

# Interim Guidance

## Interim Quality Assurance Requirements for the Procurement of COVID-19 Medical Devices

Approved on: 25 June 2021 | Date updated: 27 October 2021

### Objective

1. This document provides operational guidance on the Board Decisions on Additional Support for Country Responses to COVID-19 and the Global Fund COVID-19 Response Mechanism (C19RM)<sup>1</sup> as it relates to new Quality Assurance (QA) Requirements to be applied for procuring COVID-19 Medical Devices with Global Fund resources.
2. For the purpose of this Interim Guidance, COVID-19 Medical Devices are defined as medical devices listed in Annex 1, procured with Global Fund resources and used as part of a country's COVID-19 response.
3. The Quality Assurance requirements stated in this Interim Guidance are not applicable to Medical Devices which are covered by other QA requirements outlined in any Global Fund Quality Assurance Policy or in the Guide to Global Fund Policies on Procurement and Supply Management of Health (e.g., condoms and Core personal protective equipment).

### Clinical Standards

4. All COVID-19 Medical Devices are to be consistent with current national or institutional standard treatment guidelines or with the World Health Organization (WHO) treatment guidelines or guidance or information notes released by the Global Fund.
5. Considering new, emerging evidence and rapidly evolving recommendations, it is imperative that Recipients<sup>2</sup> regularly refer to the latest WHO guidance documents.<sup>3</sup>

<sup>1</sup> Decision GF/B42/EDP11 as extended by GF/B43/EDP12 and Decision GF/B44/EDP18

<sup>2</sup> The term "Recipient" used in this Interim Guidance includes in particular Principal Recipients, grantees, sub-recipients, sub-sub-recipients and procurement service agents.

<sup>3</sup> Available at <https://www.who.int/news-room/feature-stories/detail/a-guide-to-who-s-guidance>

# Quality Assurance Requirements

## Risk Classification

6. For the purpose of this Interim Guidance, COVID-19 Medical Devices are classified per the Globally harmonized principles of the Medical Device Classification<sup>4</sup> consisting of four classes, where Class A represents the lowest hazard and Class D the highest, as follows:

Class	Level	Device examples*
A	Low Hazard	Laryngoscope Oxygen mask
B	Low-moderate	Thermometer Electrocardiograph Oxygen Bottle/Cylinder Pulse oximeter, without alarm, cables & sensor Oxygen Concentrator <u>not</u> being used in a potentially hazardous situation (e.g., ICU) Oxygen generator (PSA or VPSA Technology) when <u>not</u> connected to an active device (e.g., patient-interactive ventilator or respirator)
C	Moderate-high Hazard	Patient ventilator Infusion Pump Pulse oximeter, with alarm or with cables & sensor Pulse oximeter probes Oxygen concentrator being used in a potentially hazardous situation (e.g., ICU) Oxygen generator (PSA or VPSA Technology) when connected to an active device (e.g., patient-interactive ventilator or respirator)
D	High Hazard	None identified to date

\* This table is for orientation purposes. Please refer to Annex 1 for more information.

<sup>4</sup> See <http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf>

## **Requirements for All Classes of COVID-19 Medical Devices**

7. All COVID-19 Medical Devices procured with Global Fund resources need to comply with the relevant quality standards that are established by the National Regulatory Authority (NRA) in the country of use and have been authorized for use by the same NRA in accordance with its standard practices for registration or other forms of authorization.

## **Specific Requirements for COVID-19 Medical Devices of Higher Risk**

8. Global Fund resources may only be used to procure COVID-19 Medical Devices for class C and Class D that meet either one of the following standards, such as:
  - Prequalified by the World Health Organization (WHO) Prequalification Programme;
  - Authorized for use by one of the Regulatory Authorities of the Founding Members of the Global Harmonization Task Force (GHTF)<sup>5</sup>: or
  - Recommended for use by the Expert Review Panel.

## **Recognition of the Emergency Situation and Related Emergency Procedures**

9. The Global Fund retains the WHO definition of Public Health Emergency of International Concern (PHEIC), as defined in the International Health regulation (IHR). It relies on WHO's emergency processes and those of Stringent Regulatory Authorities (as defined in the Global Fund QA Policies)<sup>6</sup> during a PHEIC. This ensures efficient support to country efforts in facing serious public health emergencies while maintaining an adequate level of assurance on the quality, safety and efficacy of the COVID-19 Medical Devices procured with Global Fund resources.
10. In addition to Section 7 above, COVID-19 Medical Devices eligible for procurement using Global Fund resources may be:
  - Products approved pursuant to the WHO Emergency Use Listing (EUL) procedures; and/or
  - Products approved pursuant to any other emergency procedure set up by one of the Regulatory Authorities of the Founding Members of the GHTF.<sup>7</sup>

## **Procuring COVID-19 Medical Devices Reviewed by Expert Review Panel**

11. Before procuring COVID-19 Medical Devices that have been subject to a review by the Expert Review Panel, the Recipient shall inform the Global Fund in writing by submitting a duly completed notification form<sup>8</sup>. Procurement of products examined by the Expert Review Panel can only proceed after the Recipient receives a "no objection"

<sup>5</sup> Namely the regulatory authorities of the United States, the European Union, Japan, Canada and Australia. See [https://www.theglobalfund.org/media/5885/psm\\_qadiagnostics\\_policy\\_en.pdf](https://www.theglobalfund.org/media/5885/psm_qadiagnostics_policy_en.pdf)

<sup>6</sup> See the QA Policy for Diagnostics Products: [https://www.theglobalfund.org/media/5885/psm\\_qadiagnostics\\_policy\\_en.pdf](https://www.theglobalfund.org/media/5885/psm_qadiagnostics_policy_en.pdf)

<sup>7</sup> Namely the regulatory authorities of the United States, the European Union, Japan, Canada and Australia. See [https://www.theglobalfund.org/media/5885/psm\\_qadiagnostics\\_policy\\_en.pdf](https://www.theglobalfund.org/media/5885/psm_qadiagnostics_policy_en.pdf)

<sup>8</sup> After any products are approved through an ERP process, a Notification Form for the Procurement of ERPD COVID-19 Medical Devices will be made available at <https://www.theglobalfund.org/en/covid-19/health-product-supply/quality-assurance/>.

letter from the Global Fund's Quality Assurance Team for the requested selection, and the relevant procurement contract shall not exceed twelve months.

## **Operationalization**

### **Conditions Applied to the Duration of the Decision**

12. This Interim Guidance is applicable until 31 December 2023 per the Global Fund Board decision<sup>9</sup>, unless modified or extended by the Board.

### **Listing of Eligible COVID-19 Medical Devices**

13. The Global Fund Secretariat's Quality Assurance (QA) Team will examine the decisions of the various Regulatory Authorities in accordance with the QA requirements stated herein and will identify the Medical Devices which satisfy the above-mentioned requirements.
14. Based on the above, a non-exhaustive lists list of eligible COVID 19 Medical Devices which can be procured with Global Fund resources will be published and regularly updated on Global Fund website for orientation purposes:
  - COVID-19 page: <https://www.theglobalfund.org/en/covid-19/>
  - Quality Assurance page: <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/>

### **National Registration**

15. To facilitate implementation of on this Interim Guidance, National Regulatory Authorities are encouraged to take benefit of the WHO Collaborative Procedure between the WHO Prequalification of Medicines Programme and National Regulatory Authorities in the assessment and accelerated National Registration of WHO-prequalified medical devices.<sup>10</sup>

### **Market Surveillance and Control**

16. In close collaboration with the relevant National Regulatory Authority, Recipients shall ensure adequate surveillance of the compliance of COVID-19 Medical Devices with QA requirements throughout the supply chain in line with relevant WHO or Founding Members of GHTF guidelines on Post-Market Surveillance.<sup>11</sup>
17. The surveillance activities should be concentrated where risks are likely to be higher or noncompliance more frequent and implemented following a detailed surveillance plan. Recipients may request the Global Fund to include the cost of conducting market control activities in the budget.

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<sup>9</sup> GF/B44/EDP18

<sup>10</sup> More information available at <https://extranet.who.int/pqweb/medicines/collaborative-registration-faster-registration>

<sup>11</sup> Until such guidance becomes available from WHO or others, in the interim, further guidance may be provided and published on Global Fund webpages.

## **Safety and Vigilance**

18. The Global Fund would like to emphasize the critical need for timely collection of safety information on medical devices used under emergency access situations, despite the difficulties that the emergency situation might present, in order to inform public health decisions and ensure patients' safety.
19. Recipients shall develop and maintain a system acceptable to the Global Fund for reporting to the appropriate regulatory authorities any defects or safety information relating to COVID-19 Medical Devices and for facilitating communications with manufacturers, procurement agents, distributors and end-users in the event of defects.<sup>12</sup>

## **Transitional Arrangements**

20. It is expected that any Emergency procedures put in place by the various Stringent Regulatory Authorities will become obsolete as the registration process returns to normal, (non-emergency) mode. The implementation of the above quality assurance requirements related to the emergency procedures will cease when COVID-19 Medical Devices become eligible for procurement following the standard Global Fund QA requirements stated above in order to satisfy country needs.

## **Global Fund Quality Assurance Team Support**

21. The Global Fund Secretariat's QA Team remains available to provide support to facilitate interpretation of such policy decisions and provide advice on QA-related matters. Recipients should send queries to the QA Team through their Global Fund Country Team.

## **Derogations Implied within Emergency Procedures**

22. It is acknowledged that decisions taken within the framework of the various emergency procedures are not based on harmonized requirements for quality and performance at the international level. This may lead to differences in the level of assurance provided by different Stringent Regulatory Authorities. However, this risk is inherent to the current global regulatory arrangements.

## **Registration within the Price and Quality Reporting (PQR) Tool**

23. Recipients are required to report procurement transactions of COVID-19 Medical Devices of class C and Class D in the Price and Quality Reporting (PQR) system.

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<sup>12</sup> Guidance is available from the GHTF through the International Medical Device Regulators Forum; see <http://www.imdrf.org/documents/doc-ghtf-sq2.asp>.

## Annex 1: List of COVID-19 Medical Devices

The table below, which matches the Health Product Management Template, lists the products for which these Interim QA Requirements are applicable.

Logistics Cost Category	Category	International Non-proprietary Name	Specification	Class
Medical Oxygen Liquid & Gas	Medical Oxygen - liquid oxygen	Medical gas cylinder, portable	Compressed oxygen or compressed medical air, with valves and regulators.	B
Medical Oxygen Liquid & Gas	Medical Oxygen - liquid oxygen	Oxygen plant	Pressure Swing Adsorption (PSA) Oxygen Generator Plants	B/C <sup>1</sup>
Medical Oxygen Liquid & Gas	Medical Oxygen - liquid oxygen	Oxygen plant	Spare parts and accessories	N/A
Medical Oxygen Liquid & Gas	Medical Oxygen - liquid oxygen	Oxygen plant	Warranty, maintenance and service	N/A
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Airway	Nasopharyngeal airway	A/B <sup>2</sup>
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Airway	Oropharyngeal airway, Guedel, sterile, single-use	A/B <sup>2</sup>
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	CO2 detector	Colorimetric end tidal CO2 detector	A
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Cricothyrotomy	Set, emergency, 6 mm, sterile, single use	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Endotracheal tube	Endotracheal tube (specify in comments with cuff, without cuff)	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Endotracheal tube	Endotracheal tube introducer (specify in comments Bougie or Stylet)	A
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Flow splitter	Flow splitter, for oxygen concentrator, 5 flowmeters, range 0.125 – 2 l/m	B

<sup>1</sup> Class B unless connected to an active device (e.g., patient-interactive ventilator or respirator), in which case Class C.

<sup>2</sup> Classification depends on duration of use. Class A <60mins, Class B >60mins.

<b>Logistics Cost Category</b>	<b>Category</b>	<b>International Non-proprietary Name</b>	<b>Specification</b>	<b>Class</b>
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Flowmeter, medical O2, Gas Cylinder	Thorpe tube, pressure-compensated, with pressure regulator & pressure-reducing valve, Barbed green "Christmas tree" connector to connect to tubing/patient delivery device	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Flowmeter, medical O2, Gas Cylinder	Thorpe tube, pressure-compensated, with pressure regulator & pressure-reducing valve, DISS female/male connector (or other) & adapter to connect with humidifier	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Flowmeter, medical O2, Gas Cylinder	Thorpe tube, pressure-compensated, with pressure regulator & pressure-reducing valve, DISS female/male connector (or other) & adapter to connect with regulator	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Flowmeter, medical O2, Terminal (wall) Unit	Thorpe tube, pressure-compensated, with pressure regulator, Barbed green "Christmas tree" connector to connect to tubing/patient delivery device	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Flowmeter, medical O2, Terminal (wall) Unit	Thorpe tube, pressure-compensated, with pressure regulator, DISS female/male connector (or other) & adapter to connect with humidifier	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Flowmeter, medical O2, Terminal (wall) Unit	Thorpe tube, pressure-compensated, with pressure regulator, DISS female/male connector (or other) & adapter to connect with regulator	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Humidifier	Humidifier, non-heated, reusable	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Infusion giving set	Infusion giving sets for adult and pediatric use with IV catheters and scalp vein sets (all size)	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Laryngoscope	Laryngoscope – adult/child	A

<b>Logistics Cost Category</b>	<b>Category</b>	<b>International Non-proprietary Name</b>	<b>Specification</b>	<b>Class</b>
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Laryngoscope	Laryngoscope – neonate	A
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Nasal Cannula	High flow with tubing & patient interfaces, with accessories	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Nasal Catheter	High flow with tubing & adapters, lubricated, non-sterile	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Nasal prong	Prongs, nasal, Oxygen, adult, single use	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Nasal prong	Prongs, nasal, Oxygen, child, single use	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Nasal prong	Prongs, nasal, Oxygen, neonate, single use	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Other	Other - Enter details in Comments	N/A
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Oxygen mask	Oxygen mask with connection tube, reservoir bag and value, adult, single use	A
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Oxygen mask	Oxygen mask with connection tube, reservoir bag and value, child, single use	A
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Oxygen mask	Venturi mask with percent O2 Lock and tubing, adult	A
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Oxygen mask	Venturi mask with percent O2 Lock and tubing, child	A
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Pulse oximeter probes	Handheld pulse oximeter probes, adult	C
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Pulse oximeter probes	Handheld pulse oximeter probes, neonatal	C
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Pulse oximeter probes	Handheld pulse oximeter probes, pediatric	C



<b>Logistics Cost Category</b>	<b>Category</b>	<b>International Non-proprietary Name</b>	<b>Specification</b>	<b>Class</b>
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Pulse oximeter probes	Tabletop pulse oximeter probes, adult	C
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Pulse oximeter probes	Tabletop pulse oximeter probes, neonatal	C
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Pulse oximeter probes	Tabletop pulse oximeter probes, pediatric	C
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Resuscitator	Resuscitator, adult	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Resuscitator	Resuscitator, child	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Suction device	Suction devices (Electrical recommend)	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Tubing	Oxygen administration tubing, non-sterile	B
COVID Medical Oxygen Consumables	Medical Oxygen - consumables	Tubing	Suction tubing, silicone, non-sterile	B
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	COVID Equipment	Spare parts and accessories	N/A
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	COVID Equipment	Warranty, maintenance and service	N/A
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Mechanical ventilation	Patient ventilator, for critical / intensive care, for adult & paediatric, with breathing circuits & patient interface	C
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Mechanical ventilation	Patient ventilator, for transport, for adult & paediatric, with breathing circuits & patient interface	C
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Non-invasive ventilation	BiPAP, with tubing & patient interfaces, with accessories	B

Logistics Cost Category	Category	International Non-proprietary Name	Specification	Class
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Non-invasive ventilation	CPAP, with tubing and patient interfaces, adult & paediatric, with accessories	B
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Non-invasive ventilation	High-Flow Nasal Cannula (HFNC) Oxygen Therapy Devices	B
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Oxygen analyser	Electrochemical, battery-powered, handheld	N/A <sup>3</sup>
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Oxygen analyser	Ultrasonic, battery-powered, handheld	N/A <sup>3</sup>
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Oxygen concentrator	Oxygen concentrator, portable, with accessories	B/C <sup>4</sup>
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Oxygen concentrator	Oxygen concentrator, stationary/bedside, with accessories	B/C <sup>4</sup>
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Oxygen concentrator	Spare parts and accessories	N/A
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Oxygen concentrator	Warranty, maintenance and service	N/A
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Pulse oximeter	Oxygen saturation monitor, portable fingertip, battery-powered	B/C <sup>5</sup>
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Pulse oximeter	Oxygen saturation monitor, portable handheld, battery-powered, with cables & sensor	C
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Pulse oximeter	Oxygen saturation monitor, tabletop, AC-powered, with cables & sensor	C
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Surge suppressor	Surge protector device, with multiple protected output sockets, hospital grade	N/A
COVID Medical Oxygen Equipment	Medical Oxygen - equipment	Voltage stabilizer	Electronic, microprocessor controlled voltage stabilizer, with voltage monitor	N/A
COVID Supportive Hospital Equipment	Other Health Equipment	Blood Gas Analyser	Portable, with cartridges and control solutions	B

<sup>3</sup> If the Oxygen Analyser is being used to monitor gas supply only, then this would not be considered a medical device.

<sup>4</sup> Class B, unless being used within a potentially hazardous situation (e.g., ICU), in which case would likely be Class C.

<sup>5</sup> Class B, unless incorporating an alarm in which case would be Class C.

<b>Logistics Cost Category</b>	<b>Category</b>	<b>International Non-proprietary Name</b>	<b>Specification</b>	<b>Class</b>
COVID Supportive Hospital Equipment	Other Health Equipment	Electrocardiogram (ECG) digital monitor and recorder	Equipment	B
COVID Supportive Hospital Equipment	Other Health Equipment	Electrocardiogram (ECG) digital monitor and recorder	Spare parts and accessories	N/A
COVID Supportive Hospital Equipment	Other Health Equipment	Electrocardiogram (ECG) digital monitor and recorder	Warranty, maintenance and service	N/A
COVID Supportive Hospital Equipment	Other Health Equipment	Electronic drop counter	Electronic drop counter, IV fluids	C
COVID Supportive Hospital Equipment	Other Health Equipment	Infusion pump	Infusion pump, with accessories	C
COVID Supportive Hospital Equipment	Other Health Equipment	Patient monitor	Patient monitor, multiparametric with EKG/ECG	B
COVID Supportive Hospital Equipment	Other Health Equipment	Patient monitor	Patient monitor, multiparametric without EKG/ECG	B
COVID Supportive Hospital Equipment	Other Health Equipment	Thermometer	Non-contact infrared thermometer	B
COVID Supportive Hospital Equipment	Other Health Equipment	Thermometer	Thermometer, clinical, non-contact, incl bat	B
COVID Supportive Hospital Equipment	Other Health Equipment	Ultrasound	Portable, w/linear and phased array cardiac transducer (5.0-7.5 MHz), w/trolley	B/C <sup>6</sup>
COVID Supportive Hospital Equipment	Other Health Equipment	UPS units	Equipment	N/A
COVID Supportive Hospital Equipment	Other Health Equipment	UPS units	Spare parts and accessories	N/A
COVID Supportive Hospital Equipment	Other Health Equipment	UPS units	Warranty, maintenance and service	N/A
COVID Supportive Hospital Equipment	Other Health Equipment	X-ray: Equipment	Darkroom Automatic X-ray Film processor	C
COVID Supportive Hospital Equipment	Other Health Equipment	X-ray: Equipment	Daylight Automatic X-ray Film Processor	C

<sup>6</sup> Class B if being used in a non-critical diagnostic capacity. Class C if being used in diagnosis in clinical situations where the patient is in immediate danger (e.g., interventional cardiac procedures).

<b>Logistics Cost Category</b>	<b>Category</b>	<b>International Non-proprietary Name</b>	<b>Specification</b>	<b>Class</b>
COVID Supportive Hospital Equipment	Other Health Equipment	X-ray: Equipment	Mobile basic diagnostic x-ray system, analogue	C
COVID Supportive Hospital Equipment	Other Health Equipment	X-ray: Equipment	Mobile basic diagnostic x-ray system, digital	C
COVID Supportive Hospital Equipment	Other Health Equipment	X-ray: Equipment	Mobile flourosopic x-ray system, analogue	C
COVID Supportive Hospital Equipment	Other Health Equipment	X-ray: Equipment	Mobile flourosopic x-ray system, digital	C
COVID Supportive Hospital Equipment	Other Health Equipment	X-ray: Equipment	Other type	C
COVID Supportive Hospital Equipment	Other Health Equipment	X-ray: Equipment	Radiographic film view box, non-powered	N/A
COVID Supportive Hospital Equipment	Other Health Equipment	X-ray: Equipment	Spare parts and accessories	N/A
COVID Supportive Hospital Equipment	Other Health Equipment	X-ray: Equipment	Warranty, maintenance and service	N/A