Technical specifications gynaecological examination/treatment table

1 Scope of chapter

This chapter specifies technical requirements for gynaecological tables, devices used by physicians in obstetrical and/or gynaecological examinations and treatments for the early detection and treatment of a range of gynaecologic conditions.

Content herein focuses on present state of practice using up-to-date available technologies; however, authors are aware that innovations in manufacturing, healthcare facilities and practice will advance the field of cervical cancer
screening, diagnostics and treatment. The specifications herein do not preclude appropriate upcoming products and/or technologies, which will be analysed in future revisions of this publication.

Brief description
A gynaecological table is a table used in hospitals, clinics and medical practices, where a female patient can lay down and the medical practitioner/hospital doctor can perform gynaecological, obstetrical and urological examinations and treatments. It allows the examiner to have an effective view on the vagina and urethra of the female patient while examining or operating, with a minor discomfort for the patient herself, thanks to the different allowed configurations and accessories.

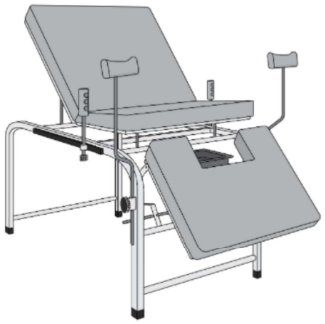
2 Background on Gynaecological examination / treatment table

As specified in guidance provided in WHO's Comprehensive Cervical Cancer Control: a guide to essential practice [1], cervical cancer screening and treatment require a list of equipment and supplies, including an examination table covered by clean paper or cloth.
A gynecological examination or treatment table is a specialized piece of medical equipment used in the diagnosis and treatment of cervical cancer. This table provides a comfortable and secure platform for patients to undergo various gynecological procedures, including pelvic exams, Pap tests, and colposcopies. During these procedures, the patient lies down on the table with her legs supported in stirrups, allowing the healthcare provider to access the cervix and vagina for examination and treatment. The gynecological examination table is an essential tool in the detection and management of cervical cancer, as it enables healthcare providers to detect abnormalities early and provide timely interventions to improve patient outcomes.

3 Types of Gynaecological examination / treatment tables

The main types of gynaecological examination / treatment tables are mechanical tables and electric/hydraulic tables.
Mechanical tables are generally less expensive, more durable, and easier to maintain. They don't require a power source and can be used in areas where electricity is limited or not available. They are also quieter and may provide a more stable platform for certain procedures. However, mechanical tables can be harder to adjust and may require more physical effort to position patients, which can be challenging for those with limited mobility or larger body size.
On the other hand, electric tables provide more flexibility and easier adjustments. They can be raised, lowered, and tilted with the push of a button, making them ideal for patients with mobility issues or those who require frequent position changes during a procedure. They also tend to be more comfortable for patients and can

provide better access for healthcare providers. However, electric tables are typically more expensive, may require more maintenance, and may not function during power outages.

Type	**Mechanical table**[1]	**AC-Powered or hydraulic table**
Image		
Brief description	Gynaecological examination and delivery table, 2/3 sections Mounted on 4 sturdy supports, all finished with height adjustable feet All sections fitted with non-removable padded upholstery Robust mechanics allow for manual repositioning of all sections between gynaecological and obstetric use.	Electrically-powered chair, which provides a plurality of functions for both gynaecological and obstetric procedures. 2/3 sections, completely electrically controlled: height, seat, back section.
Advantages	- Portable - Availability of different accessories - Less expensive - More durable - Easier to maintain	- Portable - Availability of different accessories - Easier adjustments
Limitations	- Harder to adjust	- Require electrical power - More expensive - Require more maintenance

4 Equipment requirements

The following paragraphs describe elements of a gynaecological table and considerations to be made in device selection.

Dimensions: it is important to consider the overall dimension of the table, in particular the space that is filled when it is set in all its different positions and configurations and the extent of the movements to be made to achieve those positions.

[1] https://supply.unicef.org/s0002174.html

Portability: According to the intended use of the table, meaning both for examination and treatment or only examination or only treatment, the number of sections of which the table is comprised is worth considering and whether the table should be portable or not.

Multiple positions: The table should have a variety of positions (e.g. lithotomy, Trendelenburg, etc.) to accommodate different procedures.

Power source: the feasibility of a power source availability (220V or 120V, and 50 or 60 Hz, according to different national standards) accessible in the examination room or facility to allow for use and/or charging, if the table has electric features. A table can also operate with a hydraulic pump and is generally operated by means of a pedal. There are also tables that integrate both types of drive. Therefore, there is the need to check for the availability of electrical and/or hydraulic source.

Materials: most of the tables have a frame made of stainless steel, which is biocompatible, easy to clean and to manage. Moreover, the table should have a smooth, non-porous surface that is easy to clean and disinfect.

Compatible accessories: the table should be compatible with all the accessories needed during surgery, treatment or examination, such as leg rests, IV rod, etc.

Patient safety: it is important to consider the antibacterial, antifungal and fireproof properties of the materials in which the table is made. The maximum load that the table is able to withstand and its width are two other important selection criteria, in particular to avoid the risk of sagging of the table and falling of the patient if the latter suffers from obesity.

5 Operational considerations

Installation and commissioning

1. Choosing the right location: The first step is to choose an appropriate location for the table. It should be in a spacious room with sufficient lighting and ventilation. For electric/hydraulic tables the room should also be equipped with power outlets and plumbing connections.
2. Assembling the table: Before installation, ensure that all the parts of the table are available, and assemble it according to the manufacturer's instructions. This may require the use of specialized tools.
3. Positioning the table: Once the table is assembled, it shall be positioned in the room in such a way that it allows easy access for both the healthcare provider and the patient.
4. Connecting the plumbing and power supply: for electric/hydraulic tables the plumbing and power supply shall be connected to the table, and ensure that they are working properly.
5. Testing the table: Once the table is installed, all its functions shall be tested to ensure that it's working correctly. Check the height adjustment, tilting, and locking mechanisms, as well as any other features that the table may have.
6. Train the staff: Before commissioning the table for use, the healthcare staff shall be trained on how to use it safely and effectively. This includes how to position the patient, adjust the table, and clean it after use.

It's important to follow the manufacturer's guidelines for the safe use and maintenance of the table. This will help to ensure that it lasts longer and remains safe for use by patients.

Regular maintenance of the table is crucial for its optimal performance and longevity. This includes cleaning and disinfecting the table after each use, lubricating moving parts, and replacing worn-out components as needed.

Use instructions

Specific instructions for use shall be available from the manufacturer for each model, however following are some typical use instructions for Gynaecological examination / treatment tables:

- Positioning the patient: The patient should be positioned comfortably on the table, with their legs in stirrups and their buttocks close to the edge of the table.
- Adjusting the height: The healthcare provider should adjust the height of the table to a comfortable working height.
- Tilting the table: The table can be tilted to different angles, depending on the procedure being performed. For example, the table may be tilted slightly downwards for a Pap smear or tilted slightly upwards for a vaginal exam.
- Using the footrests: The patient's feet should be placed in the footrests, which can be adjusted to a comfortable height and angle.
- Adjusting the backrest: The backrest of the table can be adjusted to different angles, depending on the patient's comfort and the procedure being performed.
- Using the stirrups: The stirrups should be adjusted to a comfortable height and angle, so that the patient's legs are supported and the healthcare provider has easy access to the vaginal area.
- Using the lights: The table may be equipped with overhead lights or task lights to provide sufficient illumination for the procedure.
- Using the drawers: The table may have drawers for storing equipment and supplies needed for the procedure.
- Cleaning the table: After use, the table should be cleaned and disinfected according to the manufacturer's guidelines to prevent the spread of infections.

Decontamination and reprocessing

Health care-associated infections (HAI) are one of the most common adverse events in healthcare delivery. Not only do they have a significant impact on morbidity and mortality, but they also present an economic burden to health care facilities and countries. As part of a larger infection prevention and control (IPC) program [2], decontamination of instruments and medical devices plays a critical role in HAI prevention.

The PAHO/WHO manual titled *Decontamination and reprocessing of medical devices for health-care facilities* [3] outlines the decontamination life cycle, which includes cleaning, disinfection and sterilization. Please refer to this manual for details on specific methods of decontamination, sterilization and reprocessing of medical devices. Always follow the device manufacturer’s instructions for decontamination so as to not cause any damage and ensure proper decontamination.

Specific to gynaecologic / obstetric tables, it is important to not use harsh or corrosive cleaning agents on any part of the device as they can cause damage to the surface; use approved disinfectant and cleaning agents. The following steps should be followed:

- Clean the table: Clean the table with a mild detergent and warm water, using a soft cloth or sponge. Pay special attention to the areas where bodily fluids may have been deposited, such as the stirrups, footrests, and table surface.
- Rinse the table: Rinse the table thoroughly with clean water to remove any residual detergent.
- Disinfect the table: Disinfect the table with a suitable disinfectant that is approved for use on medical equipment. Follow the manufacturer's instructions for the correct concentration, contact time, and method of application.
- Let the disinfectant sit: Allow the disinfectant to sit on the table surface for the recommended contact time to ensure maximum effectiveness.
- Rinse and dry the table: Rinse the table thoroughly with clean water to remove any residual disinfectant. Wipe the table dry with a clean cloth or allow it to air-dry.

- Check for damage: Inspect the table for any signs of damage, such as cracks or tears in the upholstery, loose bolts or screws, or damaged electrical components.
- Store the table: Store the table in a clean, dry, and well-ventilated area, away from sources of moisture or direct sunlight.

Health-care waste management

Knowledge about the potential for harm due to healthcare waste has become more important to governments, health care workers and civil society. Improper handling and disposal of healthcare facility waste is widely recognized as a source of avoidable infection; therefore, it is critical for healthcare facilities to appropriately manage disposal of healthcare waste, including but not limited to hazardous waste. Hazardous waste includes sharps, infectious waste (contaminated with blood and other body fluids), pathological waste (such as human tissue) and chemical waste. For details on how to dispose of hazardous waste, please refer to facility and/or local guidelines and regulations and the WHO manual titled Safe management of wastes from health-care activities. [4]

Any consumables (swabs, cotton balls, gloves) should be disposed of using the appropriate protocols for the health facility.

Storage and packaging

Labelling on the primary packaging should include the name and/or trademark of the manufacturer and should adhere to the most current version *of ISO 15223 – 1: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*. Depending on the country, specific requirements for the information to be provided on the label may exist, such as the requirement for specific languages, warnings and regulatory conformity symbols.

As a minimum, the storage area should be clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof. The device should be stored in its original packaging in a storage cabinet.

In recognizing that environmental conditions in many LRS are quite varied and can be extreme, it is the responsibility of the procurement body to ensure the expected storage conditions are within the manufacturer's storage recommendations for any specific device. If the device will require that the storage environment be climate-controlled, appropriate temperature and humidity control systems, including monitoring, should be applied to avoid malfunctioning.

However, in general, these devices should be able to withstand storage temperatures ranging from 15°C to 40°C, relative humidity ≤ 85% (non-condensing), and be protected from dripping water.

Maintenance and repair

Before each use of the table, the operator needs to check the overall status of the device, through visual inspection and check of any mechanical damage.

Lubrication of all the mechanical joints/pins / moving parts / tightening of the bolts should be carried out at least once in three months, to avoid unnecessary sound and wear and tear of the tables.

If a device appears damaged or does not function as expected, it should immediately be taken out of service for repair or replacement.

6 Quality Management Systems and post-market surveillance

A quality management system delineates a systematic approach to ensure ongoing quality of outputs. It is critical that all products are manufactured within a robust quality management system at the manufacturer. A QMS includes but is not limited to: standard operating procedures, documentation, design and manufacturing controls and third-party assessments. Maintenance of a QMS requires appropriate human resources and their

management, infrastructure, timely and appropriate procurement, stock management, maintenance, and a rigorous pre- and in-service training curriculum.

Post-market surveillance is an obligation of the medical device manufacturer in order to investigate and act on any adverse event and product failure and/or error. One of the most relevant sources of information to the post-market surveillance plan are the complaints made by end-users when an issue is detected. The manufacturer should conduct a root cause analysis and determine whether the risk/benefit ratio is maintained. In addition, sometime there are malfunctions or a deterioration in the characteristics and/or performance of the device that might lead to or might have led to the death. These situations are called incidents and the manufacturer must report them to the competent authorities as per vigilance reporting systems. The field safety corrective actions, such as a recall or changes implemented to the product (including labelling), are notified by the manufacturer through a field safety notice to the National regulatory agencies / authorities (NRA), which will also conduct their own market surveillance activities and oversee the manufacturer's investigation incidents and complaints. WHO guidance on QMS and post-market surveillance for medical devices can be found in WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices.[5]

7 Standards and regulatory compliance

- Medical device quality, performance, operations, and safety: ISO 13485, ISO 14971, ISO 15223-1;
- Biocompatibility: ISO 10993, all applicable parts;
- Electrical safety: IEC 60601, all applicable parts.
- IEC 60601-2-46 Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables*
- IEC 60601-2-52 Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds*

*Note: There is no specific standard for gynaecological tables but some requirements of the technical standards for medical beds and operating tables may apply .

It is important to observe all applicable national laws and regulations related to medical devices manufacturing, procurement and/or use. In the absence of a medical devices' regulatory agency, it is strongly recommended to consider which regulatory and/or normative body assessment was completed for each product prior to making a procurement decision. The risk class depends mainly on the regulatory framework of a country and therefore it may differ according to jurisdiction.

8 Key tender/request for quotation specifications for a Gynaecological examination / treatment table

Product description	An obstetric table is a device with adjustable sections designed to support a patient in the various positions required during obstetric and gynaecologic procedures during examination / treatment / birth / labour.
Key product features	Minimum overall table dimensions: 1.8m long x 0.6m wide. The top of the bed is preferable to be in 3 sections, in each section is fixed a mattress. These 3 sections are separable and allow separate movements. Overall height is adjustable for ease of user access and the leg section is removable when necessary.

	Can operate mechanically or powered.
Components, accessories, consumables	Armrest Leg slings with support Stainless-steel bowl IV pole
Operational requirements	Operating temperature/humidity: 10°C to 40°C, 15%-90% Storage temperature/humidity: 0°C to 50°C, 15%-90% Ingress protection rating: IPX6 The unit is suggested to be connected to a reliable power source and/or hydraulic pump. Electrical source requirements (based on country/setting of use): » Amperage: _____ » Voltage: _____ » Plug type: _____.
Documentation requirements	Instructions for use and service manual to be provided. User language preference prioritized, otherwise English is mandatory.
Warranty	Minimum one year.
Applicable standards	Following the active version of the standards below (or equivalent): • ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes; • ISO 14971: Medical Devices - Application of Risk Management to Medical Devices; • ISO 15223-1: Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements. • ISO 20417: Medical devices — Information to be supplied by the manufacturer. Safety & product standards: • IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; • IEC 60601-1-2: Medical electrical equipment - Part 1-2 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. • ISO 10993-1: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.
Regulations	Compliance with (where applicable, but not limited to): • National regulatory Authority requirements compliance; • Approval by regulatory body of country of manufacturer (if applicable). • Suggested, compliance with the legal requirements from at least one of the following

	• regulatory frameworks: ○ United States regulations: US FDA Device Class I; ○ European regulatory framework: ▪ Council Directive 93/42/EEC of 14 June 1993 on Medical Devices, class I; ▪ Regulation (EU) 2017/745 of the European Parliament and the Council, class I. ○ Other regulatory body in an IMDRF founding member country such as Australia, Canada, or Japan.

9 Chapter references

[1] World Health Organization (2014). Comprehensive cervical cancer control: a guide to essential practice, 2nd ed. World Health Organization. http://www.who.int/iris/handle/10665/144785.

[2] IPC is a scientific approach encompassing epidemiology, social science and health system strengthening to provide a comprehensive approach to infection prevention control. The WHO has comprehensive guidelines on core components of IPC programmes: https://www.who.int/gpsc/core-components.pdf.

[3] World Health Organization and Pan American Health Organization (2016). Decontamination and Reprocessing of Medical Devices for Health-care Facilities. https://www.who.int/infection-prevention/publications/decontamination/en.

[4] World Health Organization (2014). Safe management of wastes from health-care activities, 2nd ed. https://www.who.int/water_sanitation_health/publications/wastemanag/en/.

[5] World Health Organization (2017). WHO Global Model Regulatory Framework for Medical Devices including In Vitro Diagnostics (IVDs). http://apps.who.int/medicinedocs/en/d/Js23213en.

[6] WHO technical specifications for 61 medical devices (2014): https://www.who.int/publications/m/item/who-technical-specifications-for-61-medical-devices

10 Technical specifications for Gynaecological examination / treatment tables

MEDICAL DEVICE SPECIFICATION (including information on the following where relevant/appropriate, but not limited to)		
I	Version no.	1
II	Date of initial version	March 2023
III	Date of last modification	
IV	Date of publication	
V	Completed / submitted by	WHO
Name, category and coding		
1	WHO Category / Code	Gynaecological examination / treatment table
2	Generic name	Gynaecological examination / treatment table
10	Alternative name/s (optional)	Table, obstetric (and accessory); Table, obstetrical, AC-powered (and accessory); Birthing table
11	Alternative code/s (optional)	
12	Keywords (optional)	Gynaecology table, delivery, labour, maternity, gynaecological

		examination
Purpose of use		
14	Clinical or other purpose	Designed to support a woman's body in an appropriate position during labour and delivery and in other examination/treatment procedures
15	Level of use (if relevant)	Clinic, health centre, (district) hospital, specialized clinic
16	Clinical department / ward (if relevant)	Gynaecology; outpatient clinic; oncology; obstetrics; surgery; nursing services
17	Overview of functional requirements	Supports patient during labour and delivery. Support patient during gynaecological examination / treatment. Allows separate movement of head, torso and legs. Allows overall height adjustment for ease of user access. Use of table for X-ray / fluoroscopy is not required. Leg section removable when necessary.
Technical characteristics		
18	Detailed requirements	Must accommodate patients up to at least 190 kg. All movements must be easily controlled and motorized or operated mechanically or hydraulically. Vertical height movement range to include 0.65 to 1.0 m from floor level. Controllable global movements to include up/down and Trendelenburg at least ±30 deg. Individual movements to allow at least head +20 deg, leg raise/lower +20 / -90 deg. Head and lower ends: easily removable (for resuscitation). In case of mechanically powered tables: All movement and control via gas-spring operated by head/side levellers. In case of AC-powered tables: With dual-sided pedal control. Manual emergency movement and reset. Control panel and remote control.
19	Display parameters	In case of AC-powered tables: Display is to be backlit and allows easy viewing in all ambient light levels.
20	User adjustable settings	Height, Trendelenburg angle, section movements
Physical / chemical characteristics		
21	Components (if relevant)	Minimum overall table dimensions: 1.8m long x 0.6m wide. Oil reservoir or parts requiring oiling to be easily accessible. Control panel to be clearly labelled and easy to operate. Base to be stable and must not obstruct operator access to patient. Supplied with two armrests at least 0.4m long, that fit adjustable positions on each side of table. Supplied with two leg slings, two vertical supports for leg slings and two knee supports. Supplied with removable or foldable side restraints on each side of table. Leg section of table to be removable to allow lithotomy position. Removable handles on each side must be securely fastened for patient traction. Supplied with removable stainless-steel bowl, mounted for afterbirth collection.

		Supplied with padded mattress, in sections that match layout of table sections. Supplied with IV pole with at least two hanging hooks and secure table mounting. All exposed metal parts to be constructed of stainless steel. All non-metal parts to be constructed of durable, waterproof, washable and antistatic material. No sharp edges or points to be present. Mounted on castors of minimum diameter 12cm, with braking facility on each castor. The top of the bed shall be in 3 sections. Ratchet operated rising backrest, retractable foot end and a fixed centre part. Three separate mattresses of at least 100mm thickness for each section fixed in. Position to the top of the bed by Velcro strips on the underside of each mattress.
22	Mobility, portability (if relevant)	Mounted on castors of minimum diameter 12cm, with braking facility on each castor.
23	Raw materials (if relevant)	All exposed metal parts to be constructed of stainless steel. All non-metal parts to be constructed of durable, waterproof, washable and antistatic material.
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Only for powered tables. Electrical source requirements: Amperage: _____; Voltage: _____; Frequency: _____; Phases: _____. Power input to be _____ fitted with _____ compatible mains plug, Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage. Manual operation to be possible in the event of power failure. Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral, Main power supply off switch to be fitted at least 3m from table. Compliance with _____ electrical standards and regulations.
Accessories, consumables, spare parts and other components		
25	Accessories (if relevant)	Pair of adjustable leg crutches with anti-static pads. Liquid collection pan.
26	Sterilization process for accessories (if relevant)	NA
27	Consumables / reagents (if relevant)	NA
28	Spare parts (if relevant)	Supplier to provide details of all available spare parts with specifications and costs.
29	Other components (if relevant)	Supplier to provide details of all other available fittings with specifications and costs.
Packaging		
30	Sterility status on delivery (if relevant)	NA

31	Shelf life (if relevant)	NA
32	Transport and storage (if relevant)	Storage area should be clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof.
33	Labelling (if relevant)	Labelling on the primary packaging should include the name and/ or trademark of the manufacturer and should adhere to the most current version of ISO 15223 – 1: Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements.
Environmental requirements		
34	Context-dependent requirements	Capable of being stored continuously in ambient temperature ranging from 0°C to 50°C, relative humidity 15%-90% (non-condensing). Capable of operating continuously in ambient temperature of 10°C to 40°C and relative humidity of 15 to 90%.
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
36	Requirements for commissioning (if relevant)	
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided.
38	User care (if relevant)	Table layout to enable easy cleaning and sterilization of all surfaces, with no fluid traps.
Warranty and maintenance		
39	Warranty	Minimum one year. Specific inclusions and exclusions to be listed. Contact details of manufacturer, supplier and local service agent to be provided.
40	Maintenance tasks	Replacement oil or grease sufficient for two years' maintenance.
41	Type of service contract	
42	Spare parts availability post-warranty	
43	Software / hardware upgrade availability	
Documentation		
44	Documentation requirement	• Instructions for use and service manuals to be provided (including procedures for decontamination) • User language preference prioritized, English is mandatory. • Contact details of manufacturer, supplier and local service agent. • Certificate of inspection to be provided. • List to be provided of equipment and procedures required for routine maintenance. • List to be provided of common spares and accessories, with part numbers and costs.
Decommissioning		
45	Estimated life span	20 years

Safety and standards		
46	Risk classification	Class I Regulation (UE) 2017/745 Directive 93/42/EEC and s.a.a. Class I, US FDA
47	Regulatory approval / certification	Compliance to (where applicable, but not limited to): - National Regulatory Agency/Authority (NRA) requirements compliance - Approval by regulatory body of country of manufacturer (if applicable) And at least one of: - FDA 510k clearance (US FDA) - CE mark (EU), with indication of Notifying Body (when applicable) - Other regulatory body in an IMDRF founding member country such as Australia, Canada, or Japan.
48	International standards	Compliant with active version of the following standards (or equivalent): **General manufacturing:** • ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes • ISO 14971: Medical Devices - Application of Risk Management to Medical Devices • ISO 15223-1: Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements • ISO 20417: Medical devices — Information to be supplied by the manufacturer. **Safety & product standards:** • IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • IEC 60601-1-2: Medical electrical equipment - Part 1-2 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests • ISO 10993-1: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
49	Regional / local standards	Country-specific and regional standards may apply
50	Regulations	Council Directive 93/42/EEC of 14 June 1993 on Medical Devices and s.a.a. Regulation (EU) 2017/745 of the European Parliament and the Council and s.a.a. US FDA, CFR Title 21, part 820 and part 884, 884.4900 – Obstetric table and accessories