4.8. Key tender/request for quotation specifications for a colposcope

Following are the key features that may be noted in a tender or request for quotation; see Annex 4 for detailed standardized WHO technical specifications.

Product description	A colposcope is a low magnification light-illuminated visualization instrument primarily used alongside screening tools for screening, diagnosing and managing precancerous cervical lesions in women. It allows the examiner to view the epithelial tissues of the cervix and other anogenital areas. For purposes of cervical precancer assessment, it helps determine the transformation zone type and the grade of suspected epithelial abnormality. In addition, colposcopy facilitates and optimises biopsy and excisional treatment.
Key product features	• **Magnification:** A range of optical magnification between 3x to 15x (either stepped or continuously variable); • **Illumination:** » Light sources shall be either halogen or LED to guarantee full-spectrum visible light (white light): * Halogen light: 15 V/150 W * LED: 20,000-35,000 LUX (at 300 mm working distance). » An illumination adjustment knob to change the intensity of light; » A fan to cool the bulbs (if halogen bulbs are used). • **Green light filters;** however, blue filters are also acceptable but not the preferred option.
Components, accessories, consumables	• Stand or mount to allow for hands-free operation • LED TV or medical grade monitor if not integrated (optional) • Single-use sheath (if using invasive portable model).
Operational requirements	• Temperature: 15°C to 35°C • Relative humidity: ≤85% • (Storage temperature: 15°C to 40°C, 85%, non-condensing) • Ingress protection rating: IPX2 • The unit is suggested to be connected to a reliable power source • Electrical source requirements (based on country/setting of use): » Amperage: _____ » Voltage: _____ » Plug type: _____.
Documentation requirements	• Instructions for use and service manuals to be provided • User language preference prioritized, otherwise English is mandatory.
Warranty	Minimum one year.

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.

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.

For vaginally-inserted colposcopes:

- Biocompatibility:
    - » ISO 10993-1: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process;
    - » ISO 10993-5: Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity;
    - » ISO 10993-10: Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization;
- Endoscopy (pertaining to inserted scope):
    - » ISO 8600-1: Endoscopes – Medical endoscopes and endotherapy devices – Part 1: General requirements;
    - » ISO 8600-3: Optics and optical instruments – Medical endoscopes and endoscopic accessories – Part 3: Determination of field of view and direction of view of endoscopes with optics;
    - » ISO 8600-4: Endoscopes – Medical endoscopes and endotherapy devices – Part 4: Determination of maximum width of insertion portion;
    - » ISO 8600-5: Optics and photonics – Medical endoscopes and endotherapy devices – Part 5: Determination of optical resolution of rigid endoscopes with optics;
    - » ISO 8600-6: Optics and photonics – Medical endoscopes and endotherapy devices – Part 6: vocabulary.

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 II; • European regulatory framework: » Council Directive 93/42/EEC of 14 June 1993 on Medical Devices (Class IIa); » Regulation (EU) 2017/745 of the European Parliament and the Council; » Manufacturer must affix the CE marking and indicate the Notified Body number on the label and in the device, when possible. • Other regulatory body in an IMDRF founding member country such as Australia, Canada, or Japan.

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[11] 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.

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Section 2 – Treatment technologies

This section includes three technologies that can be used for the treatment of precancerous lesions. The selection of one technology over another, or using a mix of technologies would depend on several factors including, but not limited to: the nature of the cervical lesion, available healthcare workforce, level of training and specialty area of healthcare providers, availability of technical support, financial resources, supportive infrastructure (water, electricity, CO_2 and/or N_2O gas access), and other technological resources available. Table 7 presents the different technologies that can be used for treatment of precancerous lesions: thermal ablation, cryotherapy, and LEEP.

Table 7: Comparison overview of technologies to treat cervical lesions

	Thermal Ablation	Cryotherapy	LLETZ (LEEP)
Brief description	Destroys tissue by heating	Destroys tissue by freezing	Removes tissue by cutting, allowing for biopsy of removed tissue
Infrastructure requirements	Requires reliable power supply	Requires continuous reliable power supply (if using electrically cooled cryosurgery units)	Requires continuous, reliable power supply
Operator qualifications required	Basic	Skilled	High skill and specialized training required
Required accessories or consumables	N/A	Continued supply of medical gas or reservoir solution	Smoke evacuation device
Cost considerations	Initial equipment cost only, and maintenance costs	Ongoing cost of consumables, specially medical gas, and infrastructure requirements	Initial cost, plus maintenance, consumables and additional capital cost of smoke evacuation system
Advantages	Can be battery operated, enabling portability		Biopsy of lesion is possible. Electro Surgical Unit (ESU) can be used for other procedures
Limitations	Biopsy of lesion is not possible	Biopsy of lesion is not possible	• Operator qualifications and haemorrhage risk limit the use this procedure in lower level settings • Smoke evacuation device highly recommended

Each of these types of technologies will be further explained in the following chapters.

Chapter 5:
Technical guidance and specifications for thermal ablation devices

5.1. Scope of chapter

This chapter specifies technical requirements for a thermal ablation system, a device which uses heat to treat cervical intraepithelial neoplasia (CIN). Although thermal ablation has not been evaluated as widely as cryotherapy, it has been used effectively in some settings dating back to 1966[1,2,3] and has been deemed as effective as cryotherapy in treating all grades of CIN lesions. More recently, rechargeable, battery-driven portable devices have come onto the market, making the method more suitable for LRS.

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

Brief description

Thermal ablation devices use a heated probe tip to destroy cervical tissue with abnormal cell growth:

- The probe should be easily directed to the target tissue;
- Visual and/or audible cues communicate to the clinician when the target temperature has been reached and the appropriate treatment time has elapsed;
- The target temperature for treatment is 100°C;
- The probe tips should be round in shape, ranging from 8mm to 25mm in diameter, should not stick to cervical tissue, and be easy to decontaminate between patients;
- Units are AC or battery powered.

5.2. Background on thermal ablation devices

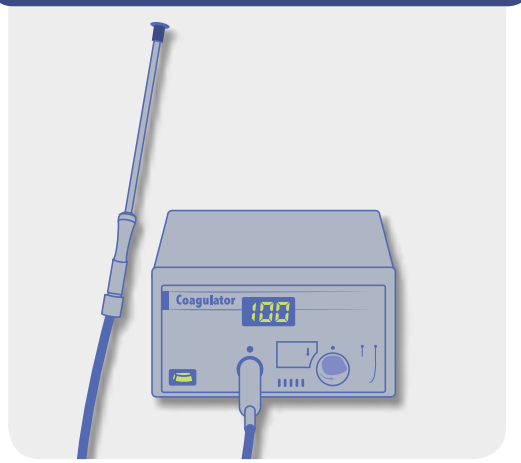
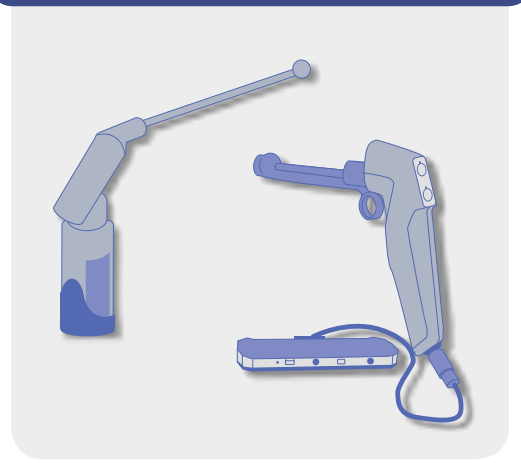
A thermal ablation device is a self-contained, electrically powered medical instrument designed to destroy tissue of the uterine cervix with low-grade heat. It may also be referred to as thermal coagulation or Semm cold coagulation, after the inventor of the device . The term "cold" has been used due to a treatment temperature of 100°C, which is lower than that used for standard clinical electrocautery (usually between 400-600°C).[4,5] At this treatment temperature, there is no charring or smoke plume to evacuate, an advantage if multiple applications are performed during a single treatment.[3,7] Thermal ablation is similar to cryotherapy (see Chapter 6), sharing the same intended use, albeit by a different mechanism.

Thermal ablation is appropriate for use in LRS because it is effective (documented effectiveness range between 87-97%[3]), has limited side-effects, is inexpensive compared with other treatment options, and is technically simpler to implement. It can be portable and does not require compressed gases. Treatment time recommended is 20-30 seconds per application, and it is common that up to 4 to 5 applications are necessary to cover the entire transformation zone.

5.3. Types of thermal ablation devices

There are generally two types of units, the handheld and the benchtop. Table 8 illustrates both, with descriptions of each model type.

Table 8: Comparison between benchtop and handheld thermal ablation devices

Type	Benchtop	Handheld
Image		
Brief description	Current benchtop models are no larger than 30 x 15 x 20 cm and weigh about 3.5 kg; thus, it can be transported but is not considered to be "portable". The probe including tip and shaft is attached to the handle, which is connected to the main unit by a cable.	Handheld thermal ablation devices, such as those that can be easily carried in a case or backpack (including accessories), comprise of a handle and a detachable probe, which has an integral tip that is applied to the lesion. Features may vary from one make to another, and parts are not interchangeable.
Product features	Stationary (~3.5 kg)	• The handle is fitted with one or more integrated controls located such that they can be operated with one hand; • The handle may have an integrated light source to aid in visualizing the cervix; • These are powered by a rechargeable and interchangeable battery and can treat at least 30 patients (minimum cumulative run-time of 1 hour on a single charge); back-up batteries should always be charged, ready for use.
Limitations	• Requires reliable electricity • Not portable.	• Procurement of back-up batteries required.

5.4. Equipment Requirements

The probe shaft and tip should be made from surgical-grade materials; the **probe shaft** should either itself be thermally-insulated or have a guard to prevent burns to the vaginal walls. If a protective sleeve is used over the probe, it needs to be cleaned and disinfected between patients. Illumination with a light source or from the thermal ablation unit itself is an advantage to workflow.

The depth of necrosis should be sufficient to destroy the tissue by ensuring the underlying tissue reaches a temperature of 100°C.[8,9] The device should prevent temperatures higher than that required for ablation and should have an automatic timer to control the duration of heat application.

The handle of either the benchtop or handheld unit shall be made of a material that can withstand routine cleaning. The probe (shaft and tip) should be removable to facilitate decontamination.

Environmental operating conditions for these units are from 5-40°C and relative humidity of ≤85%, non-condensing. Benchtop device should have grounding to prevent shock or leakage of electricity.

The depth of necrosis should be sufficient to destroy the tissue by ensuring the underlying tissue reaches a temperature of 100°C.

5.4.1. Probes

Probes shall be removable to allow for the interchange between various shapes and sizes, depending on need, as well as to facilitate decontamination. The following provides guidance on shape, size, material and other relevant details of the probes to be included or considered for procurement, regardless of whether benchtop or handheld units are being used:

Shape: The surface of the tip that contacts the cervix should be smooth with no sharp edges. A flat probe is always necessary to ensure full ablation of the transformation zone; however, nipple-shaped probes with an extrusion not exceeding 5 mm are very useful to anchor the probe to the centre of the cervix (see Figure 7). *(Note: conical tips or probes that extend into the endocervix should not be used for thermal ablation treatment of precancerous cervical lesions.)*

Dimensions: probe tip diameters may range from 8 mm to 25 mm, where common sizes are 8 mm, 12 mm, 16 mm, 19 mm and 25 mm (larger diameters are only suitable for use on large parous cervices and thus do not have as broad an application as smaller-sized probe tips). Multiple probe tip sizes should be available. The overall length of the probe with tip should be between 170 and 200 mm (see Figure 9).

Material: The surface of the probe should not easily adhere to the tissue. Probe tips may be coated with a non-stick material, such as polytetrafluoroethylene (PTFE) or polyether ether ketone (PEEK), which is non-cytotoxic and fit for in vitro use. The probe shaft should be rigid so that it cannot flex during normal use, and be thermally insulated to help prevent accidental burns to any tissue that it may come into contact with, such as the vaginal wall. All materials must be capable of routine decontamination (high-level disinfection, HLD, and sterilization – see Chapter 5.5.2.).

Probes shall be removable to allow for the interchange between various shapes and sizes, depending on need, as well as to facilitate decontamination.

Figure 10: Shapes for probe tips, not specific to thermal ablation (for illustrative purposes only)

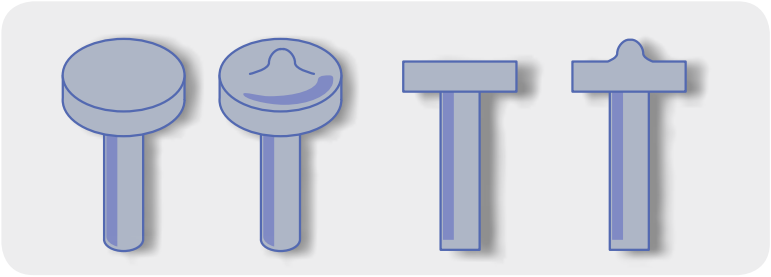
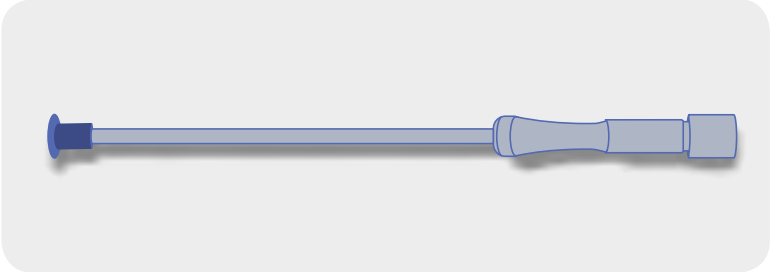


Figure 11: Image of probe-tip illustrating a nipple-tip extrusion

Figure 12: Image of integrated probe tip, shaft, and handle for a variety of probe tip shapes.



5.4.2. Additional Requirements

5.4.2.1. Accessories

The thermal ablation devices are used with a speculum for viewing and accessing the cervix[10] (see Chapter 1) and a light source (external or built-in) of at least 100W or 100W-LED equivalent, and/or a magnification lamp to improve visualization during the procedure. It is recommended that any such light source provide the white light spectrum, similar to daylight. Yellow, tungsten-based light sources should be avoided if possible.[11]

5.4.2.2. Power source/mains

Regardless of type of thermal ablation device, there must be a continuous, reliable electrical power supply (220V or 120V, and 50 or 60 Hz, according to different national standards) accessible in the exam room or facility to allow for use and/or charging.

For battery-powered devices, consideration should be given to how many patients need to be treated between charge cycles. A battery with a cumulative run-time of at least 1 hour should be capable of treating at least 30 patients, which should accommodate outreach activities such as mobile clinics. In addition, a back-up battery with the same capacity should be considered and should always be charged, ready for use.

For battery-powered devices, consideration should be given to how many patients need to be treated between charge cycles.

Should a device with battery power be procured, the user should have access to battery replacements as the batteries might not last the entire life span of the device. The user should refer to manufacturer guidelines for storage and usage instructions.

5.5. Operational considerations

Continued research into thermal ablation devices, standardized treatments (ideal probe size, timing of each ablation cycle to ensure the entire squamocolumnar junction (SCJ) zone is ablated) and other low-cost, effective, reliable, and quality treatment devices will aid the efforts to eventually eliminate cervical cancer.

5.5.1. How to use a thermal ablation device

It is important that the user be familiar with the thermal ablation instrument(s), and that the instructions for use are read prior to performing any treatments as there may be differences between products. When using a thermal ablation device:

1. Ensure the device will be used under optimal operating conditions, according to manufacturer's recommendations;

2. Select the appropriate device-specific probe with probe tip for the intended treatment and connect to the unit (benchtop models have cables, handheld units do not);

3. Set the probe to the required temperature (if applicable) and ensure probe tip is not in contact with any heat sensitive material when it is turned on;

4. Note that some probes must reach required temperature prior to vaginal insertion, whereas others are intended to reach the required temperature after vaginal insertion.

The following optional device functionalities will affect workflow; the user should be aware of which features their device has and prepare for their work accordingly:

- Automatic heating to a pre-set target temperature (100°C) with a single switch button can help workflow when treating many patients;

- Visual or audible cues to indicate how much time has elapsed in the treatment cycle (though use of a stopwatch is perfectly acceptable);

- Availability of extra, swappable and quick-charging batteries, if portable;

- Automatic shut-off at the end of a treatment cycle can help to conserve battery power between treatments.

Appropriate clinical training should be provided in advance of using thermal ablation units. It is necessary to establish and/or maintain an on-going, competency-based capacity-building program to sustain clinical practice with all in-service programs, tools and resources, based on the standard clinical guidelines and local CMS pedagogy. Please refer to guidance provided in the WHO guidelines for the use of thermal ablation for cervical pre-cancer lesions.[12]

It is important that the user be familiar with the thermal ablation instrument(s), and that the instructions for use are read prior to performing any treatments as there may be differences between products.

5.5.2. Decontamination and reprocessing

Health care-associated infections (HAI) are one of the most common adverse events in health care 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[13], 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[14] 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.

The probe shaft and tip form an integral unit; thus, it is decontaminated and reprocessed as one. Equipment and accessories in direct contact with the patient must be decontaminated according to manufacturer's instructions for use and local protocol. The rest of the device is to be cleaned and/or disinfected. Solutions for cleaning and disinfection need to be used according to the manufacturer's instructions as their specified disinfectant exposure time must be observed.

Other tools and materials used in thermal ablation (for example specula) should be cleaned and disinfected and sterilized, as appropriate, between patients.

5.5.3. 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.[15]

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

5.5.4. 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 and warnings.

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 on a shelf or on 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 premature material disintegration.

However, in general, these devices should be able to withstand storage temperatures ranging from 15°C to 40°C, relative humidity ≤ 60% (non-condensing), and be protected from dripping water.

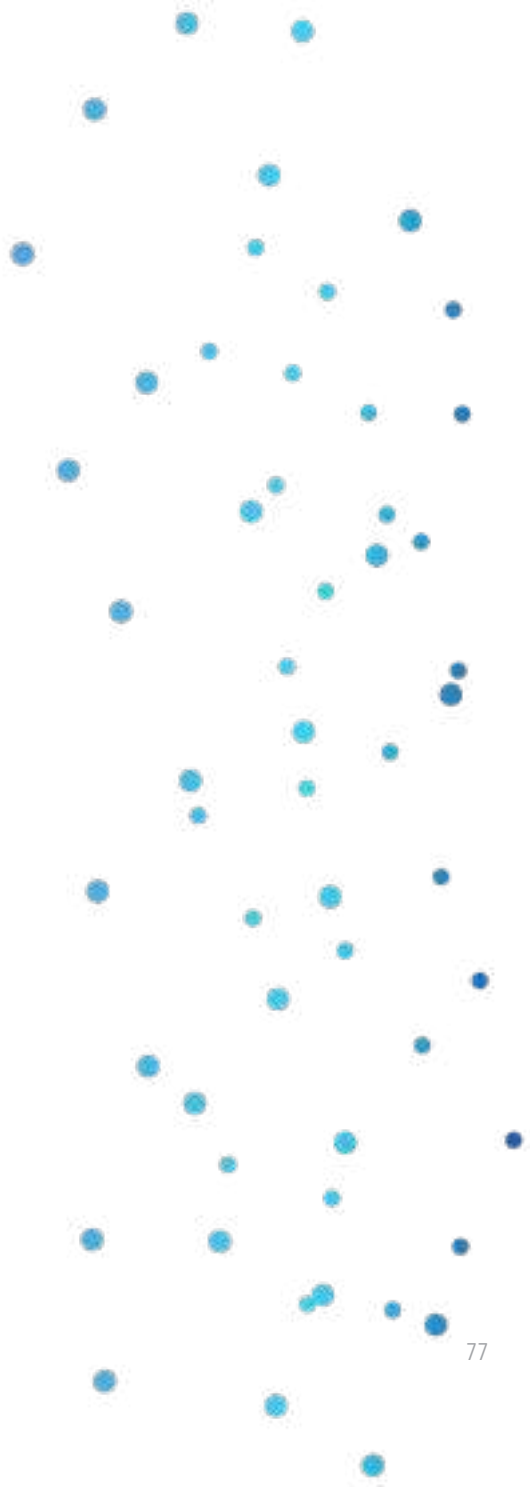
5.5.5. Maintenance

Depending on the unit, maintenance procedures will vary. Self-contained, portable devices shall have manufacture certification and contain microprocessors capable of internal checks to verify that the probe and handle are working properly. For benchtop models, daily functional tests should be conducted and it should be serviced on a regular basis for the service life of the device

Any requisite PPM, outlined in the service manuals, shall be duly carried out so as to prolong the use-life of the device. Any technical service as such, including PPM, shall be performed by the original equipment manufacturer or trained clinical engineering professionals.

If a device appears damaged or indicates a different visual cue during set-up or operation, it should immediately be taken out of service. Ensure coating covers probe tip and remains intact. Rechargeable batteries should be replaced and disposed of according to the manufacturer's instructions.

As a minimum, the storage area should be clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof.



5.6. 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 manfactured 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, infrastrucutre, 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 malfunction or failure. Post-market surveillance typically consists of complaint handling by end-users when an issue is detected. When information is made known to the product manufacturer, they must determine if the risks have increased and whether the benefits of the product outweigh the harms or risks. Any field safety corrective actions, such as a recall or change to the product (including labelling), are notified by the manufacturer through a field safety notice. National regulatory agencies / authorities (NRA) will also conduct their own market surveillance and oversee the manufacturer's investigation of 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.[16]

5.7. Standards and regulatory compliance

Thermal ablation devices are a type of medical devices so the following standards categories apply:

- Medical device quality, performance, operations, and safety: ISO 13485, ISO 14971, ISO 15223-1 (See Chapter 5.8 and Annex 5);
- Biocompatibility: ISO 10993, all applicable parts (See Chapter 5.8 and Annex 5);
- Electrical safety: IEC 60601, all applicable parts (See Chapter 5.8 and Annex 5);
- Secondary cells (batteries): IEC 62133, parts 1 and 2 – if applicable (See Chapter 5.8 and Annex 5).

It is important to observe all applicable local laws and regulations related to medical devices and their manufacturing, procurement and use. In the absence of a regulatory agency, it is strongly recommended to consider which regulatory and/or normative body assessment was completed for each product prior to procurement decisions. The risk class depends mainly on the regulatory framework of a country and therefore it may differ according to jurisdiction. For more details with regard to other regional regulations and standards, see the specifications table in Chapter 5.8 and in Annex 5.

It is important to observe all applicable local laws and regulations related to medical devices and their manufacturing, procurement and use.

5.8. Key tender/request for quotation specifications for a thermal ablation device

Following are the key features that may be noted in a tender or request for quotation; see Annex 5 for detailed standardized WHO technical specifications.

Product description	Thermal ablation devices use a heated probe tip to destroy cervical tissue with abnormal cell growth. They are available in benchtop console form or can be battery operated and portable.
Key product features	• Probe tip temperature controlled to reach 100°C • Visual and/or audible cues to ensure working temperature reached • Simple and easy to use, appropriate for all levels of care.
Components, accessories, consumables	• Minimum of 2 probe tips required: » One probe must be flat; » The second probe can be either flat or can have a gentle nipple extrusion not exceeding 5mm (so as to anchor in centre of cervix but not to ablate endocervix); » Probes should not have any sharp edges; » Varying diameters, ranging from 8 mm to 25 mm; » Biocompatible, material that will not adhere to cervix; » Reusable and thus decontamination is needed.
Operational requirements	• Temperature: 15-35°C; • Relative humidity: ≤85% (non-condensing); • Ingress protection: » Console: IP21 » Instrument cable, therapy probe: IPX7. • (Storage temperature: 15-30°C, storage relative humidity: ≤60%, non-condensing); • The unit is suggested to be connected to a reliable power source; • Electrical source requirements (based on country/setting of use): » Amperage: _____ » Voltage: _____ » Plug type: _____.

Documentation requirements	• Instructions for use and service manuals to be provided • User language preference prioritized, otherwise English is mandatory.
Warranty	Minimum one year
Standards	Following with active version of the standards listed below (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. 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. Battery-operated only: • IEC 62133 - Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells: » Part 1: Nickel » Part 2: Lithium. Probe-specific requirements: • ISO 10993-1: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process; • ISO 10993-5: Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity; • ISO 10993-10: Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization.

Regulatory requirements	Compliance with (where applicable, but not limited to): • National regulatory agency requirements compliance • Approval by regulatory body of country of manufacturer (if applicable). • And at least one of: • United States regulations: US FDA Device Class II • European regulatory framework: » Council Directive 93/42/EEC of 14 June 1993 on Medical Devices; » Regulation (EU) 2017/745 of the European Parliament and the Council; » Manufacturer must affix the CE marking and indicate the Notified Body number (when applicable) on the label and in the device, when possible. • Other regulatory body in an IMDRF founding member country such as Australia, Canada, or Japan.

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

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Section 2 – Treatment technologies

Chapter 6: Technical guidance and specifications for a cryosurgical unit

Brief description

A cryosurgical unit includes cooled cryoprobe and accessories, intended to destroy cervical tissue with abnormal cells by applying an extremely cold probe to the tissue:

- The cryotip should be round in shape and 17-23 mm in diameter, the overall length of the cryoshaft and cryotip assembly should be between 170 and 200 mm;
- Temperature at probe edge is capable of reaching -20 °C or even colder.

Two types of cryosurgical units are discussed in this chapter:

Gas:

- The cryosystem includes hand-held unit (comprise of cryotip, shaft, trigger and handle), connector/pressure gauge assembly (hose, pressure release valve, pressure gauge, exhaust port and connector to the cylinder), and gas supply;
- It can be part of a console or stand-alone;
- A closed system probe should be used, in which the cryogen flows to and circulates in the probe head;
- Carbon dioxide (CO_2) or nitrous oxide (N_2O) are commonly used.

Electric:

- The cryosystem includes cryotips, a hand-held device, pen cores and a Stirling cooler to cool the tip;
- Units are hand-held with a cooling console/base unit;
- It can be AC or battery powered.

Note to reader:

WHO's Comprehensive Cervical Cancer Control: a guide to essential practice,[1] coupled with this chapter, are intended to serve as the clinical and technical guidance for cryotherapy.

WHO technical specifications for Cryosurgical equipment for the treatment of precancerous cervical lesions and prevention of cervical cancer has been replaced with the present document.

WHO IARC has developed training material:[2] https://screening.iarc.fr/elearningifcpc.php

6.1. Scope of chapter

This chapter defines technical requirements for a cryosurgical unit that delivers cryotherapy to treat cervical intraepithelial neoplasia (CIN).

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

This chapter defines technical requirements for a cryosurgical unit that delivers cryotherapy to treat cervical intraepithelial neoplasia (CIN).

6.2. Background for cryotherapy

Cryotherapy, an ablative therapy used since 1967, uses extremely low temperatures to freeze and destroy abnormal tissue for the destruction of cervical intraepithelial neoplasia (CIN).[3] It is also known as cryocautery, cryosurgery, or simply "cryo". It is a relatively simple procedure appropriate for use in LRS because it is easy to learn, the device is portable, and the treatment is considered to be very safe and effective, with success rates between 85-94%,[4] and with minimal risk of excessive bleeding or significant pain.[5] Cryotherapy is similar to thermal ablation (see Chapter 5), sharing the same intended use, albeit by a different mechanism.

It functions by freezing the identified abnormal area(s) of the cervix by applying a highly cooled probe, causing cryonecrosis of epithelial cells due to intracellular fluid crystallization and consequent irreversible membrane rupture.[6]

The application of cryotherapy takes only a few minutes, and although usually causes some lower abdominal discomfort and uterine cramping, the side effects are considered both minimal and tolerable.

Cryotherapy systems can be cooled by either pressurized gas (CO_2 or N_2O) or super-cooled from an electrical power supply. Systems cooled by pressurized gas require the reliable acquisition, safe transportation and safe handling of a medical gas.[84] For electric based systems, a continuous, reliable power source is required as well as an ethanol-based medium to prevent the probe core from freezing to the wall of the unit.

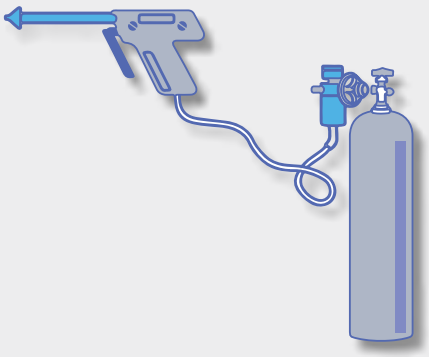
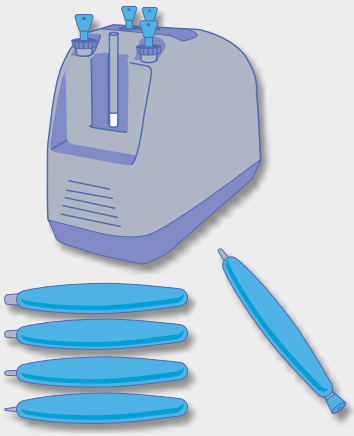
Cryotherapy is usually performed on an outpatient basis and can be performed at all levels of the health system by adequately trained healthcare providers.[1]

Cryotherapy systems can be cooled by either pressurized gas (CO_2 or N_2O) or super-cooled from an electrical power supply.

6.3. Types of cryotherapy units

6.3.1 Different types of cryosurgical units

Table 9: Comparison between gas and electrically cooled cryotherapy units

Type	Gas cooled	Electrically cooled
Image		
Brief description	Gas-based cryosurgical equipment is relatively ubiquitous and is available from many manufacturers. The cryosystem includes cryotips, hand-held device, connector/pressure gauge assembly (hose, pressure release valve, pressure gauge, exhaust port and connector to the cylinder), and gas supply. This is a closed system probe in which the cryogen flows to and circulates in the probe head and exhausted back down the shaft.	Electric systems are designed to provide cryotherapy without the use of compressed gas. There is a cooler in the base that cools a core using electricity. The core is then removed from the base and inserted into the probe head for use. A variety of reusable tips are available for use.
Advantages	Comes in various sizes to fit different clinical needs. Available in most markets. Widely used, lots of evidence and clinical guidelines available.	No gas required and therefore no medical gas supply chain required.
Limitations	Gas supply requires local supply chain and can be harmful to users (particularly N_2O).	Requires continuous, reliable electricity. Newer technology compared to gas-cooled, and therefore not as ubiquitous. May require continuous supply of reservoir solution (ethanol-based) to coat cores prior to cooling.

6.4. Equipment requirements

All cryosurgical equipment should be capable of reaching and maintaining a cryotip temperature below - 50°C at the centre and below -20°C around the side edges of the cryotip.

All cryosurgical equipment should be capable of reaching and maintaining a cryotip temperature below -50°C at the centre and below -20°C around the side edges of the cryotip.

6.4.1. Hand-held unit

The hand-held part is typically gun shaped, with the cryoshaft connecting the probe tips, which can be attached to and removed from the handle, and subsequently, the gas or electricity supply mechanism. It shall be made of a material that withstands routine decontamination. One or more integrated triggers and other controls on the handle of the unit should allow for temperature regulation to control the freezing-thawing cycle that takes place in the cryotip.

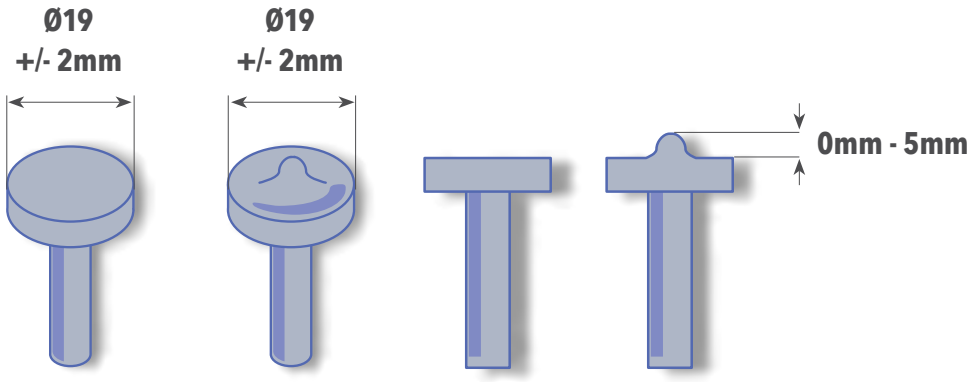
If temperature regulation is part of the hand-held device, as with gas-cooled systems, the device should be designed to give the user sensory feedback indicating its "on" or "off" status, as well as with a latching mechanism to allow the user to lock the trigger in the ON position. The controls are located such that they can be operated with just one hand.

6.4.2. Cryoprobe

The cryoprobe consists of cryotip and the cryoshaft. The cryotip is removable to allow for the interchange between various tip shapes and sizes, depending on need, as well as to facilitate cleaning and disinfection. The following provides guidance on shape, size, material and other relevant details of the cryoprobes to be included or considered for procurement, regardless of type of cryotherapy unit being used:

Shape: The surface of the tip that contacts the cervix should be smooth with no sharp edges. A flat probe is always necessary to ensure full ablation of the transformation zone; however, nipple-shaped probes with an extrusion not exceeding 5 mm are very useful to anchor the probe to the centre of the cervix (see Figure 10). *(Note: conical tips or probes that extend into the endocervix should not be used for cryotherapy of precancerous cervical lesions.)*

Figure 13: Illustrations of suggested cryotips and dimensions



Dimensions: The cryotip should have a 17-23 mm diameter (larger diameters are only suitable for use on large parous cervices and thus do not have as broad an application as smaller-sized probe tips). Multiple probe tip sizes should be available. The overall length of the cryoshaft and cryotip assembly should be between 170 and 200 mm.

Materials: the cryotip shall be made from surgical-grade materials to allow for direct contact with human tissue (must be non-cytotoxic, see Chapter 6.7 standards and regulations), and to facilitate the repetitive decontamination without compromising its integrity.

Due to the risk of damaging surrounding tissue, safety features to protect the vagina upon entry and exit of the cooled probe tip are recommended. The probe shaft should either itself be a non-thermal conductor or must have a guard to prevent burns to the vaginal walls. The shaft should be rigid so that it does not flex during normal use.

Specific to gas-based units, in addition to potential challenges associated with the sourcing, delivery, storage, and handling of liquid nitrogen in LRS, **only closed systems, which use a compressed gas-based cryogen flowing through the shaft in a hollow tube and is exhausted back through the hand-held device, are recommended for precancerous cervical lesions.**

Due to the risk of damaging surrounding tissue. Safety features to protect the vagina upon entry and exit of the cooled probe tip are recommended.

6.4.3. Additional Requirements

6.4.3.1. Accessories - all

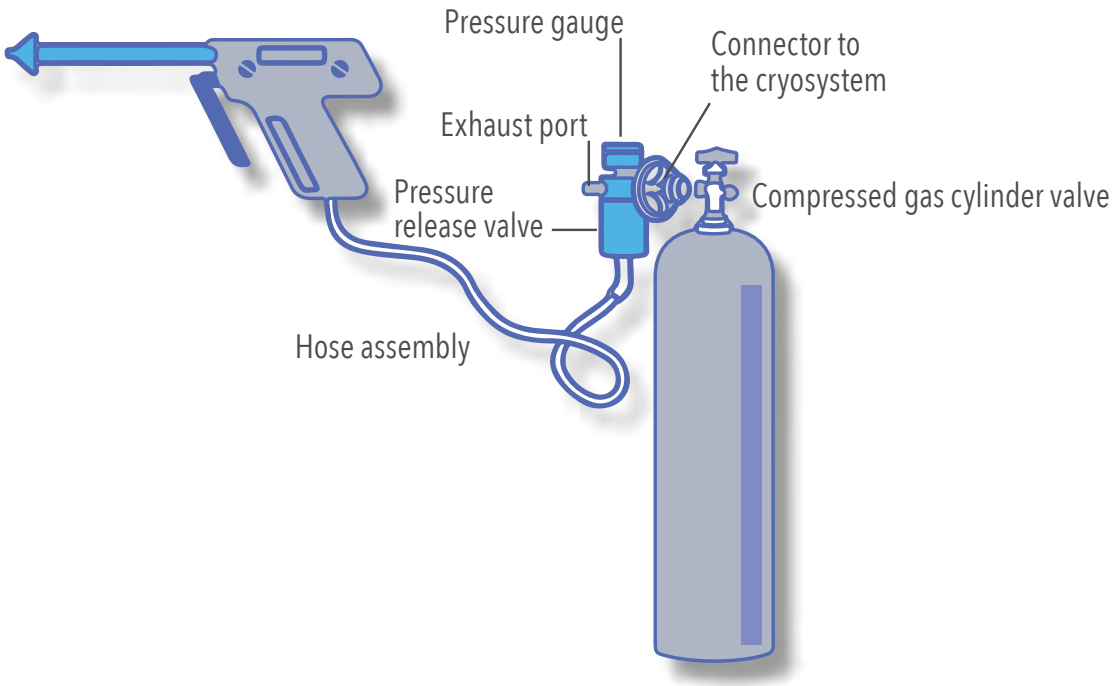
Cryotherapy units are used with a speculum for viewing and accessing the cervix[6] (see Chapter 1) and a light source (external or built-in) of at least 100W or 100W-LED equivalent, and/or a magnification lamp to improve visualization during the procedure. It is recommended that any such light source provide the white light spectrum, similar to daylight. Yellow, tungsten-based light sources should be avoided if possible.[8]

It is recommended that any such light source provide the white light spectrum, similar to daylight.

6.4.3.2 Requirements for gas-based units

Connector/Pressure gauge assembly: A hose assembly connects the hand unit to a connector/pressure gauge assembly that connects to the high-pressure gas cylinder. It comprises a high pressure hose to facilitate gas flow to the unit, as well as to return used gas to the assembly to be vented through an exhaust port (venting of the gas within the handset is not acceptable) – see Figure 11 below.

Figure 14: Hose and connector/pressure gauge assembly used in cryotherapy



The hose shall be rated for a pressure of at least 13,790 kPa (2000 psi), or twice the maximum gas cylinder pressure, with a minimum length of 150 cm to allow sufficient free movement of the clinician while operating the device. Returned gas is depleted into the air through the exhaust port (see Figure 11).

The gas connector permits the system to connect directly to the compressed gas cylinder. It is made of metal and should be rated for use with pressurized gases. It must be compatible with the cylinder valve fitting available locally (e.g. pin-index or bullnose) where the equipment is to be used.

The gas connector permits the system to connect directly to the compressed gas cylinder.

A pressure gauge indicates the pressure within the cylinder. It may be colour-coded to indicate the safe working range for the device.

A pressure relief valve protects the device, the user, and the patient from potentially excessive tank output pressure. The valve has an internal rupture disk, which bursts at a set pressure, preventing the device from over-pressurization.

A pressure regulator, silencer, temperature sensor and active defrosting function may or may not be incorporated into the unit. For the pressure regulator, it is important to ensure that local gas suppliers have cylinders that are fitted with accessories compatible with the device connector assembly.

Gases Carbon Dioxide (CO_2) and Nitrous Oxide (N_2O): Either CO_2 or N_2O are suitable to be used in cryotherapy; the choice of gas must be made at the time of purchase based on local availability and clinical preference, to ensure proper fittings (as each gas has its unique valve fitting assembly). Most manufacturers offer the option of using either.

Both CO_2 and N_2O have temperature and pressure ratings at which the gas liquefies; see Table 10 (their critical point):

Table 10: Critical points of CO_2 and N_2O

Gas	Critical Temperature	Critical Pressure
CO_2	31.2 °C	7378 kPa (1070.1 psi)
N_2O	36.4 °C	7245 kPa (1050.8 psi)

At normal room temperature, and under high pressure (as realized in cylinders), both gases will be in liquid form. At typical storage temperatures (20 °C to 30 °C), the pressure in a CO_2 cylinder will vary between 5860 – 7170 kPa (850 – 1040 psi); and 5060 – 6315 kPa (734 – 916 psi) for a N_2O cylinder. As temperature increases, so will the pressure of the contents. **Under high temperature conditions (i.e. >30 °C), the pressure may become too high for use with some types of cryosurgical equipment. In this case, the cylinder has to cool to below 30 °C before it can be used. Ideally, appropriate storage should be made available for these gases.**

It is recommended that if N_2O gas is to be used with cryotherapy units, gas-scavenging facilities should be used during N_2O-generated cryotherapy. Users should contact the supplier to request information on scavenging the N_2O exhaust, including the proper size and type of exhaust hose for equipment that has a N_2O scavenging port.[9] In LRS where scavenging facilities are not available, the procedure room must be well ventilated to allow for natural dissipation. It is recommended that users consider the substitution of CO_2, which is less hazardous.

A consistent gas supply in LRS might prove challenging. Medical-grade gases should be used to ensure that the quality of the gas is of an acceptable level for use with medical equipment, and that the gas will not damage the equipment. CO_2 is preferred by WHO guidelines where both gases are available. CO_2 is often cheaper and more readily available.

Gas cylinders: Gas pressure in CO_2 or N^2O cylinders are typically 5515-6895 kPa (800-1000 psi). In addition to analogue number readings, the gauges used on cryosurgical equipment are commonly colour-coded to indicate acceptable operational ranges (red: critical, yellow: low, green: acceptable operating pressure).

Different standards, regulations, and requirements apply to gases and gas cylinders depending upon country, region and application. Cylinders are normally made of steel but can be made of aluminium or carbon composites. They come in a wide range of sizes; for NO_2, from 450-18,000 L gas, for CO2, from 450-3,600 L gas.[7] It is best to opt for the largest cylinder size available subject to practical considerations relating to storage and handling on site.

Some manufacturers will provide an empty gas cylinder with the equipment package; however, it is essential to confirm with a local gas supplier prior to purchase if they have the correct fittings to be able to refill the cylinder. Additionally, it is advisable to check with the local gas supplier what the differences would be in refilling your own cylinder, as opposed to leasing one of theirs in a cylinder 'swap-out'.

The cylinder must be standing upright to deliver gas. The safety rules for the cylinder must be followed. Safe transport and storage of compressed gases can be difficult. It is important to follow local regulations regarding transport, supply and use of compressed gas cylinders.

6.4.3.3 Electricity-based cryotherapy units: Power Supply

If using electrically cooled cryosurgical units, there must be a continuous, reliable electrical power supply (220V or 120V, and 50 or 60 Hz, according to different national standards) accessible in the exam room to allow for use by cooling and maintaining cores at required temperatures.

For treatment, when cores have reached the required temperature, they are removed from the base unit and are then placed into the handheld unit to cool the cryotip. At this point, they will no longer be continuously cooled. Once the cryotip makes contact with the tissue, the core will start to warm. It is important that the user be familiar with the amount of time the cryotip will remain cold enough for effective ablation, and to know when to insert a new, adequately cooled core to complete the procedure.

6.5. Operational considerations

6.5.1. How cryotherapy is used

Cryotherapy is indicated as an option for the treatment of cervical precancerous lesions; the success rate of cryotherapy is quite high for low-grade disease.[10] It can be performed at the first assessment visit following "screen and treat" protocol or after a diagnostic biopsy. WHO recommends the double freezing method, which comprises a 3-minute freeze, 5-minute thaw, 3-minute freeze cycle in preference to single-freeze therapy.

Cryotherapy is indicated as an option for the treatment of cervical precancerous lesions; the success rate of cryotherapy is quite high for low-grade disease.

During usage, units scheduled for use with CO_2 should be able to reach temperatures at least as low as – 68°C; N_2O units should be able to reach temperatures at least as low as -89°C; and, electrically cooled systems should be able to reach lows of between -110°C to -105°C. With these temperatures, the temperature at the probe's edge will be capable of reaching < -20°C, a requisite for successful therapy. These figures have been summarized in Table 11:

Table 11: Cryo equipment temperature[83]

Cooling method	Temperature of central tissue	Temperature at probe edge	Temperature of central tissue	Temperature at edge of tissue
CO_2	< -68°C	-20°C	-68°C	About -20°C
N_2O	< -89°C	-20°C	-89°C	About -20°C
Cores, electricity	-110°C to -105°C	-20°C	• -80°C at time = 0 • -50°C at ~2 min. The core is not being cooled continuously during treatment cycle. Core exchange is required.	About -20°C
Conditional on: • **Contact between probe head and epithelium being completely uniform** • **Maintenance of gas system pressure at >40 kg/cm² to achieve required temperature.**				

(adapted from IARC's technical publication Colposcopy and Treatment of Cervical Precancer)

For cryotherapy, all equipment should be specific for the intended purpose of treating precancerous cervical lesions. Instructions for use and service manuals outlining the basic operation of all components shall accompany each unit. These shall cover assembling the equipment, risk of use, and required maintenance.

Appropriate clinical training should be provided in advance of using cryotherapy equipment. It is necessary to establish and/or maintain an on-going, competency-based capacity-building programme to sustain clinical practice with all in-service programmes, tools and resources, based on the standard clinical guidelines and local CMS pedagogy.

Appropriate clinical training should be provided in advance of using cryotherapy equipment.

Please consult WHO's Comprehensive Cervical Cancer Control: a guide to essential practice[11] and the WHO Guidelines for screening and treatment of precancerous lesions for cervical cancer prevention[11] for guidance on the proper preparation for and procedure of cryotherapy, and Colposcopy and treatment of cervical intraepithelial neoplasia: a beginners manual.[12]

IARC, has developed some Training packages Specifically chapter 12 explains the Treatment of cervical intraepithelial neoplasia by cryotherapy. It can be seen at[2] https://screening.iarc.fr/colpochap.php?lang=1&chap=12.php

6.5.2. Decontamination and Reprocessing

Healthcare-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 healthcare facilities and countries. As part of a larger infection prevention and control (IPC) programme,[13] 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 healthcare facilities[14] 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 not to cause any damage and ensure proper decontamination.

Equipment and accessories in direct contact with the patient must be decontaminated, cleaned, and then either sterilized or disinfected, using a high-level disinfectant (HLD). The rest of the device is to be cleaned and/or disinfected; solutions for cleaning and disinfection need to be used according to the manufacturer's instructions as their specified disinfectant exposure time must be observed.

Other tools and materials used in cryotherapy (for example specula) should be cleaned and disinfected between patients.

6.5.3. Health-care Waste Management

Knowledge about the potential for harm due to healthcare waste has become more important to governments, healthcare 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 the 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 healthcare activities.[15]

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

6.5.4. 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 and warnings.

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 on a shelf or on 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 premature material disintegration.

However, in general, these devices should be able to withstand storage temperatures ranging from 15°C to 40°C, relative humidity ≤ 85% (non-condensing) for gas-based systems, and ≤60% (non-condensing) for electrically cooled systems, both should be protected from dripping water.

6.5.5. Maintenance

Essential spare parts and consumables such as, cryo-tips, reservoir solution (for the electrically cooled cryocores), the hose assembly, O-ring and Bodok seals (sealing washers) (for gas-based systems) should be purchased from the original equipment manufacturer (OEM) and adequate inventory shall be maintained by ordering replacements in a timely manner.

Planned preventative maintenance (PPM) schedules are important to follow per the manufacturer's service manual, especially for gas-based systems. Annual general equipment inspections should be performed routinely by the clinical engineering staff to detect any impending problems, such as cracked gauge faces, dry-rotted tubing and hoses, if any leaks are discovered, O-rings or washers in the joint are to be replaced. For the handheld units, maintenance should be performed regularly based on manufacturer's recommendation. Lack of maintenance can affect the performance of the device.

Specific to gas-based systems, cylinders must be stored appropriately and below 30°C, clearly identified from other gases, and when used, done so in well-ventilated areas. It is very important to check all connections and joints for leaks after turning on the cylinder valve. If a cylinder falls over or if the valve is otherwise damaged or broken, it can turn the cylinder into a dangerous projectile because of contents under pressure, which can cause extensive damage, serious injury and even death.[16]

The cylinders themselves must undergo hydrostatic testing every 10 years;[17] the purchaser of gases should ensure that their supplier carries out the requisite maintenance of equipment. Such maintenance tasks require specialized personnel and are not recommended to be performed in the hospital due to safety concerns.

Planned preventative maintenance (PPM) schedules are important to follow per the manufacturer's service manual, especially for gas-based systems.

6.6. 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 manfactured 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, infrastrucutre, 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 malfunction or failure. Post-market surveillance typically consists of complaint handling by end-users when an issue is detected. When information is made known to the product manufacturer, they must determine if the risks have increased and whether the benefits of the product outweigh the harms or risks. Any field safety corrective actions, such as a recall or change to the product (including labelling), are notified by the manufacturer through a field safety notice. National regulatory agencies / authorities (NRA) will also conduct their own market surveillance and oversee the manufacturer's investigation of 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.[18]

6.7. Standards and regulatory compliance

A specific international reference standard (e.g. ISO) does not exist for cryosurgical units; however, the following standards categories apply:

- Medical device quality, performance, operations, and safety: ISO 13485, ISO 14971, ISO 15223-1 (See Chapter 6.8 and Annex 6)
- Biocompatibility: ISO 10993, all applicable parts (See Chapter 6.8 and Annex 6)
- Electrical safety: IEC 60601, all applicable parts (See Chapter 6.8 and Annex 6)
- High-pressure gases: ISO 21969, all applicable parts, (See Chapter 6.8 and Annex 6)

It is important to observe all applicable local laws related to medical devices and their procurement. In the absence of a regulatory agency, it is strongly recommended to consider which regulatory and/or normative body assessment was completed for each product prior to procurement decisions. The risk class depends mainly on the regulatory framework of a country and therefore it may differ according to jurisdiction. For more details regarding other regional regulations and standards, see the specifications table in Chapter 6.8 and in Annex 6.

It is important to observe all applicable local laws related to medical devices and their procurement.

6.8. Key tender/request for quotation specifications for a cryotherapy device

Following are the key features that may be noted in a tender or request for quotation; detailed standardized WHO technical specifications can be found in Annex 6.

Product description	A cryosurgical unit, either a console or hand-held, is used to destroy cervical tissue with abnormal cell growth. It comprises a gas or electrically-cooled cryoprobe, capable of reaching temperatures colder than -68°C.
Key product features	• Cryosystems include a hand-held unit with use-specific cryotips: » Minimum of 2 cryotips are required: * One cryotip must be flat; * The second cryotip can be either flat or can have a gentle nipple extrusion not exceeding 5mm (so as to anchor in centre of cervix but not to ablate endocervix); * Cryotip diameters ranging from 17 mm to 23 mm; * Biocompatible, material that will not adhere to cervix; * Reusable and thus de-contaminable. • The overall length of the cryoshaft and cryotip assembly should be between 170 and 200 mm; • Temperature at probe edge shall be capable of reaching less than -20 °C; • If gas-cooled, either carbon dioxide (CO_2) or nitrous oxide (N_2O) is used; • If electrically-cooled, an ethanol-based solution and electricity are necessary.
Components, accessories, consumables	For gas systems: • cryosystems include a hand-held unit (comprising a cryotip, shaft, trigger and handle), connector/pressure gauge assembly (hose, pressure release valve, pressure gauge, exhaust port and connector to the cylinder), and gas supply. For electric systems: cryotips, a hand-held device, all requisite accessories to cool the tip.

Operational requirements	• Temperature: 10-40°C; • Relative humidity: ≤85%, non-condensing; • (Storage temperature: -20 to +60°C or greater (?), storage relative humidity: 0-80%, non-condensing); • Electrically-cooled cryosystems require reliable electrical power supply (based on country/ setting of use): » Amperage: _____ » Voltage: _____ » Plug type: _____ .
Documentation requirements	• Instructions for use and service manuals to be provided. • User language preference prioritized, otherwise English is mandatory.
Warranty	Minimum one year
Standards	Following with active version of the standards listed below (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. Safety and product standards for *electrically-cooled systems*: • 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. Safety and product standards for *gas-based systems*: • ISO 21969 High-pressure flexible connections for use with medical gas systems. Probe-specific requirements: • ISO 10993-1: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process; • ISO 10993-5: Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity; • ISO 10993-10: Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization.

Regulations	Compliance with (where applicable, but not limited to): • Local national regulatory agency requirements compliance • Approval by regulatory body of country of manufacturer (if applicable). And at least one of: • United States regulations: US FDA : Device Class II • European regulatory framework: » Council Directive 93/42/EEC of 14 June 1993 on Medical Devices (Class IIb); » Regulation (EU) 2017/745 of the European Parliament and the Council; » Manufacturer must affix the CE marking and indicate the Notified Body number on the label and in the device, when possible. • Other regulatory body in an IMDRF founding member country such as Australia, Canada, or Japan.

Chapter 6 references

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Section 2 – Treatment technologies

Chapter 7: Technical guidance and specifications for ESUs used in LLETZ

Brief description

The LLETZ, or LEEP, can use typical ESUs; General requirements of an ESU:

- Minimum 1 monopolar handpiece port, 1 monopolar return electrode port (with alarm for poor contact quality), 1 bipolar outlet;
- Different and adjustable current modes: coagulation mode (up to 80 W / 150 Ω), cutting mode (up to 110 - 200 W / 300 -400 Ω), and blended current mode;
- Hand or foot switch to activate different electrodes or settings.

LLETZ-specific minimum requirement: 1 monopolar outlet, 1 monopolar return electrode; blended current option, and must cover the following power output ranges that can be selected by the user:

- coagulation 30 - 50 W
- cutting 30 - 50 W.

Electrodes: wired, in various sizes and shapes; comes with a minimum: ball electrode (3mm or 5mm), square loop electrode (smaller size), semicircular loop electrode (larger size); and, a ground plate.

ESUs are powered by electricity. It is recommended to use a continuous power supply along with voltage stabilization to avoid interruption during treatment. Battery powered ESUs are available, can be portable, and appropriate for use in rural settings with appropriately qualified staff.

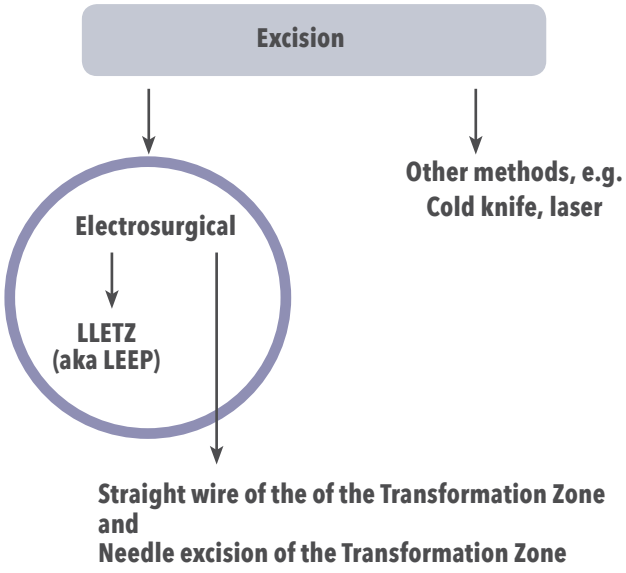
7.1. Scope of chapter

This chapter defines technical specifications for an electrosurgical unit (ESU) for Large Loop Excision of the Transformation Zone (LLETZ), also known as Loop Electrosurgical Excision Procedure (LEEP), and provides details for other important equipment to perform a successful LLETZ procedure.

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

Content herein focuses on present state of practice using up-to-date available technologies.

(adapted from algorithm provided by W. Prendiville)



7.2. Background for ESU and LLETZ

The passage of electricity to and through tissue produces heat. Faraday discovered that at a very high frequency (> 100 kHz), doing so does not contract muscle tissue. ESUs were subsequently developed to perform the safe passage of electricity through the human body in controlled circuits, and to use the localized point-of-contact effect – the heat – for medical purposes. Electrosurgery has been used for more than a century, for many types of surgical procedures, for both cutting and coagulating tissue. The technology's haemostatic effect makes ESUs useful for procedures on organs rife with capillary beds such as the liver, spleen, thyroid, and the lungs.[1]

The passage of electricity to and through tissue produces heat. Faraday discovered that at a very high frequency (> 100 kHz), doing so does not contract muscle tissue.

There are two types of output modes for clinical use: monopolar and bipolar. The prefixes mono- and bi- refer to the number of active electrodes. In monopolar electrosurgery, an active electrode carries current to the tissue, which is then spread through the body, then collected and returned to the ESU by a ground/neutral plate electrode.[2] In bipolar mode, both electrodes are high-density power and are situated across from each other. Bipolar electrosurgery is primarily used to coagulate tissue.

ESUs are programmed to deliver power in watts, defined as the rate which energy is used and commercially billed to the users.

LLETZ was developed in Bristol, United Kingdom, in 1986 using a low-voltage across a loop of thin wire, usually blending diathermy currents to enable both cutting and coagulation, under local anaesthesia. The process is also known as LEEP.[3] LLETZ is the removal of abnormal areas from the cervix, using a loop made of thin wire heated with electricity. It may be performed at the first patient visit after screening, and has been well recognized as a standard practice to treat CIN. The procedure can be performed on an outpatient basis and usually takes 10-15 minutes; however, a patient should stay in-facility for a few hours if at risk of bleeding.

Table 12 lists equipment and supplies required by highly skilled personnel to perform a successful LLETZ.

Table 12: Required equipment to perform a LLETZ procedure

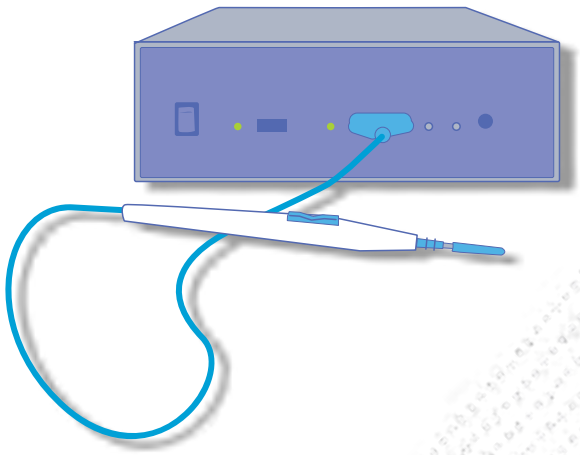
- Electrosurgical unit:
  - » Current generator
  - » Electrode(s)
- Colposcope
- Speculum, preferably with side retractors
- Smoke evacuation device
- Forceps
- 5 ml syringes with a long 23-27-gauge needle (such as dental or spinal needle)
- Suture kit: Needles, sutures, and other requisite material
- Specimen containers
- Medical adhesive

7.2.1. Electrosurgical unit

An ESU converts low-frequency alternating current (AC) into higher voltage radiofrequency (RF) output. It has a broad application and is commonly used in many different surgeries, including dermatological, gynaecological and cardiac procedures, among many others.

A general, non-LLETZ-specific ESU has been described herein should the healthcare facility wish to use a the device for other types of surgical procedures. However, because LLETZ only requires some functionalities provided by an ESU, the minimum device requirements for a successful LLETZ are specified to ensure that these are covered by the device functionality. For example, LLETZ only requires monopolar electrosurgery, and the requisite current is lower than that used for some other procedures.

Figure 15: Image of a standard ESU



7.2.1.1. General ESU

This Chapter discusses the basic mechanism and specifications of ESU used in health care facilities.

This Chapter discusses the basic mechanism and specifications of ESU used in health care facilities.

The face of an ESU is a control panel for adjusting and displaying settings, including the main power switch (ON/OFF), a power indication light, electrode (monopolar, bipolar and ground plate) ports, mode selection (mono- or bipolar), operating mode selection (RF for coagulation or cutting), and blended operating mode (if option available). There may be other indications, including: low battery light, charging indication, charger input, and ground plate displace warning light in more advanced or portable equipment. The ESU is usually operated by a foot pedal (the user activates the electrode by foot), allowing full freedom of hands with the electrodes themselves to carry out the procedure.

It is crucial for the ESU to be able to generate current at a RF range from 200,000 -500,000 Hz, which will allow for desired thermal effects without muscle contraction or nerve stimulation.

There are two main current modes: coagulation and cutting. In the coagulation mode, an interrupted or low-current (up to 80 W) /high-voltage waveform is generated. This output denatures the protein and leads to a homogenous thermal coagulum. During cutting mode, a high-current (up to 110-200 W) /low-voltage waveform is generated. This output rapidly vaporizes the tissue and produces a clean incision with haemostasis or minimal bleeding.[4]

There is usually a 'blend current' option to generate a current combining both types of current, in a variety of combinations (e.g., blend 1, blend 2, blend 3) that can be set by the user.

Some ESUs have a resistance recognition system, a contact quality monitor (CQM) in the ground plate circuitry in order to support clinicians when poor contact with the ground plate (return electrode) is detected; some CQMs can cut the electric current if there is no longer good contact between the ground plate and patient body. Typically, these ground plates are split, where an even flow of current is necessary through both (which will indicate good contact) to enable electricity to pass around the circuit. An alarm in all CQMs warns the operator if contact is poor.[5]

7.2.1.2. Minimal requirement of ESU to be used for LLETZ procedures

There are some specific requirements of standard ESUs that are necessary for a successful LLETZ, namely monopolar mode, the option for blended current, and a CQM.

There are some specific requirements of standard ESUs that are necessary for a successful LLETZ, namely monopolar mode, the option for blended current, and a CQM.

For LLETZ, electrical current passes from the ESU through an electrode (a loop) to the tissue, and then through the body to the return electrode (ground plate) and ultimately back to the ESU. Hence, the unit must have the monopolar mode with one hand piece port and one return (ground plate) electrode port as a minimum.

LLETZ uses 30-50 watts of coagulation and cutting, hence the ESU must be able to cover that range. A blended current option is highly recommended as it is usually used in the procedure with about 20% coagulation and 80% cutting for optimal effect.[6] Blended current enables the simultaneous cutting through tissue and achieving relative haemostasis of the stromal vessels, without inflicting significant damage on the biopsy specimen or the cervical wound left behind.

For patient safety and to decrease burn risk, it is recommended to have a CQM with an in-built alarm.

7.2.2. Electrodes

Two different types of electrodes are used for LLETZ: a hand-piece electrode and a ground plate (return electrode).

7.2.2.1. Hand-piece electrode

Electrodes are usually made of stainless steel or tungsten wire. Loops of different sizes and shapes are used for taking diagnostic biopsies. At a minimum, two loop sizes (specific sizes determined by the manufacturer, generally one small and one large), as well as a ball electrode (see Figure 13) are required, for example:

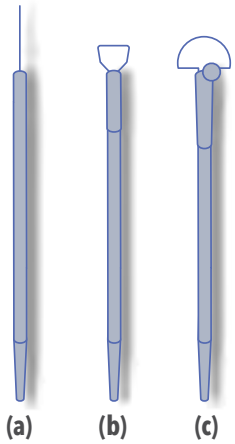
Electrodes are usually made of stainless steel or tungsten wire.

- Small electrode: 15mm x 5 mm deep, generally used for small lesions in nulliparous women;
- Larger electrode: 20mm x 8 mm deep, generally used for larger lesions and multiparous women;
- Ball electrodes: 3mm or 5mm, generally used to achieve haemostasis after excision of the transformation zone or to seal a biopsy site.

Electrodes can be single-use or reusable. For more details, refer to WHO guideline Comprehensive Cervical Cancer Control: a guide to essential practice for more procedure instructions.[7]

Proper decontamination is required for reusable electrodes after each use. See Chapter 7.5.2.

Figure 16: Different types and sizes of el ectrodes

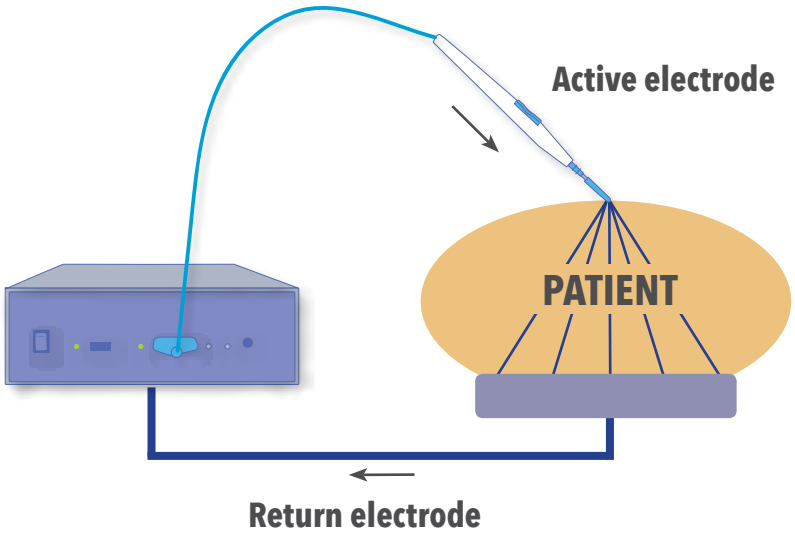


(a) ball electrode
(b) square loop electrode
(c) semicircular loop electrode

7.2.2.2. Ground plate (Return electrode)

Ground plate (also known as neutral electrode, return electrode, or dispersive pad) is the electrode that attaches to the patient and functions by closing the circuit, returning the current back to the ESU. The ground plate itself is usually affixed with a medical adhesive, and the plate is usually reusable. The ground plate should be positioned relatively close to the point of contact; for LLETZ, a convenient and appropriate position is under the patient's buttocks (see Figure 14). It ensures complete contact and reduces the risk of burn injury.

Figure 17: Illustration of the electrical current flowing in a monopolar ESU



7.3. Other equipment used in LLETZ

Other equipment used in LLETZ are briefly discussed here, including power supply and smoke evacuation device. Colposcopes are discussed in Chapter 4 (specifications Annex 4), and specula in Chapter 1. In addition, the use of a light source of at least 100W or 100W-LED equivalent, and/or a magnification lamp should be used to improve visualization during the procedure. It is recommended that any such light source provide the white light spectrum, similar to daylight. Yellow, tungsten-based light sources should be avoided if possible.[8]

Other equipment used in LLETZ are briefly discussed here, including power supply and smoke evacuation device.

7.3.1. Power supply

Consideration of power supply is important when using ESUs. To ensure patient safety, it is important to connect the ESU unit to a continuous, reliable power supply. In addition to the mains or generator, an uninterruptible power supply (UPS) can act as a holdover power source to complete a procedure in the event of a power loss.

Some manufacturers equip ESUs with a battery to increase its portability. Procurement of such devices does not preclude the need for electricity for charging. In addition, there are several other factors to be considered for battery powered ESUs to meet contextual need, including battery specifications (cell type, capacity, voltage), charge and discharge specifications, service life (how many approximate charge cycles), safety features and reliability.[9]

If a device with battery power is procured, the user should have access to battery replacements as the batteries might not last the entire life span of the device. The user should refer to manufacturer's instructions regarding storage and operation instructions.

7.3.2. Smoke evacuation

Electrosurgery produces harmful chemical and biological by-products in the vaporized tissue plume, which can be carcinogenic.[10] Thus, this vaporized tissue plume should be evacuated for all procedures by using a smoke evacuation system. Depending on the amount of plume that may be produced during the procedure, or depending on facility infrastructure and available resources, there are different systems that can be used.

Electrosurgery produces harmful chemical and biological by-products in the vaporized tissue plume, which can be carcinogenic .

During LLETZ, a dense smoke plume is created within the confined space of the vaginal canal. In addition to the aforementioned carcinogenic potential that can be harmful to clinicians, this plume blocks visual sight of the cervix, which could impede work. It is strongly recommended to use a smoke evacuator or a simple suction device. Some ESUs have smoke evacuators built into the system, providing an integrated clinical flow; however, these units are more expensive. If simple suction is used, the suction tubing is usually attached to the speculum to keep the operative area clear by evacuating the smoke to external and internal filters.[11]

Health facilities should choose the smoke evacuation system based on local needs and budget.

7.4. Handling and use

7.4.1. General safety precautions when using ESUs

In some cases, the current can cause local burns; any metal jewellery worn by the patient must be removed prior to an ESU procedure.[106] It is important to check for implanted electrical devices (IEDs) prior to electrosurgery. IEDs, such as cardiac pacemakers, ventricular assist devices, and neurologic stimulators, can be interrupted or damaged by the current generated by ESUs. It is recommended to avoid monopolar electrosurgery on patients with IEDs. For patients with an IED who require electrosurgery, the IED-related expert (such as cardiologist or neurologist, etc.) must be consulted prior to procedure, the electrode should be applied as far as possible from the IED, the use of capacity-coupled return electrodes should be avoided, and good contact of the ground plate is to be ensured.

Do not use the device in the presence of flammable anaesthetics or oxidizing gases (such as nitrous oxide or oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as an explosion may occur.

Do not place instruments near or in contact with flammable materials (such as gauze or surgical drapes).

7.4.2. Additional safety precautions for LLETZ

LLETZ uses monopolar electrosurgery and therefore needs a ground plate for the electricity to return to the ESU after achieving its effect at the point of contact between the loop and the tissue. If there is poor ground plate contact, an injury can occur if the current finds an easier pathway to return to ground. Examples of such sites are the metal stirrups of some gynaecological couches, jewellery, or other metal body adornments. However, if the ground plate is large and in good contact with the skin, the aforementioned is unlikely to cause injury.

During the procedure, it is possible to injure the vaginal wall and tissues immediately adjacent to it. The loop should be moved slowly through the cervix underneath the transformation zone; it should not bend during the process. If it does that means the operator is pushing it too quickly, and the electrosurgical effect changes from fulgurative to desiccative.

It is not recommended to use insulated specula as a poorly insulated speculum is likely to cause more damage than an uninsulated speculum.

7.5. Operational considerations

7.5.1. How ESUs are used for LLETZ

All equipment should be fit for the intended purpose of treating precancerous cervical lesions. Each unit should be accompanied by training materials specifying basic operation of all components, assembling the equipment, risk of use, and maintenance.

All equipment should be fit for the intended purpose of treating precancerous cervical lesions.

Appropriate clinical training should be provided in advance of using ESUs. Clinical guidelines on the use of equipment are available in the WHO's WHO's Comprehensive Cervical Cancer Control: a guide to essential practice.[7]

Training videos have been developed by WHO IARC , the related to this content is: Colposcopy and treatment of cervical intraepithelial neoplasia, a beginners manual, specifically Chapter 14. Treatment of cervical intraepithelial neoplasia by Loop Electrosurgical Excision Procedure (LEEP), which can be viewed at: https://screening.iarc.fr/colpochap.php?lang=1&chap=13.php

7.5.2. Decontamination and reprocessing

Health care-associated infections (HAI) are one of the most common adverse events in health care 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) programme[13], 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[14] 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 not to cause any damage and ensure proper decontamination.

Proper sterilization and post-sterilization handling are required for all electrodes for infection prevention and control. All equipment and accessories in direct contact with the patient must be decontaminated, cleaned, and then either sterilized or disinfected, using a high-level disinfectant (HLD). The rest of the device is to be cleaned and/or disinfected; solutions for cleaning and disinfection need to be used according to the manufacturer's instructions as their specified disinfectant exposure time must be observed. Other tools and materials used for LLETZ (for example specula) should be cleaned and disinfected between patients.

7.5.3. 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.[15]

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

7.5.4. 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 and warnings.

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 on a shelf or on 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 premature material disintegration.

However, in general, these devices should be able to withstand storage temperatures ranging from 15°C to 40°C, relative humidity ≤ 60% (non-condensing), and be protected from dripping water.

7.5.5. Maintenance

There are PPM requirements for ESU devices. Typical maintenance includes checking integrity of mounts, plug, cord and external circuits; verification of the connection of dispersive electrodes, proper operation of controls and switches; checking for any current leakage from chassis or electrodes; verify and document output waveform characteristics on the ESU analyser (if possible). These activities should be outlined in the service manual and shall be carried out by clinical engineering professionals. Suppliers should provide a warranty of at least two years.

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

Post-market surveillance is an obligation of the 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 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.[16]

7.7. Standards and regulatory compliance

There do not exist specific industry reference standards (e.g. ISO) for electrosurgical units (ESUs); however, the following standards categories apply:

- Medical device quality, performance, operations, and safety: ISO 13485, ISO 14971, ISO 15223-1 (See Chapter 7.8 and Annex 7);
- Biocompatibility: ISO 10993, all applicable parts (See Chapter 7.8 and Annex 7);
- Electrical safety: IEC 60601, all applicable parts (See Chapter 7.8 and Annex 7);
- Secondary cells (batteries): IEC 62133, parts 1 and 2 – if applicable (See Chapter 7.8 and Annex 7).

It is important to observe all applicable local laws related to medical devices and their procurement. In absence of a regulatory agency, it is strongly recommended to consider which regulatory and/or normative body assessment was completed for each product prior to procurement decisions The risk class depends mainly on the regulatory frameworkof a country and therefore, it may differ according to jurisdiction. For more details with regard to other regional regulations and standards, see the specifications table in Chapter 7.8 and in Annex 7.

7.8. Key tender/request for quotation specifications for an ESU for LLETZ

Following are the key features that may be noted in a tender or request for quotation; detailed standardized WHO technical specifications can be found in Annex 7.

Product description	Electrosurgical units (ESUs) are used to carry out LLETZ (LEEP) procedures with the safe passage of electricity at a high frequency to and through tissue for both cutting (with wire electrodes) and coagulating (with ball electrodes). ESUs require highly-trained clinicians and are meant for use at higher-level health facilities.
Key product features	• Control panel for adjusting and displaying power settings; • Hand or foot switch to activate different electrodes or settings; • Minimum 1 monopolar handpiece port, 1 monopolar return electrode port (with alarm when poor contact quality), 1 bipolar outlet (bipolar not required for LLETZ); • Radiofrequency range from 200,000 Hz to 5,000,000 Hz. General ESU Modes: • coagulation mode: up to 80 W / 150 Ω • cutting mode: up to 110 - 200 W / 300 -400 Ω • blended current mode optional. LLETZ-specific setting: • blended current option mandatory • coagulation: 30 - 50 W settings available • cutting: 30 - 50 W settings available.
Components, accessories, consumables	Electrode: wired, various sizes and shapes, at a minimum has: • electrode (3-5mm ball) • square loop electrode (smaller) • semicircular loop electrode (larger); and • return electrode (typically a pad). A contact quality monitor (CQM) as an added feature, with either alarm or current shut-off, is highly recommended for patient safety.

Operational requirements	• Temperature: 5-40°C; • Relative humidity: ≤85% non-condensing; • The unit is suggested to be connected to a continuous, reliable power source (leverage surgical ward UPS); • Electrical source requirements (based on country/setting of use): » Amperage: _____ » Voltage: _____ » Plug type: _____ .
Documentation requirements	• Instructions for use and service manuals to be provided • User language preference prioritized, otherwise English is mandatory.
Warranty	Minimum one year.
Standards	Compliant with active version of the following standards (or equivalent): General • ISO 13485: Medical Devices - Quality Management Systems; • 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; Specific • ISO 10993-1: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process; • ISO 10993-5: Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity; • ISO 10993-10: Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization; • ISO 13402: Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion and thermal exposure. Safety and 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; • IEC 60601-2-2: Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories. If battery-powered: • IEC 62133: Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells: » Part 1: Nickel » Part 2: Lithium.

Regulations	Compliance to (where applicable, but not limited to): • NRA requirements compliance • Approval by regulatory body of country of manufacturer (if applicable). • And at least one of: • United States regulations: US FDA 510(k): Device Class 2; • European regulatory framework: » Council Directive 93/42/EEC of 14 June 1993 on Medical Devices (Class IIb); » Regulation (EU) 2017/745 of the European Parliament and the Council; » Manufacturer must affix the CE marking and indicate the Notified Body number on the label and in the device. • Other regulatory body in an IMDRF founding member country such as Australia, Canada, or Japan.

Chapter 7 references

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Section 3 – Procurement Guidance and further research

Chapter 8: Procurement guidance for medical devices

There are a number of medical devices and IVDs (devices, herein) on the market for the diagnosis and treatment of precancerous lesions for the prevention of cervical cancer, but not all of them are procured appropriately to match need of identified use-case.

Thus, key specifications that can be included in a tender in order to help managers and procurement personnel to purchase the correct product are described in each corresponding chapter; however, care should be taken to adapt contents to suit the needs of the end users if necessary.

In addition to outlining specifications, a request for supplemental information is also useful to include in a tender/request for quotation to aid in the decision making. Such information includes, but is not be limited to, the following:

- lead-time from receipt of contract/purchase order;
- method of shipment;
- shipping route;
- INCOTERMS (See details in Chapter 8.3);
- shipment/delivery costs, if applicable;
- weight and dimension of shipment;
- validity of quotation;
- payment terms;
- general and any special terms and conditions that will appear on the contract and/or the purchase order;
- evidence of ISO compliance when applicable;
- copy of regulatory approvals/clearances (e.g. US FDA, CE, or other acceptable SRAs; and,
- copy of proof of registration in the country of import.

Once a tender is awarded, it is important that the purchaser to obtain necessary documents in order to facilitate the movement of commodities or devices and to clear customs in an expeditious manner as possible. The following information and documentation should be obtained, as a minimum, in advance:

- delivery date;
- copy of the certificate of origin;
- copy of the certificate of conformity;
- commercial invoice;
- final transportation documents (waybill).

It is also important to note that countries who have not historically regulated medical devices are moving in this direction It is becoming increasingly common for aspects of regulation to be in place, and very likely that both the device manufacturer as well as make and model of specific devices must be registered in order for importation to take place.

In the absence of a registered product/manufacturer, an importer can often work with the Ministry of Health to apply for an import waiver. However, import waivers are usually only issued on a per shipment basis, thus it is important to also work with manufacturers to ensure that they apply to the local regulatory authority (or body responsible) in order to become registered for future procurements. In some countries, the registration process can take from one to three years; the earlier the manufacturer applies, the better, to ensure entrance of the shipment to the recipient country.

8.1. Nomenclature

The nomenclature, or naming system, of medical devices is used to generically identify medical devices and related health products. Nomenclature is a crosscutting system that can support medical devices at all levels: manufacturers, regulators, in procurement, and for final users in hospitals (stock management, post-market feedback loops, etc.).

Having a nomenclature system in place for medical devices can help to facilitate their management and regulation by standardizing terms, facilitating clear communication across all levels. With over 10,000 types of commercialized medical devices available, procurement decisions are often complicated by the lack of standardization of description of functionality of devices.

There are three main components to nomenclature: classification, nomenclature, and coding. If appropriately developed, these collective aspects of nomenclature can overcome linguistic barriers.

Classification or categorization is the grouping of all products in a logical, hierarchical manner. Devices share properties, enabling relationships, and it is important that these are appropriately mapped out by considering function, applications, operation principles, type of use, material and other properties, etc.

Nomenclature is the term given to and description of a type of product. This follows the classification and associated set of rules and criteria. It is important that these are clear, concise, and generic so as to avoid confusion and maintain agnosticism.

Coding is the process of assigning a unique identifier, or code, to each term of the classification and nomenclature system. Coding supports classification, such that hierarchy and relationships are evident in any type of medical device code.

A robust, well-utilized nomenclature system can simplify asset management in facilities: functional inventories, product availability, and the monitoring and evaluation of devices. Further, nomenclature can accelerate the regulatory process, support registration for market approval, and enhance post-market surveillance by tracking usage and enabling follow-up.

Globally, there are multiple classification, coding, and nomenclature systems which are often proprietary. To date, most international organizations and even UN agencies use varying systems. These systems are non-harmonized, which makes it very difficult to cross-map, thus rendering the full potential of such a system unachievable. Multiple, parallel systems complicate standards and regulatory processes, add unnecessary layers or challenges in procurement and supply, make for inefficient stock-keeping for and thus maintenance of devices more disorganized, hinder the reporting of adverse events and associated recalls related to faulty medical devices or malfunctions.

Globally, there are multiple classification, coding, and nomenclature systems which are often proprietary.

WHO has been working to develop the International classification, coding and nomenclature system of Medical Devices which leverages WHO's International Classification of Disease hierarchy, relationship, and classification platform (Active at time of publication: ICD-11). A code for each of the devices in this book will be found in this nomenclature, which will be further developed in the near future. The benefit is that this new WHO nomenclature will be open source and can be used by manufacturers, regulators, procurers, and even inventories in hospitals free of charge.

8.2. Incoterms

There are standard International Commercial Terms, known widely as "Incoterms®", which have been developed and trademarked by the International Chamber of Commerce (ICC). Incoterms are a suite of pre-defined terms, widely used in global commercial transactions. The use of Incoterms is encouraged by trade councils, courts, and international lawyers as they take into consideration international commercial law, and help to simplify the movement of goods in what is otherwise a very grey area.

With any international procurement, Incoterms can help to delineate tasks borne by seller and buyer with respect to transaction obligations (e.g. transport and delivery), and with whom lie risks and costs at every step of the way, including highlighting at which point the responsibility shifts from seller to buyer. Using Incoterms helps to clarify, for example, who is paying customs clearance charges, import duties and taxes, final delivery costs, etc.

As the terms themselves are so widely known and accepted, they are regularly incorporated into a purchase order and subsequently a sales contract; however, they are not themselves a contract, they do not themselves determine prices, currency rates, or override any local law.

There are standard International Commercial Terms, known widely as "Incoterms®", which have been developed and trademarked by the International Chamber of Commerce (ICC).

At time of publication, current terms were Incoterms 2010; however, ICC has already started drafting Incoterms 2020. For further information, please visit the ICC's website where Incoterms 2010 rules can be found, along with detailed guidance: https://iccwbo.org/resources-for-business/incoterms-rules/

8.3. Donations

Donations of medical equipment can be very helpful in bridging inequity between technologies produced by the global healthcare innovation community and users in low resource settings. However, if poorly executed, donations can turn into a burden for the recipient, wasting an enormous amount of money, human resources and time.

Donations must be seen as a standard procurement. The only deviation relates to the initial financial transaction, where cost is borne by the donor. Factors that will enable a successful medical donation include, but are not limited to:

- A partnership between donor and recipient
- An understanding of and appreciation for the challenges of the recipient's context
- Inventory to identify gaps in priority medical equipment so as to not procure blindly.

The recipient can then better plan for:

- Short- and longer-term integration of new equipment such as:
    - » Immediate need for infrastructure to support donations
    - » Needs for necessary accessories, spare parts and consumables
    - » Capacity building programs for end-users and clinical engineering staff.

- Tracking and monitoring of donations for:
    - » Follow-up issues as they relate to safety (post-market surveillance)
    - » Quantification of impact of donations.

For more information, please refer to WHO's Medical device donations: considerations for solicitation and provision.

Section 3 – Procurement Guidance and further research

Chapter 9: For further research

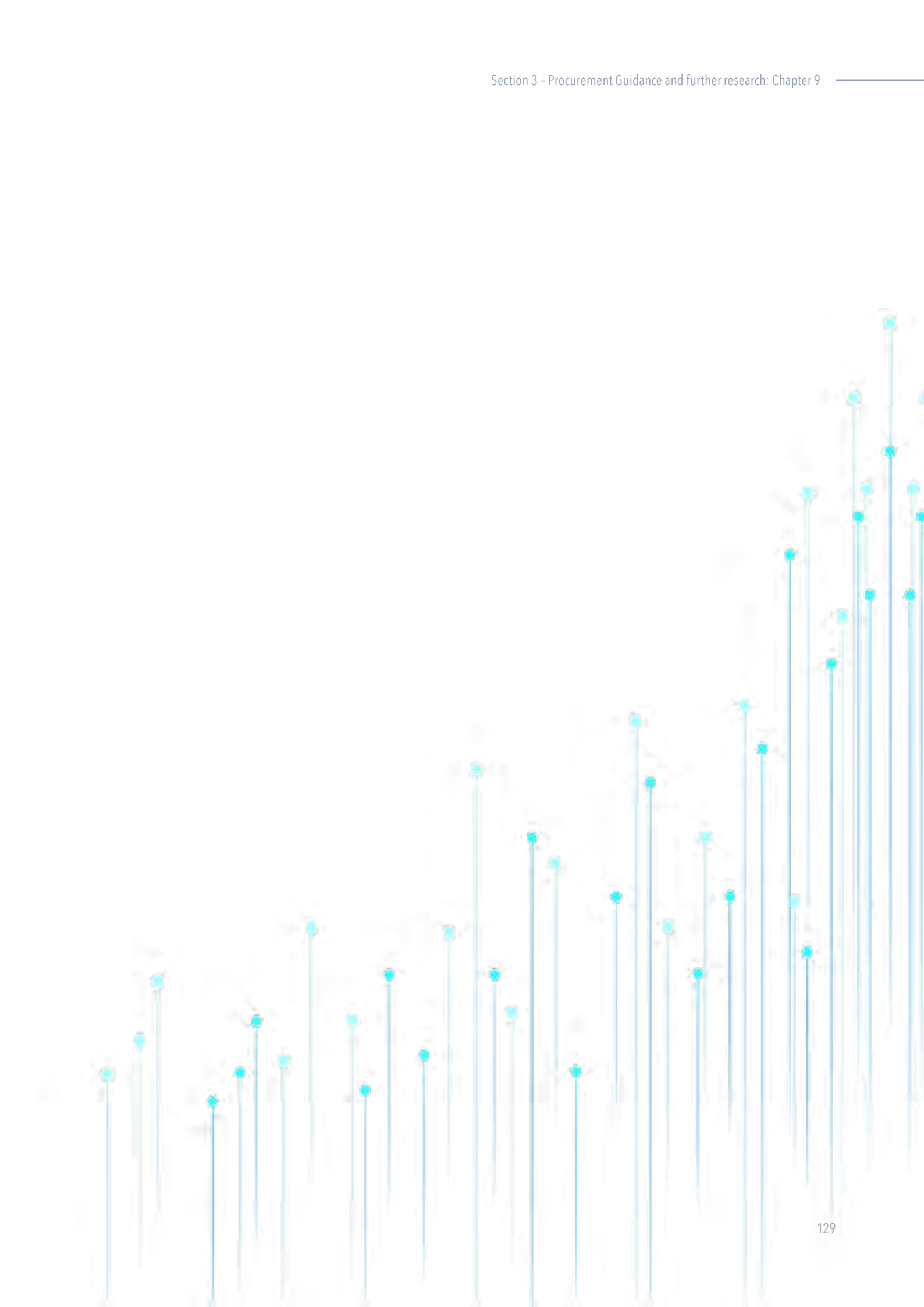
Technical specifications play a vital role in procuring affordable, high quality and appropriate medical devices and IVDs (devices, herein) for the diagnosis and treatment of precancerous lesions for the prevention of invasive cervical cancer. Stakeholder collaboration can ensure that the most effective and robust equipment is available. In collaboration with PATH and the Clinton Health Access Initiative (CHAI), WHO has gathered internal and external experts to determine and develop technical specifications. The challenges faced during this process were:

- discrepancies among existing standards and professional association guidelines
- lack of international standards for certain health technologies
- making unbiased optimal recommendations in a smaller market with limited vendors.

Some manufacturers from low-income countries find it difficult to comply with ISO, one of the most used international standards, as they are not publicly available and are not free of charge. It is difficult for manufacturers in these countries to make affordable devices for health facilities in low-resource settings while following these standards. However, quality and safety must never be sacrificed in order to lower development costs. Thus, careful consideration should be given when deciding not to apply a specific standard.

Quality and safety must never be sacrificed in order to lower development costs.

Research of innovative applications using medical devices plus artificial intelligence to support diagnostics and the appropriate methods to assess, regulate and use these devices remains a challenge and further studies need to be conducted.



Section 4

Annexes: technical specifications

Annex 1
Technical Specifications for specula for "screen & treat"

MEDICAL DEVICE SPECIFICATION (including information on the following where relevant/appropriate, but not limited to)			
i	**Version No.**	**1**	
ii	**Date of initial version**	**December 2019**	
iii	**Date of last modification**		
iv	**Date of publication**	**February 2020**	
v	**Completed / submitted by**	**WHO**	
NAME, CATEGORY AND CODING			
1	WHO Category / Code	Speculum, vaginal: XD9478	Speculum, vaginal, reusable: XD1KF1
2	Generic name	Speculum, vaginal	
3	Specific type or variation (optional)	Vaginal speculum, bivalved	
12	Keywords (optional)	surgical, gynaecology, vaginal exam	

PURPOSE OF USE		
14	Clinical or other purpose	A vaginal speculum is a device intended to open the vaginal canal to enable a healthcare provider to visually inspect the cervix and collect vaginal or cervical specimens and/or perform surgical operations in a woman's lower genital tract.
15	Level of use (if relevant)	Hospital, clinic, or health post
16	Clinical department/ward (if relevant)	Family medicine; gynaecology; obstetrics; outpatient clinic; outreach.
17	Overview of functional requirements	Bivalved vaginal specula have two blades that are self-retaining to facilitate visualization of the cervix for observation, testing, or to carry out a procedure.

TECHNICAL CHARACTERISTICS		
18	Detailed requirements	• Specify: reusable or single-use • Bivalved and self-retaining to maintain an open vaginal canal • To be available in a variety of sizes (large, medium, small, AND narrow e.g. Pedersen) • Type to be specified based on user preference or availability Example types and sizes: Collins: o Large – blade length: 110mm (+/- 5%), blade width: 40mm (+/- 5%). o Medium – blade length: 100mm(+/- 5%), blade width: 35mm (+/- 5%). o Small – blade length: 85mm(+/- 5%), blade width: 30mm (+/- 5%). Cusco: o Large – blade length: 11.5cm (+/- 5%), blade width: 3.5cm (+/- 5%). o Medium – blade length: 9.5cm (+/- 5%), blade width: 3.5cm (+/- 5%). o Small – blade length: 7.5cm (+/- 5%), blade width: 2cm (+/- 5%). Graves: o Large – blade length: 115mm (+/- 5%), blade width: 35mm (+/- 5%). o Medium – blade length: 95mm(+/- 5%), blade width: 35mm (+/- 5%). o Small – blade length: 75mm(+/- 5%), blade width: 20mm (+/- 5%). Pederson (narrower version of graves): o Large – blade length: 115mm (+/- 5%), blade width: 25mm (+/- 5%). o Medium – blade length: 95mm(+/- 5%), blade width: 22mm (+/- 5%). o Small – blade length: 75mm(+/- 5%), blade width: 13mm (+/- 5%). * More sizes and types available (e.g. larger, smaller, wider)
19	Displayed parameters	N/A
20	User adjustable settings	N/A
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	N/A
22	Mobility, portability (if relevant)	N/A

23	Raw Materials (if relevant)	Reusable: metal alloys (typically non-quenched, non-magnetic, austenitic stainless steel) and shall be autoclavable.	Single-use: high-strength plastic (for example acrylics) and are supplied as sterile.
PHYSICAL/CHEMICAL CHARACTERISTICS			
24	Electrical, water and/or gas supply (if relevant)	N/A	
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS			
25	Accessories (if relevant)	N/A	
26	Sterilization process for accessories (if relevant)	N/A	
27	Consumables / reagents (if relevant)	N/A	
28	Spare parts (if relevant)	N/A	
29	Other components (if relevant)	N/A	
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS			
30	Sterility status on delivery (if relevant)	Reusable: N/A	Single-use: sterile
31	Shelf life (if relevant)	N/A	

32	Transportation and storage (if relevant)	Storage area should be clean and dust-free, dry, cool, well-lit, ventilated and vermin-proof. Store device in original packaging on a shelf or on in a storage cabinet. Devices should be able to withstand storage temperatures ranging from 15°C to 30°C, relative humidity ≤ 85% (non-condensing), and be protected from dripping water.
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	Environmental conditions vary globally and can be extreme; however, the following are tenable: - Operating temperature: 15°C to 35°C - Operating relative humidity: ≤ 85%, non-condensing It is the responsibility of the procurement body to ensure that the manufacturer's recommended operation and storage conditions are respected. If the device requires that the operating and/or storage environment be climate-controlled, appropriate temperature and humidity control systems, including monitoring, should be applied to avoid premature material disintegration and/or device failure.
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements (if relevant)	N/A
36	Requirements for commissioning (if relevant)	N/A
37	Training of user/s (if relevant)	Clinical staff training in vaginal examinations and gynaecological procedures.
38	User care (if relevant)	N/A
WARRANTY AND MAINTENANCE		
39	Warranty	One year