> <li>• low battery pre-alarm and alarm</li> <li>• AC power failure.</li> </ul> Maintenance required (preferable).
4	Consumables, <b>labelled “single use”</b> , (included and mentioned in a disaggregated list)	Disposable syringes of different volumes.
5	Accessories, reusable (included and mentioned in a disaggregated list)	Clamp for mounting pump on IV stand. Clamp for out of hospital transport, preferable (if applicable).
6	Spare parts (included and mentioned in a disaggregated list)	As per manufacturer. Include calibration software and hardware. Include list of spare parts with their part numbers and costs.
7	Portability	At least RS232 and/or USB interface for data transmission. Wireless connectivity, preferable.
8	Power supply (voltage, frequency and plug vary across the countries)	Operates from AC mains power: 100–240 V~/50–60 Hz. Built-in rechargeable battery. Automatic switch from AC mains power mode to battery operating mode and vice versa. Internal rechargeable battery having at least 5 hours backup for 10 mL/hr flow rate with 50 mL syringe. Battery-powered alarm for power failure or disconnection. Total battery re-charging time not greater than 6 hours.



## COVID-19 Technical specifications for infusion devices

		<p>12 V DC socket for recharging during outside transportation (preferable). Appropriate external device to protect the equipment against over-voltage and over-current line conditions (between plug and socket). <b>Equipment must be connected to a reliable and continuous source of energy.</b></p>
9	Documentation (included)	Instruction for use; service manual and product information to be provided in English, at least.
10	Primary packaging label	<p>Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).</p>
11	Standards, for the manufacturer	<p>Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).</p>
12	Regulatory approval/certification	<p>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)</p>
13	Standards, for product performance	<p>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): specific to infusion equipment for: ISO 7886-2:1996 Sterile hypodermic syringes for single use – Part 2: Syringes for use with power-driven syringe pumps. ISO 8536-8:2004 Infusion equipment for medical use – Part 8: Infusion equipment for use with pressure infusion apparatus. ISO 8536-9:2004 Infusion equipment for medical use – Part 9: Fluid lines for use with pressure infusion equipment. ISO 8536-10:2004 Infusion equipment for medical use – Part 10: Accessories for fluid lines for use with pressure infusion equipment. ISO 8536-11:2004 Infusion equipment for medical use – Part 11: Infusion filters for use with pressure infusion equipment. ISO 8536-12:2007 Infusion equipment for medical use – Part 12: Check valves. ISO 9626:1991 Stainless steel needle tubing for the manufacture of medical devices.</p> <p>General for medical equipment: IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.</p>



## COVID-19 Technical specifications for infusion devices

		IEC 60601-1-1:2000 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests. IEC 60601-2-24 Ed. 2.0:2012 (b) Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers.
14	Warranty	Minimum 2 years. Availability of accessories, consumables and spare parts for at least 5 years.
		<i>Any variation to be indicated in the offer.</i>

### 3.3 Drop counter

		Drop counter
	Naming	<b>Not specifically classified with EMDN (infusion instruments with code Z120303, and infusion instruments – others with code: Z12030399 are linkable codes). Alternative names: drops monitor; infusion rate monitor.</b>
1	General technical requirements	Capable to monitor the flow rate of IV fluids by monitoring the drops through the drip chamber of a standard IV administration set. Equipment provided already calibrated (if necessary) and “ready to use”. Provided with display for data and settings easy visualization, LCD preferable. Equipment capable to work with most common tubing sets and drips (adult and paediatric). Ingress protection not less than IP22. Continuous operation within specification in ambient temperature of at least 5–40 °C, relative humidity of at least 10–85% non-condensing. 90% relative humidity (preferable). Equipment with adjustable flow rate (mL/hr) and/or drops per minute and/or total volume administered. Treatment time adjustable (preferable).
2	Monitored and controlled parameters (by user)  Displayed parameters (colour and graphic preferable)	At least the following parameters can be displayed: <ul style="list-style-type: none"> <li>• calculated flow rate</li> <li>• fluid volume</li> <li>• drops per minute</li> <li>• treatment time (preferable).</li> </ul>
3	Alarms	At least the following video and/or audio alarms available:



## COVID-19 Technical specifications for infusion devices

		<ul style="list-style-type: none"> <li>• battery low</li> <li>• flow rate and/or volume and/or drops per minute set values has been reached</li> <li>• set rate changes (preferable)</li> <li>• empty bag/bottle (preferable).</li> </ul>
4	Consumables, <b>labelled “single use”</b> , (included and mentioned in a disaggregated list)	Intravenous compatible tubing set for both adult and paediatric: quantity to be defined.
5	Accessories, reusable (included and mentioned in a disaggregated list)	As per manufacturer proposal.
6	Spare parts (included and mentioned in a disaggregated list)	As per manufacturer proposal. Include calibration software and hardware, if applicable Include list of spare parts with their part numbers and costs.
7	Portability	N/A
8	Power supply (voltage, frequency and plug vary across the countries)	Operates with built-in rechargeable battery and/or AC mains power: 100–240 V~/50–60 Hz. Automatic switch from AC mains power mode to battery operating mode and vice versa (if applicable). Internal rechargeable battery with at least 24 hours working time. Battery charger provided. Built-in battery charger (preferable). Low battery alarm available.
9	Documentation (included)	Instruction for use; service manual and product information to be provided in English, at least.
10	Primary packaging label	Name and/or trademark of the manufacturer. Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
11	Standards, for the manufacturer	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
12	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)



## COVID-19 Technical specifications for infusion devices

13	Standards, for product performance	<p>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) for:</p> <p>General medical equipment:</p> <p>IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance or ANSI/AAMI ES60601-1:2005+A2 (R2012) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.</p> <p>IEC 60601-1-1:2000 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems.</p> <p>IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.</p>
14	Warranty	<p>Minimum 2 years.</p> <p>Availability of accessories, consumables and spare parts for at least 5 years.</p> <p><i>Any variation to be indicated in the offer.</i></p>

### 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/>
- Revision and comments from WHO experts ad hoc panel (WHO consultants: Gabriela Jimenez Moyao, Francesco Ribolzi) and clinical engineers and other experts ad hoc panel (Riad Farah, Bill Gentles).
- All members of both 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 for Medical Devices and In Vitro Diagnostics, WHO.

### References and resources

ECRI (2013). Evaluation & Guidance – Infusion pump integration: why is it needed, and what are the challenges? 1 July 2013



## COVID-19 Technical specifications for infusion devices

([https://www.ecri.org/components/HDJournal/Pages/hd201307guid\\_InfusionPumpIntegration.aspx?tab=1](https://www.ecri.org/components/HDJournal/Pages/hd201307guid_InfusionPumpIntegration.aspx?tab=1), accessed 27 June 2020).

ECRI (2014). Evaluation & Guidance – Four key questions about syringe infusion pumps. 16 July 2014 (<https://www.ecri.org/components/HDJournal/Pages/Four-Key-Questions-about-Syringe-Infusion-Pumps.aspx>, accessed 27 June 2020).

ECRI (2015). Evaluation & Guidance – Dose error reduction systems: features and functions. 4 April 2014, updated 25 February 2015 (<https://www.ecri.org/components/HDJournal/Pages/Dose-Error-Reduction-Systems-Features-and-Functions.aspx?tab=1>, accessed 27 June 2020).

ECRI (2018). Product Comparison – Infusion pumps, large-volume. 1 July 2018 (<https://www.ecri.org/components/HPCS/Pages/Infusion-Pumps,-Large-Volume.aspx>, accessed 27 June 2020).

ECRI (2020a). Evaluation & Guidance – Evaluation background: large-volume infusion pumps. 3 February 2016, updated 23 April 2020 (<https://www.ecri.org/components/HDJournal/Pages/Eval-Background-Large-Volume-Infusion-Pumps.aspx>, accessed 27 June 2020).

ECRI (2020b). Evaluation & Guidance – Evaluation background: infusion pump quality analytics software and services. 4 May 2016, updated 18 March 2020 (<https://www.ecri.org/components/HDJournal/Pages/Eval-Background-Infusion-Pump-Quality-Analytics.aspx>, accessed 27 June 2020).

ECRI (2020c). Evaluation & Guidance – Infusion pumps: the essentials. 25 February 2015, updated 18 May 2020 ([https://www.ecri.org/components/HDJournal/Pages/Infusion\\_Pumps\\_The\\_Essentials.aspx](https://www.ecri.org/components/HDJournal/Pages/Infusion_Pumps_The_Essentials.aspx), accessed 27 June 2020).

IEC 60529:1989 – Degrees of protection provided by enclosures (IP code) ([https://www.iecee.org/dyn/www/f?p=106:49:0:::FSP\\_STD\\_ID:2447](https://www.iecee.org/dyn/www/f?p=106:49:0:::FSP_STD_ID:2447), accessed 27 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). Technical Specification for Medical Devices [website]. Geneva: World Health Organization; 2020 ([https://www.who.int/medical\\_devices/management\\_use/mde\\_tech\\_spec/en/](https://www.who.int/medical_devices/management_use/mde_tech_spec/en/), accessed 27 June 2020).