

Model & Specification

Ultrasonic Surgical & Electrosurgical Energy Platform

Higher Precision, Easier Operation

Model	Description	Packing(BX)
UP710	Generator	1pc
CT-01	Cart	1pc
FS-U	Footswitch for ultrasonic surgical instrument	1pc
FS-D	Double-pedal footswitch for HF instrument	1pc
FS-S	Single-pedal footswitch for HF instrument	1pc




Advanced Compact

Integrated ultrasonic surgical and HF instruments free up more space in the OR and require less maintenance





One generator for multiple energy devices

Ultrasonic module




(Advanced) bipolar module+Plasma module






Monopolar module 1



Monopolar module 2



Advanced Accurate

Multiple intelligent algorithm achieves accurate result during the whole procedure

Plasma module

Instant Response, Precise Synchronization

1200W
High-Power
Instant Ignition

Reduce Ignition
Time by
80%*

*Compared to the industry-leading level

- Zero-Delay Activation, Prevents Tissue Tugging
- More Precise for Delicate Operations like Cutting and Coagulation
- Activates in Saline, More Convenient Self-Cleaning

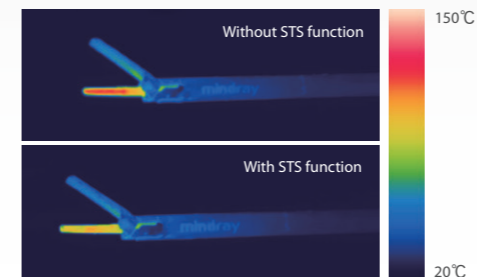
Ultrasonic Module

STS™ (Smart Tissue Sensing)

minimal thermal damage

Automatic reduction of output power after tissue disconnection means less risk of accidental scalding from ultrasonic surgical instrument.

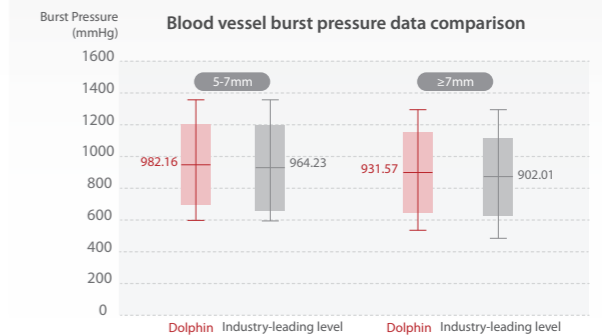
Comparison of Heat Maps of Forceps
(1 second after disconnection)



EVS™ (Enhanced Vessel Sealing)

safer sealing up to 7mm vessels

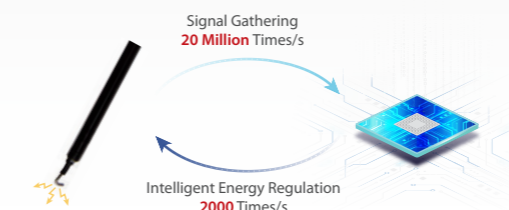
Precise output of energy based on the status of the blood vessel, providing firmer and safer 7mm vessel sealing.



HF Electrosurgical Module

Precise Energy Control Algorithm

Real-time precise energy regulation based on tissue characteristics ensures smooth cutting of different tissues with HF instrument.



Extraordinary Energy Compensation Algorithm

By compensating for transmission loss, the advanced algorithm ensures consistent energy delivery to tissues aligned with your settings, to eliminate attenuation over time.



**UP703/UP705/UP710/UP713/UP715/UP
Platinum**

**Ultrasonic Surgical & Electrosurgical
Energy Platform**

Operator's Manual



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- Release time: 2025-7
- Revision: 5.0

2.5 System Components

The system consists of the following components:

- A generator
- A transducer (optional)

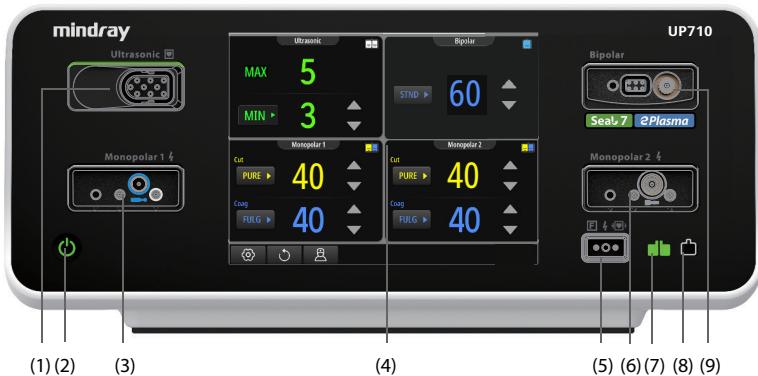
NOTE

- **Your product may not contain all of these components. For details about the availability of components, contact Mindray.**

2.5.1 UP710 Series Generator

UP710 series generator supplies electrical energy for ultrasonic assembly and bipolar instruments.

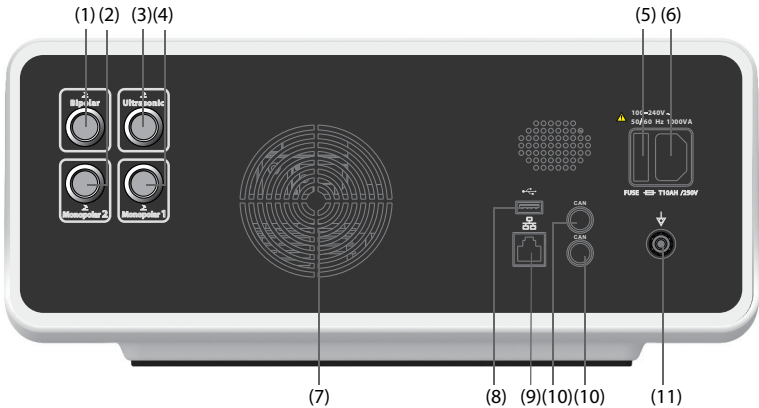
2.5.1.1 Front View of the Generator



- (1) Ultrasonic socket (applied part): connects a transducer.
- (2) Power switch: turns on or off the generator.
- (3) Monopolar socket 1 (applied part): connects a monopolar instrument.
- (4) Touchscreen: displays equipment status and changes settings.
- (5) Return electrode socket: connects a return electrode.
- (6) Monopolar socket 2 (applied part): connects a monopolar instrument.
- (7) Split return electrode indicator: indicates the connection status of the split return electrode. When the indicator is green, the split return electrode is properly connected.

- (8) Non-split return electrode indicator: indicates the connection status of the non-split return electrode. When the indicator is green, the non-split return electrode is properly connected.
- (9) Bipolar socket (applied part): connects a bipolar instrument.

2.5.1.2 Back View of the Generator



- (1) Bipolar footswitch socket: connects a single-pedal footswitch for the HF instrument to control the activation of the bipolar instrument, or connect a double-pedal footswitch for the HF instrument to control its right pedal (blue).
- (2) Monopolar footswitch socket: connects a double-pedal footswitch for the HF instrument to control the activation of the monopolar instrument attached to monopolar socket 2.
- (3) Ultrasonic footswitch socket: connects a footswitch for ultrasonic surgical instrument to control the activation of ultrasonic assembly.
- (4) Monopolar footswitch socket: connects a double-pedal footswitch for HF instrument to control the activation of monopolar instrument attached to monopolar socket 1.
- (5) Fuse holder: a compartment that keeps the fuse.
- (6) AC (Alternating Current) power input: connects the AC Mains.
- (7) Ventilation outlet: is used for heat dissipation.
- (8) USB connector: connects a USB drive for system upgrade.
- (9) Network connector: supports data transmission.
- (10) CAN (Controller Area Network) connector: connects external devices.
- (11) Equipotential grounding terminal: when using the equipment together with other devices, connect their equipotential grounding terminals together to eliminate potential difference.

2.7 Audio Indicators of the Generator

Audio Indicator	Volume	Remarks
Activation tone for coagulation mode of HF instrument	Lowest volume ≥ 45 dB(A) Highest volume ≥ 65 dB(A) (1m away from the rear of the generator)	The tone persists throughout the duration of activation.
Activation tone for cutting mode of HF instrument		
Activation tone for ultrasonic assembly		
Activation tone for electrode surgical instrument for Seal 7	≥ 45 dB(A) (1m away from the generator)	The tone persists throughout the duration of activation.
Coagulation success tone for electrode surgical instrument for Seal 7		/
Coagulation failure tone for electrode surgical instrument for Seal 7		
Information signals	Not higher than that of the system alarm of low priority	Simultaneously play the following tones: 365Hz \pm 5%, 730Hz \pm 5%, 1095Hz \pm 5%, 1460Hz \pm 5%, 1825Hz \pm 5% Last for 165 ms \pm 5%
System alarm tone	≥ 45 dB(A) (1m away from the generator)	This audio indicator complies with IEC 60601-1-8.
Return electrode alarm tone	≥ 65 dB(A) (1m away from the rear of the generator)	This audio indicator complies with IEC 60601-2-2 and IEC 60601-1-8.

CAUTION

- **The alarm tone is different from the prompt tone.**
- **Make sure that the volume of alarm tones and activation tones are adjusted to a level that can be clearly heard by the surgical team. For detailed setting methods, refer to 4.12 Setting Volume.**

- Surface of the equipment and peripheral devices have no signs of distortion, damage, or contamination.
- The coating of the blade is not peeled or damaged.
- The parts of surgical instruments that will be put inside the patient have no rough surface, sharp edges, or protrusions.
- No tissue residues are on the surgical instruments. All cords are intact and well routed.
- Connectors or plugs are not loose, distorted, damaged, contaminated, or blocked.
- All instruments and adapters are correctly connected and metal parts on connectors are not exposed.
- No irrelevant objects are on top of the equipment and the ventilation outlet is not covered by dust or other objects.
- No obstacles are in the movement range of the system or near the ventilation outlet.

CAUTION

- **If using instruments not specified by Mindray, check its compatibility and especially insulation performance. Make sure that the output voltage of the generator does not exceed the rated voltage of the instruments.**
-

4.4 Starting the System

Press the power switch on the front panel to turn on the generator. After startup, the power indicator changes from orange to green.

4.5 Check Before Operation

It is required to check and ensure that the system works properly. After turning on the system, check the following items:

- During startup, a normal startup tone is heard.
- The system self check passes and no alarm is generated.
- After startup, the indicator lights and the color is correct.
- The touchscreen displays correctly.
- The system does not emit abnormal noise, smell or excessive heat.
- Put a hand near the ventilation outlet and check that there is air flowing out.

CAUTION

- **Do not put the system into use before the system is checked and works normally.**
 - **In case of any failure, stop and remove equipment from use. Otherwise, injury to the patient or operator or damage to the equipment might result.**
-

4.6 Setting System Language At First Startup

When the equipment is started for the first time, the **General Setup** window is launched to help set the system language. Follow the procedure below:

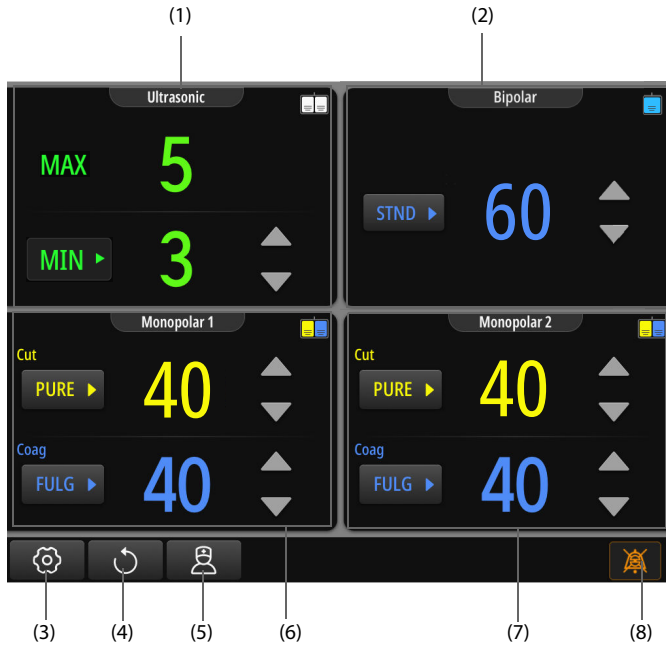
1. Select a target language, and press **OK**.
2. Press **Reboot** in the pop-up window. After the equipment is restarted, the setting takes effect.




In subsequent use, you can switch the system language by referring to *4.13.1 Setting System Language*.


4.7 Using the Touchscreen

The equipment is configured with a LCD touchscreen on which you can operate and set the equipment.

If all HF instruments and ultrasonic assembly are connected, the touchscreen display of the generator is as follows.



- (1) Ultrasonic area: Power levels in this area is highlighted if the ultrasonic assembly is connected. For detailed description, refer to 4.8.3 *Using Ultrasonic Assembly*.
- (2) Bipolar area: Power levels and modes in this area is highlighted if the bipolar instrument is connected. For detailed description, refer to 4.10.1 *Operation Area for Common Bipolar Instrument*.
- (3) Setup button  : select to display the setup menu.
- (4) Restore button  : selects to restore the latest HF instrument settings after restart.
- (5) Procedure button  : select to display the Procedure menu.
- (6) Monopolar area 1: Power levels and modes in this area is highlighted if the monopolar instrument is connected to the monopolar socket 1. The monopolar cutting area is highlighted in yellow, and the monopolar coagulation area is highlighted in blue. For detailed description, refer to 4.9.2 *Operation Area for Monopolar Instrument*.
- (7) Monopolar area 2: Power levels and modes in this area is highlighted if the monopolar instrument is connected to the monopolar socket 2. The monopolar cutting area is highlighted in yellow, and the monopolar coagulation area is highlighted in blue. For detailed description, refer to 4.9.2 *Operation Area for Monopolar Instrument*.

- (4) Neonate symbol: indicates that return electrode monitoring function for the neonate is enabled.
- (5) Power Level Decrease button ▼ : press to decrease the power level used by the monopolar instrument for cutting.
- (6) Footswitch symbol: indicates the status of the footswitch.  indicates that the footswitch is correctly connected.
- (7) Mode Setting button: selects the coagulation mode. If the monopolar coagulation mode is activated, the monopolar coagulation area shows a blue background.
- (8) Power level: displays the power level currently used by the monopolar instrument for coagulation.
- (9) Power Level Increase button ▲ : press to increase the power level used by the monopolar instrument for coagulation.
- (10) Power Level Decrease button ▼ : press to decrease the power level used by the monopolar instrument for coagulation.

4.9.3 Using Monopolar Instrument

To use the monopolar instrument, follow the procedure below:

1. Connect the monopolar instrument to the generator.
2. Set the cutting mode or coagulation mode:
 - ◆ To set the cutting mode, press the Mode Setting button in the monopolar cutting area to select **Pure** or **Blend**. The default monopolar cutting mode is **Pure**. For technical parameters and description of each mode, refer to *6.3.1 Monopolar Cutting Modes*.
 - ◆ To set the coagulation mode, press the Mode Setting button in the monopolar coagulation area to select **Soft Coag**, **Fulgurate**, or **Spray**. The default monopolar coagulation mode is **Fulgurate**. For technical parameters and description of each mode, refer to *6.3.2 Monopolar Coagulation Modes*.
3. Set power level for the mode by pressing the Power Level Increase button ▲ or the Power Level Decrease button ▼ .
4. Activate the mode by using the footswitch or fingerswitch.

NOTE

- **After connecting a monopolar instrument with fingerswitch, you are advised to test the cutting and coagulation functions of the fingerswitch buttons. Make sure that the functions are normal by checking whether the corresponding areas of the main screen show correct background colors.**

4.9.4 Enabling Monopolar Shared-Coagulation Function

When the monopolar shared-coagulation function is enabled, you can activate the instruments connected to the monopolar socket 1 and monopolar socket 2 simultaneously

5 System Alarm

5.1 Overview

This chapter describes the alarm function of the generator and lists error messages related to the ultrasonic assembly and HF instruments.

5.2 Introduction to Alarm Function

The system provides technical alarms only. Alarms are classified into high priority and low priority based on the alarm severity.

The alarm system only provides one alarm preset basing on electrical parameters. The alarm limits and algorithms cannot be changed. There is also a complete set of programs for monitoring operations of the generator and accessories. When an alarm generates, the generator gives alarm tones and displays error messages to alert the operator.

A system log of the generator records error messages and system power-off time. The generator can store 5000 history records in the log, and earlier data are overwritten by later ones if the memory is full.

The alarm system consists of latching alarms and non-latching alarms:



- A latching alarm continues to be displayed when the triggering event no longer exists and disappears after the generator is restarted.
- A non-latching alarm disappears when the triggering event no longer exists.

NOTE

- **The delay inherent in the determination of the alarm condition is less than 1s.**
 - **Alarm settings and system log are maintained when the system is power down. The duration of power interruption has no effect on the stored alarm information.**
-

5.3 Alarm Indicators

When an alarm occurs, the equipment indicates it to you through visual or audible alarm indications. For details, see the following table:

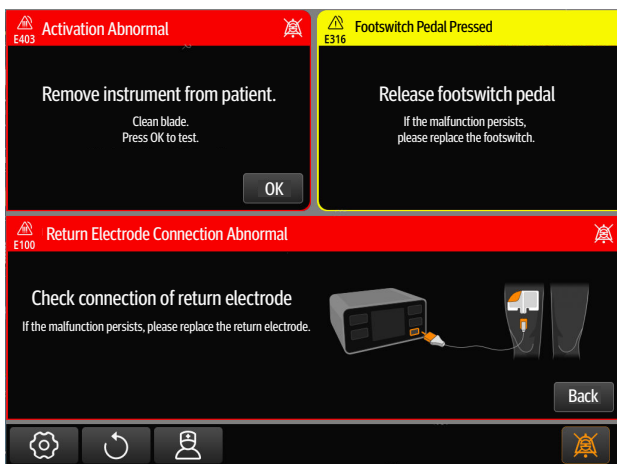
Alarm Priority	Audible Tone Pattern	Alarm Message	Symbol
High	Except return electrode alarms: Repeat pattern of 2 x 5 beep tones	White text and symbol inside a red box	
	Return electrode alarms: Low-pitched 3-beep tones		
Low	2-beep tones	Black text and symbol inside a yellow box	

NOTE

- **When a return electrode alarm occurs, the indicator on the return electrode socket lights up in red.**
- **When multiple error messages occur simultaneously in the same area, the message of the highest priority is displayed preferentially. You can view other error messages by swiping to turn pages.**
- **When multiple alarms of different priority levels occur simultaneously, the system selects the alarm of the highest priority to issue the alarm tone.**

5.4 Alarm Screen

An alarm provides a pop-up window that contains messages or pictures to help you identify the cause of the alarm, as shown in the following figure:



6 Energy Output Modes of Generator

6.1 Overview

This chapter introduces all energy output modes of the generator, including applicability, output parameters, and characteristic diagrams of each mode. For the values stated in the diagrams:

- Maximum output voltage includes tolerances.
- Resistance measurement accuracy is within 2.5%.
- Output power is measured by using Mindray-specified instruments only.

6.2 Ultrasonic Modes

The ultrasonic assembly can be used in the MAX or MIN mode. Their applicability is as follows:

- The MIN mode is applicable to cutting and sealing of vessels up to and including 5 mm in diameter or of other soft tissue.
- The MAX mode is applicable to cutting of soft tissue when bleeding control and minimal thermal injury are needed.

After setting on the generator, you can use the following functions:

- Smart Tissue Sensing (STS): By using STS, the ultrasonic surgical instrument automatically senses changes in tissue status, and the generator adjusts energy output accordingly with sound feedback. Using this mode can improve cutting efficiency and reduce the thermal injured area, thereby making surgical procedure safer and more efficient.
- Enhanced Vessel Sealing (EVS): By using EVS, energy output is adjusted in real time based on advanced algorithms, and tissue status automatically sensed by the instrument. This can significantly enhance the sealing effect on vessels up to and including 7 mm in diameter.

6.2.1 Output Parameters of Ultrasonic Modes

Output parameters of the two modes on the generator are as follows.

Power	≥ 60 W
Frequency	30 - 80 kHz

6.2.2 Selection of Ultrasonic Power Level

The power level of the MIN mode can be adjusted from 1 to 5 and the power level of the MAX mode is usually 5. You can select power levels by following suggestions below:

- For vascular tissue: As the power level increases, the cutting efficiency increases. The maximum power level is usually used to cut tissue containing small vessels. Cutting larger vessels by using the MIN mode is less efficient. However, considering the sealing effect and cutting time, you are advised to select the power level 3 to cut and seal vessels in normal cases. To seal large vessels, you can use the EVS function for optimal sealing even though the cutting efficiency is further reduced.
- For tissue such as muscle, liver, and mesentery: As the power level increases, the cutting efficiency increases. You are advised to select the power level 5 to cut for efficient surgical operation.

6.3 Monopolar Modes

Monopolar modes supported by the equipment are divided to monopolar cutting modes and monopolar coagulation modes.

6.3.1 Monopolar Cutting Modes

The equipment provides two monopolar cutting modes: Pure Cut and Blend Cut. Their applicability is as follows:

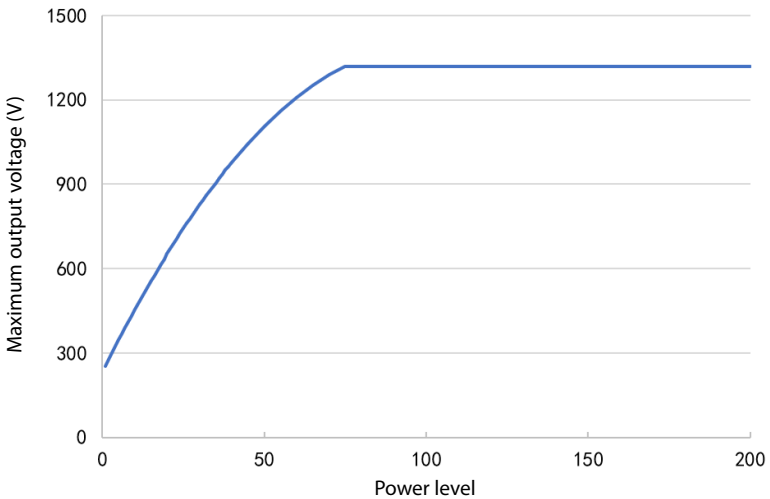
- The Pure Cut mode is applicable to smooth and precise cutting of soft tissue with little or without hemostasis.
- The Blend Cut mode is applicable to slow and dry cutting of soft tissue with significant hemostasis.

NOTE

- **Any associated equipment and active accessories used in the Blend Cut mode must be rated to withstand the combination of actual voltage and crest factor.**

6.3.1.1 Technical Parameters of Monopolar Cutting Modes

Parameter	Pure Cut	Blend Cut
Operating frequency	434 kHz \pm 10%	434 kHz \pm 10%
Modulation frequency	/	27.7 kHz \pm 10%
Duty cycle	100%	50% \pm 10%
Rated load	300 Ω	300 Ω
Rated power	300 W \pm 15%	200 W \pm 15%



6.3.2 Monopolar Coagulation Modes

The equipment provides three coagulation modes: Soft Coag, Fulgurate Coag, and Spray Coag. Their applicability is as follows:

- The Soft Coag mode is applicable to slow and deep monopolar coagulation with no sparks. Using this mode causes practically no tissue carbonization or adhesions.
- The Fulgurate Coag mode is applicable to contact-free surface coagulation of tissue. This is achieved by using electrical sparks from the active electrode.
- The Spray Coag mode is applicable to contact-free surface coagulation of tissue. This is achieved by using electrical sparks from the active electrode. Compared with the Fulgurate Coag, the Spray Coag can affect larger tissue area and achieve shallower penetration depth.

NOTE

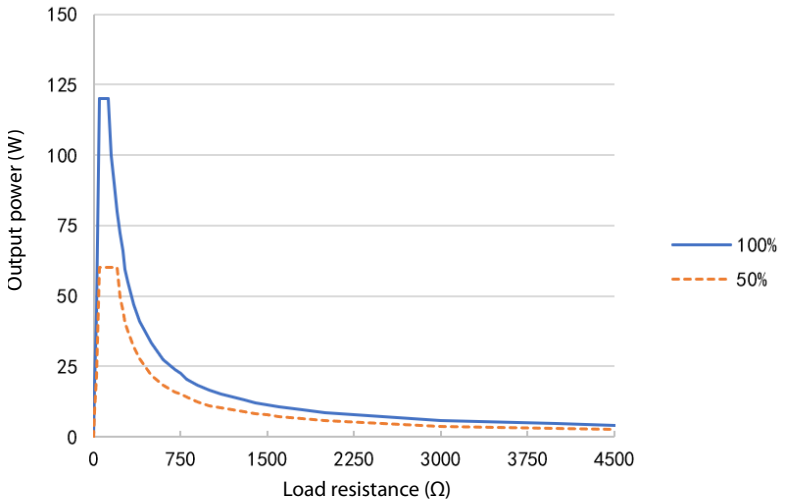
- **Any associated equipment and active accessories used in the Spray Coag and Fulgurate Coag modes must be rated to withstand the combination of actual voltage and crest factor.**

6.3.2.1 Technical Parameters of Monopolar Coagulation Modes

Parameter	Soft Coag	Fulgurate Coag	Spray Coag
Operating frequency	434 kHz ± 10%	434 kHz ± 10%	434 kHz ± 10%

Parameter	Soft Coag	Fulgurate Coag	Spray Coag
Modulation frequency	/	27.7 kHz \pm 10%	21.1 kHz \pm 10%
Duty cycle	100%	6.25% \pm 10%	4.76% \pm 10%
Rated load	100 Ω	500 Ω	500 Ω
Rated power	120 W \pm 15%	120 W \pm 15%	120 W \pm 15%
Maximum output voltage	264 V _p	3448 V _p	3932 V _p
Maximum output current	1.71A	1.05A	1.05A
Crest factor (rated load)	1.5 \pm 0.3	5.3 \pm 0.3	6.1 \pm 0.3
Power ranges and step	--; 1 - 40 W (step: 1 W); 40 - 100 W (step: 5 W); 100 - 120 W (step: 10 W)	--; 1 - 40 W (step: 1 W); 40 - 100 W (step: 5 W); 100 - 120 W (step: 10 W)	--; 1 - 40 W (step: 1 W); 40 - 100 W (step: 5 W); 100 - 120 W (step: 10 W)

6.3.2.2 Characteristic Diagrams of Soft Coag Mode



- The Precise Coag mode is applicable to low-voltage and fine coagulation of tissue. Using this mode prevents the generation of sparks and eschars and precisely controls the coagulation effect.
- The Standard Coag mode is applicable to most low-voltage bipolar coagulation of tissue. Using this mode prevents the generation of sparks and eschars and achieves consistent coagulation effect.
- The Macro Coag mode is applicable to bipolar cutting and rapid coagulation. Compared with other bipolar modes, Macro Coag delivers higher voltage and greater power.
- The Bipolar Soft Coag mode is applicable to slow and deep bipolar coagulation with no sparks. Using this mode causes practically no tissue carbonization or adhesions.

6.4.1.1 Technical Parameters of Bipolar Coagulation Modes

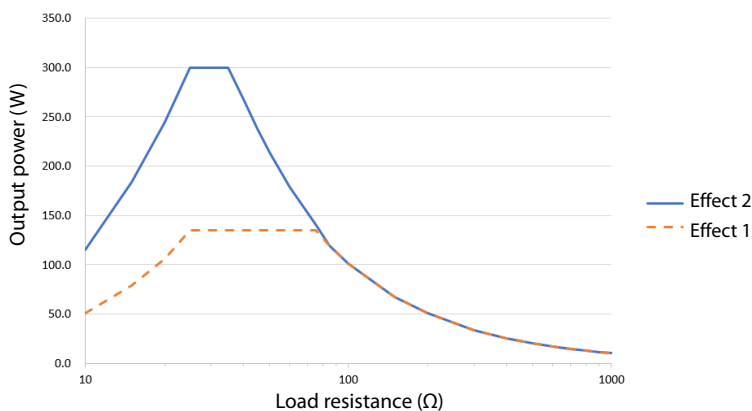
Parameter	Precise Coag	Standard Coag	Macro Coag	Bipolar Soft Coag
Operating frequency	434 kHz \pm 10%	434 kHz \pm 10%	434 kHz \pm 10%	350 kHz \pm 10%
Duty cycle	100%	100%	100%	100%
Rated load	100 Ω	100 Ω	100 Ω	50 Ω
Rated power	70 W \pm 15%	70 W \pm 15%	70 W \pm 15%	70 W \pm 15%
Maximum output voltage	284 V _p	415 V _p	530 V _p	150 V _p *
Maximum output current	1.98A	1.98A	1.87A	2.2A
Crest factor (rated load)	1.6 \pm 0.3	1.6 \pm 0.3	1.8 \pm 0.3	1.48 \pm 0.3
Power ranges and step	--; 1 - 40 W (step: 1 W); 40 - 70 W (step: 5W)	--; 1 - 40 W (step: 1 W); 40 - 70 W (step: 5W)	--; 1 - 40 W (step: 1 W); 40 - 70 W (step: 5W)	--; 1 - 10 W (step: 1 W); 10 - 70 W (step: 2W)
*: When the quick start function of Bipolar Soft Coag is enabled, the maximum output voltage is 225 V _p .				

- The Seal 7 mode is applicable to sealing of arterial/venous vessels, lymph vessels, and tissue strands ≤ 7 mm in diameter using electrode surgical instrument for Seal 7 during surgery. The mode senses the change of tissue impedance through the jaws of the instrument to automatically control the HF energy output until the sealing is complete.

6.4.2.1 Technical Parameters of Seal 7 Mode

Parameter	Seal 7 (Effect 2)	Seal 7 (Effect 1)
Operating frequency	350 kHz \pm 10%	350 kHz \pm 10%
Rated load	25 Ω	25 Ω
Rated power	300 W \pm 15%	135 W \pm 15%
Maximum output voltage	220 V	220 V
Maximum output current	3.85 A	2.50 A
Crest factor (rated load)	1.4 \pm 0.3	1.4 \pm 0.3
Note: To set effects of the Seal 7 mode, contact Mindray service personnel.		

6.4.2.2 Characteristic Diagram of Seal 7



6.4.3 Plasma Bipolar Cutting Modes

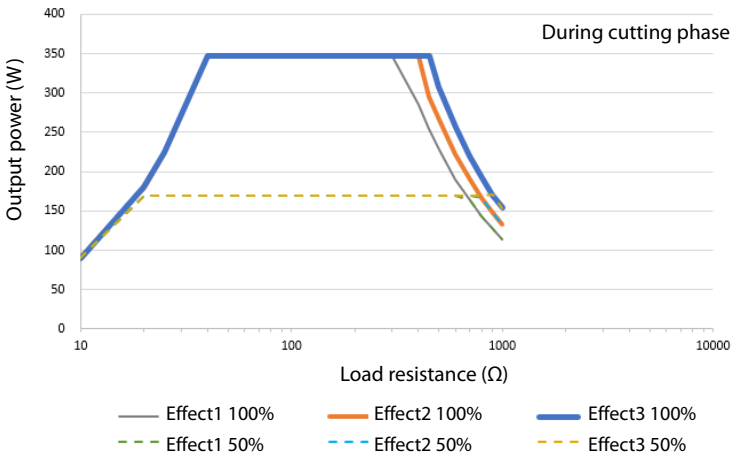
The equipment provides two plasma bipolar cutting modes: SalineCut and Vaporization. The applicability is as follows:

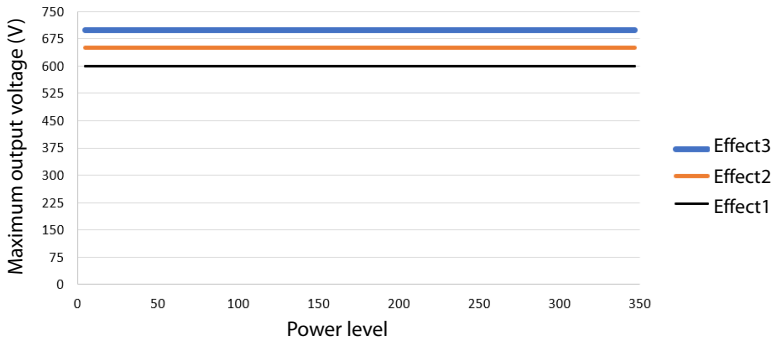
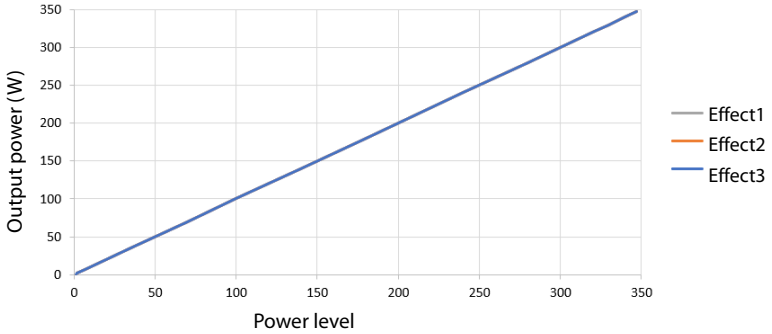
- The modes are applicable to electric cutting in conductive fluid.

6.4.3.1 Technical Parameters of Plasma Bipolar Cutting Modes

Parameter	SalineCut/Vaporization
Number of effects	1 - 3
Operating frequency	430 kHz \pm 10%
Duty cycle	100%
Rated load	75 Ω
Rated power	347 W \pm 15%*
Maximum output voltage	700 V
Maximum output current	8Arms
Crest factor (rated load)	1.4 \pm 0.3
Power ranges and step	--; 1 - 40 W (step: 1 W); 40 - 100 W (step: 5W); 100 - 340 W (step:10 W); 340 - 347 W (step: 7W);
*: The maximum output power across the rated load resistor is 400 W (with tolerance).	

6.4.3.2 Characteristic Diagrams of SalineCut/Vaporization





6.4.4 Plasma Bipolar Coagulation Mode

The equipment provides a plasma bipolar coagulation mode: SalineCoag. The applicability is as follows:

- The mode is applicable to coagulation in conductive fluid.

6.4.4.1 Technical Parameters of Plasma Bipolar Coagulation Mode

Parameter	SalineCoag
Number of effects	1 - 3
Operating frequency	430 kHz \pm 10%
Duty cycle	100%
Rated load	75 Ω

C Default Settings

C.1 Default System Settings

Parameter	Items/Options	Default Setting
Brightness	/	7
Activation/Button Volume	/	7
Alarm Volume	Low, Medium, High NOTE: The minimum alarm volume cannot be adjusted.	Medium

C.2 Default Ultrasonic Assembly Settings

Parameter	Items/Options	Default Setting
Activation Type	Both Hand and Foot, Only Hand, Only Foot	Both Hand and Foot
Advanced Features	STS(Smart Tissue Sensing)	ON
	EVS(Enhanced Vessel Sealing)	ON
	Activation Tone Change	ON

C.3 Default HF Instruments Settings

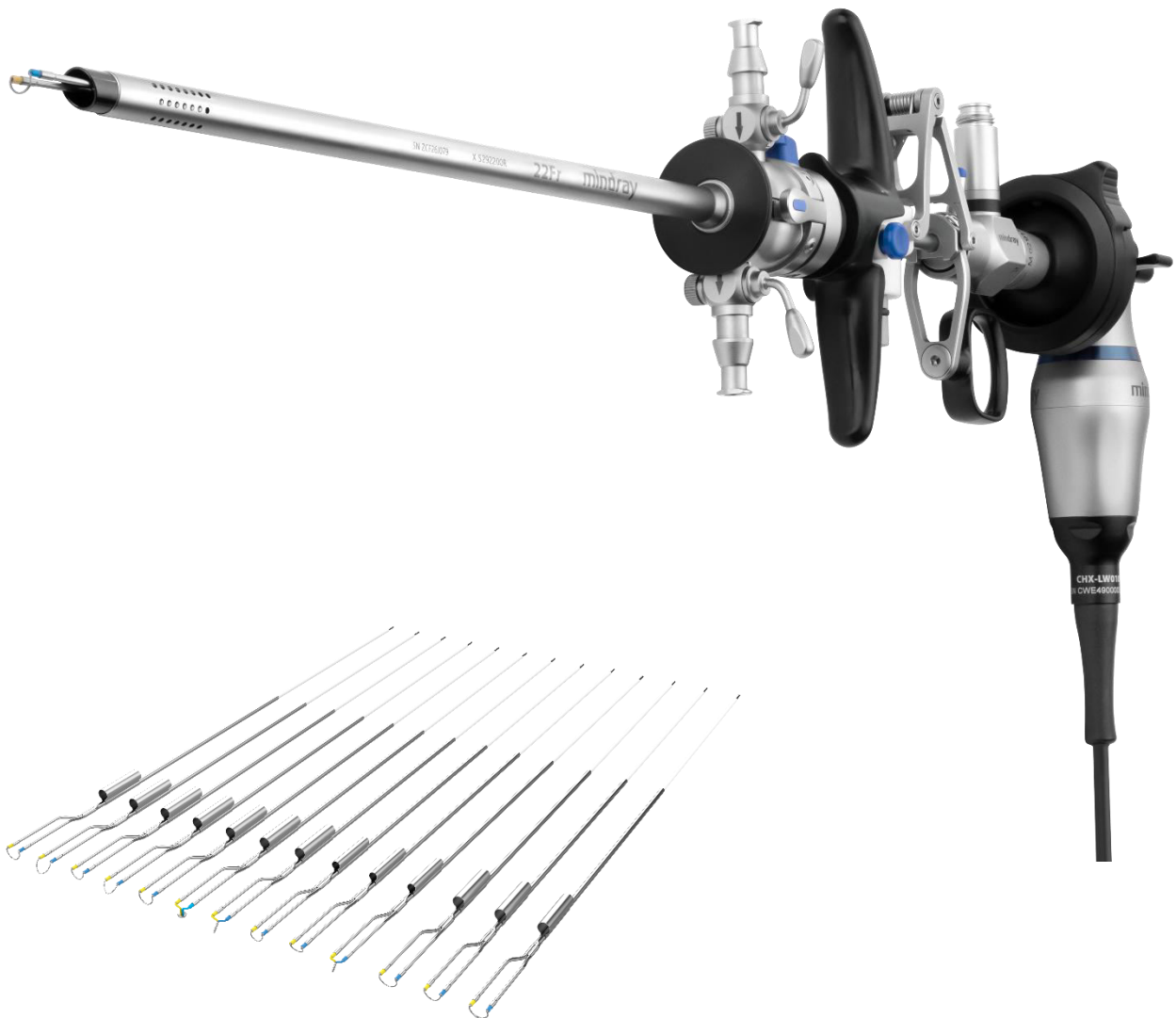
Parameter	Items/Options	Default Setting
Return Electrode	Neonatal Return Electrode Monitoring	OFF

C.4 Default User Maintenance Settings

Smooth Cutting and Coagulation

Comfortable Operation

PLASMA Resectoscope



Resectoscope, Sheaths, Obturators and Working Elements



Models of Resectoscope, Sheaths and Obturators

	Rigid Endoscope		Resectoscope Outer Sheaths	Resectoscope Inner Sheaths	Obturators		
					Standard	Visual, with Channel, 5 Fr	Deflecting
22Fr	M 02912A		X S292200R	X S292201R	X C292200R	X C292252R	/
26Fr	M 00412A	M 00430A	X S042600R	X S042601R	X C042600R	X C042652R	X C042601R

Models of Working Elements

	Working Elements			
	Passive Working Elements	Active Working Elements	Working element with channel	
22Fr	X W292200R	X W292201R	X W292220R (22Fr,1.5mm)	X W292210R (22Fr,0.8mm)
26Fr	X W042600R	X W042601R	X W042620R (22Fr,1.5mm)	X W042610R (22Fr,0.8mm)

Parameters of Endoscope

Model	Field of View	Direction of View	Working Length	Max. Width of Insertion Portion
M 00430A	70°±15%	30°±10°	302mm ± 3%	4mm
M 00412A	70°±15%	12°±10°	302mm ± 3%	4mm
M 02912A	70°±15%	12°±10°	302mm ± 3%	2.9mm

Parameters of Resectoscope Sheaths

	Product Name	Model	Maximum Insertion Portion Width	Minimum Main Channel Width	Working Length
Sheaths	Resectoscope outer sheath	X S292200R	7.5mm	7.0mm	190 mm ± 3%
		X S042600R	8.8mm	8.25mm	
	Resectoscope inner sheath	X S292201R	/	5.7mm	209 mm ± 3%
		X S042601R	/	7.0mm	

Parameters of Working Elements

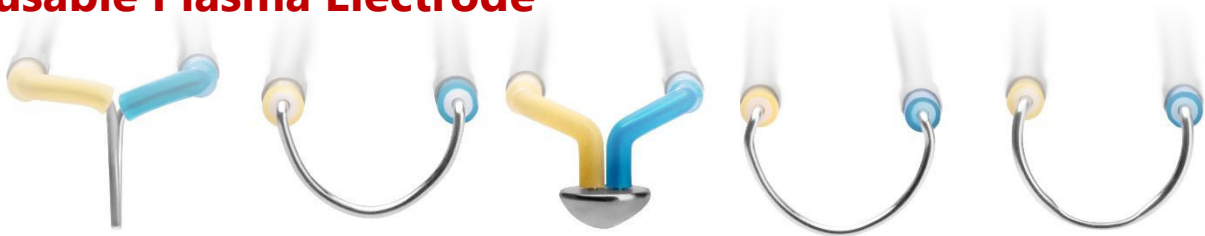
	Product Name	Model	Main Channel Width	Stroke	Minimum Fiber Channel Width
Working elements	Active working element	X W292201R	2.9mm	26 mm ± 2 mm	/
		X W042601R	4.0mm		
	Passive working element	X W292200R	2.9mm		
		X W042600R	4.0mm		

Working element with channel	X W292220R	2.9mm	1.5mm
	X W292210R		0.8mm
	X W042620R	4.0mm	1.5mm
	X W042610R		0.8mm

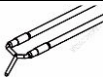

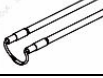
Parameters of **Obturator**

	Product Name	Model	Minimum Main Channel Width	Minimum Instrument Channel Width	Maximum Insertion Portion Width	Working Length
Obturator	Standard obturator	X C292200R	/	/	≤5.7 mm	226 mm ± 5mm
		X C042600R			≤7 mm	
	Visual obturator	X C292252R	2.9mm	5Fr	≤5.7 mm	223 mm ± 5mm
		X C042652R	4mm	5Fr	≤7 mm	
	Deflecting obturator	X C042601R	/	/	≤6.9mm	247.5 mm ± 5mm

Reusable Plasma Electrode



N o	Product Name	Model	Diagram of Working Tip	Shape of Working Tip	Maximum Insertion Portion Width	Working Length
1	Loop,22Fr,90°,12°Φ2.9mm,M,Reusable	X E112209M		Loop (medium)	5.7mm	278mm±3%
2	Loop,22Fr,120°,M,Reusable	X E10220CM		Loop (medium)	5.7mm	278mm±3%
3	Needle,22Fr,45°,Reusable	X E102205N		Needle	5.7mm	278mm±3%
4	Loop,26Fr,90°,M,Reusable	X E102609M		Loop (medium)	7.0mm	278mm±3%
5	Loop,26Fr,45°,M,Reusable	X E102605M		Loop (medium)	7.0mm	278mm±3%
6	Loop,26Fr,105°,M,Reusable	X E10260BM		Loop (medium)	7.0mm	278mm±3%
7	Loop,26Fr,90°,L,Reusable	X E102609L		Loop (large)	7.0mm	278mm±3%
8	Loop,26Fr,45°,L,Reusable	X E102605L		Loop (large)	7.0mm	278mm±3%
9	Loop,26Fr,105°,L,Reusable	X E10260BL		Loop (large)	7.0mm	278mm±3%
10	Vaporization,26Fr,90°,Reusable	X E102609V		Button (Vaporization)	7.0mm	278mm±3%

11	Needle,26Fr,45°,Reusable	X E102605N		Needle	7.0mm	278mm±3%
12	Ring,26Fr,90°,Reusable	X E102609R		Ring	7.0mm	278mm±3%
13	Ring,26Fr,105°,Reusable	X E10260BR		Ring	7.0mm	278mm±3%

Disposable Plasma Electrode

No	Product Name	Model	Diagram of Working Tip	Shape of Working Tip	Maximum Insertion Portion Width	Working Length
1	Loop,26Fr,90°,M,Disposable	X E302609M		Loop (medium)	7.0mm	278mm±3%
2	Loop,26Fr,45°,M,Disposable	X E302605M		Loop (medium)	7.0mm	278mm±3%
3	Loop,26Fr,105°,M,Disposable	X E30260BM		Loop (medium)	7.0mm	278mm±3%
4	Loop,26Fr,90°,L,Disposable	X E302609L		Loop (large)	7.0mm	278mm±3%
5	Loop,26Fr,45°,L,Disposable	X E302605L		Loop (large)	7.0mm	278mm±3%
6	Loop,26Fr,105°,L,Disposable	X E30260BL		Loop (large)	7.0mm	278mm±3%
7	Vaporization,26Fr,90°,Disposable	X E302609V		Button (Vaporization)	7.0mm	278mm±3%
8	Needle,26Fr,45°,Disposable	X E302605N		Needle	7.0mm	278mm±3%
9	Ring,26Fr,90°,Disposable	X E302609R		Ring	7.0mm	278mm±3%
10	Ring,26Fr,105°,Disposable	X E30260BR		Ring	7.0mm	278mm±3%

HF cable、Ellik Evacuator

Product Name	Model
HF Cable,Reusable	X A000002R
Ellik Evacuator (Brazil)	X A000040R
Ellik Evacuator	X A000050R

Applicable Sterilization methods

Sterilization method	Device	Temperature	/	Required minimum time
Autoclave Sterilization	Pre-vacuum	132°C - 134°C	/	4 min
Sterilization method	Manufacturer	Product	Cycle Mode	/
Low Temperature Plasma Sterilization	Advanced Sterilization Products (ASP)	STERRAD® 100NX System	Standard cycle	/
Sterilization method	EO concentration	Temperature	Relative humidity	Sterilization time
Ethylene Oxide Sterilization	About 760 mg/L	55°C	40% - 85%	60 min

It has been tested that the reusable plasma electrodes function well after the following cycles of sterilization:

- Loop electrode; ring electrode: 10 cycles

CHX-LW010

Camera Head

Operator's Manual



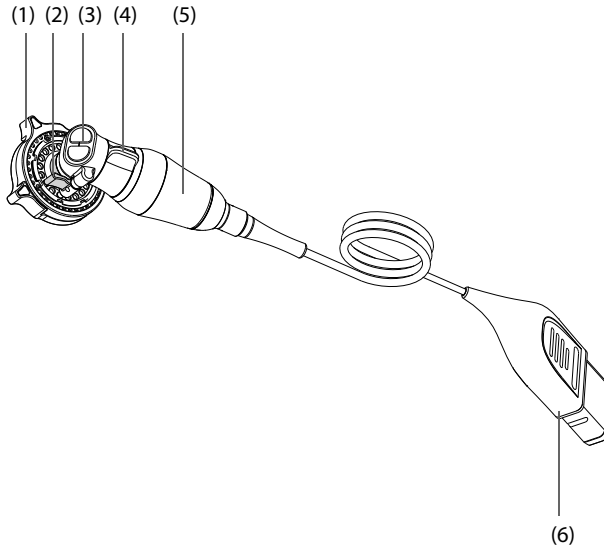
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- Release time: 2025-3
- Revision: 1.0

2.8 Working Principle of Camera Head

The camera head is used together with the CCU to support visible light imaging. It provides a 1/1.8-inch progressive scan CMOS for white light imaging, supporting 4K output display.

2.9 Appearance of Camera Head



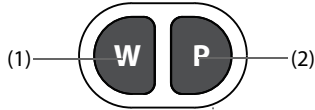
- (1) Endoscope coupler: connects and secures the endoscope.
- (2) Endoscope coupler lock: rotate it to lock or unlock the coupler. After being locked, the coupler cannot be rotated.
- (3) Camera head buttons: two functional buttons.
- (4) Focusing ring: rotate it to focus the camera head.
- (5) Handle: rotate it to change the orientation of the image.
- (6) CCU connector: connects the CCU.

2.10 Camera Head Buttons

After the camera head is connected to the CCU, the button functions are displayed on the monitor. After a button is pressed, the function prompt disappears. More descriptions are shown below:

NOTE

- You can customize the functions of the camera head buttons on the CCU. For the detailed setting method, refer to the operation's manual of the CCU.
-



- (1) **W** : short press to cycle through the tone enhancement modes, and long press to perform white balance by default.
- (2) **P** : short press to take photos and long press to record videos by default.

- **Make sure that the operating environment of the equipment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.**
-

NOTE

- **Risks might arise when the equipment is connected to other devices. Read the safety messages in the instructions for use accompanied with such devices carefully before operation.**
 - **Save the packing case and packaging materials for possible shipment or storage in the future.**
-

3.3 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier immediately. Open the package and remove the equipment and accessories carefully. Check all materials against the packing list and check for any mechanical damage. Contact Mindray in case of any problems.

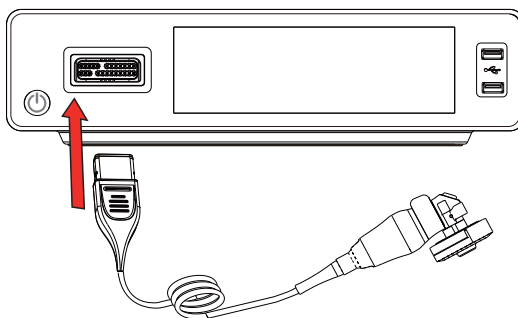
3.4 Visual Inspection of the Camera Head

Before using the product, check the following items:

- The lens of the camera head is not damaged, cracked, or contaminated.
- The cable of the camera head is not damaged or tangled.
- The connector is not loose, deformed, broken, or contaminated, which might cause poor contact.

3.5 Connecting the CCU

To connect the camera head and the CCU, plug the connector of the camera head to the camera head connector on the front panel of the CCU, as shown in the figure below:



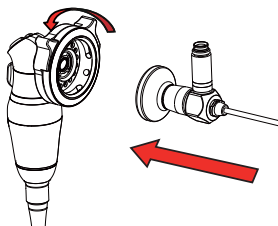
The following CCU models are compatible with this product:

Camera Head Model	Compatible CCU
CHX-LW010	UX1/UX1-TEC/UX1-SIM/UX1-NOR/UX3/UX3-TEC/UX3-SIM/UX3-NOR

3.6 Connecting the Rigid Endoscope

To connect the CHX-LW010 camera head and the endoscope, follow the procedure below:

1. Push the protrusion on the endoscope coupler as indicated by the arrow on the following figure.
2. Align the eye piece of the endoscope with the endoscope coupler on the camera head.
3. Push the endoscope to the camera head and release the protrusion on the endoscope coupler.



4. Pull the endoscope slightly to check if the endoscope is secured.

To remove the endoscope, follow the procedure below:

1. Hold the camera head with one hand, and the endoscope with the other.
2. Push the protrusion on the endoscope coupler as indicated by the arrow on the above figure. The endoscope falls off automatically.

WARNING

- **Before disconnecting the endoscope from the camera head, be sure to turn off the light of the light source. Otherwise, the brightness of light might be increased to the maximum level, causing burns or eye injuries.**
-
-

CAUTION

- **Turn off the CCU before connecting or disconnecting the camera head. Otherwise, the image sensor may be damaged, causing the image to disappear.**

Dimension	Gram Weight	Materials
1.2m x 1.2m	45g	100% polypropylene, 5-layer SMMMS laminates

4.3.5.2 EO Sterilization

To sterilize the camera head, follow this procedure:

1. Clean and disinfect the camera head and its cable as instructed in the previous sections.
2. Place the packaged container into the sterilizer.
3. Sterilize the equipment following the instructions for use of the sterilizer. You are advised to apply the following EO sterilization parameters that have been tested:

EO Concentration	Temperature	Relative Humidity	Sterilization Time
About 760 mg/L	55°C	40% - 85%	60min

4. To ensure the EO residues remain at a level that does no harm to the human body, the sterilized equipment should go through a 12-hour aeration or longer in a well-ventilated room at 55°C before reuse.

4.3.6 Low Temperature Plasma Sterilization

Validate the sterilization procedure of the low temperature hydrogen-peroxide plasma sterilizer in accordance with the operating instructions of the sterilizer.

To perform low temperature plasma sterilization, follow the procedure below:

1. Clean and disinfect the camera head and its cable as instructed in the previous sections.
2. Place the container into the sterilizer, and ensure:
 - ◆ The container is adequately exposed in the hydrogen peroxide plasma.
 - ◆ Do not allow any object to contact the inner sides of the sterilizer.
3. Sterilize the equipment following the instructions for use of the sterilizer. You are advised to use the following low temperature hydrogen peroxide plasma sterilizer that has been tested:

Manufacturer	Product	Cycle Mode
Advanced Sterilization Products (ASP)	STERRAD™ 100NX Sterilizer with ALLClear™ Technology	Standard circulation (Full period)

After sterilization, cool the equipment down to room temperature before use. If not, the lens might fog or the camera head be damaged.

A.4 Product Performance

Image transfer pixels	3840*2160 or 4096*2160 ultra high definition
-----------------------	--

Specifications

Physical specifications	Camera Head	ø 46mm x 120mm
	Cable	ø 3.6mm x 2.85m
	Weight	115g
Performance	Resolution	3840*2160 or 4096*2160 ultra high definition
	Focal Length	19.8mm
Safety specifications	Degree of protection against electrical shock	TYPE CF APPLIED PART
	Protection against harmful ingress of water	IPX7
Disinfection and Sterilization	Cleaning/Disinfection	Fully immersible in enzyme-containing cleanser. 75% Ethanol and 2% - 2.5% Glutaraldehyde are recommended
	Cleaning/Disinfection	Ethylene oxide (EO) sterilization and low temperature plasma sterilization.
Compatibility		UX series camera system


CHX-LW010

4K Pendulum Camera Head

Ultra Light-weight with 4K Clarity



Comfort in Procedure, Confidence in Care



Lighter
-40%

Traditional Pendulum

Ultra-light 4K camera head
40% lighter than a conventional 4K camera head, minimizing surgeon fatigue during prolonged procedures.

Less fatigue, better control
With the weight balanced at the thumb web, cutting stability and surgical safety are increased.

Less fatigue

Hands-free Design, Highly Efficient Operation

The pendulum design keeps the camera's view upright without being held, freeing one of the surgeon's hands to focus on the procedure and improving efficiency and safety.

The L-shaped design allows comfortable grip and free rotate of instruments, enabling easier access and precise operation during urological/gynecological procedures.



Coupler Lock Pendulum



Focus Ring



Revealing Every Detail

Small Size, 4K Resolution

The L lightweight camera features 4K resolution, a wide color gamut, and intelligent brightness control, revealing tissue details in a narrow cavity and enhancing diagnostic accuracy.

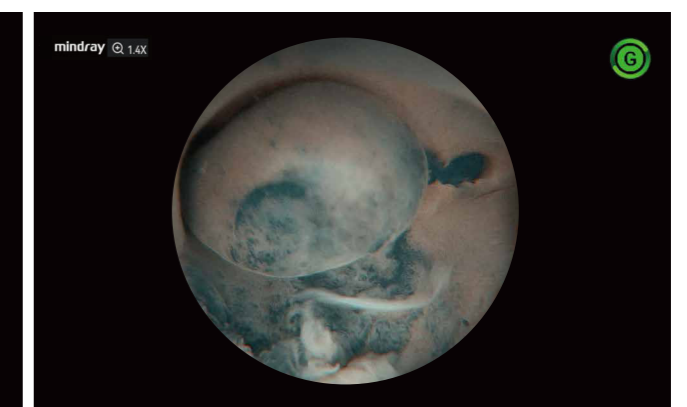


Tone Enhancement, Showing Hidden Details

The Tone Enhancement algorithm is equipped to enhance the color contrast between the mucosal layer and blood vessels, improving the detection rate of abnormal lesions.



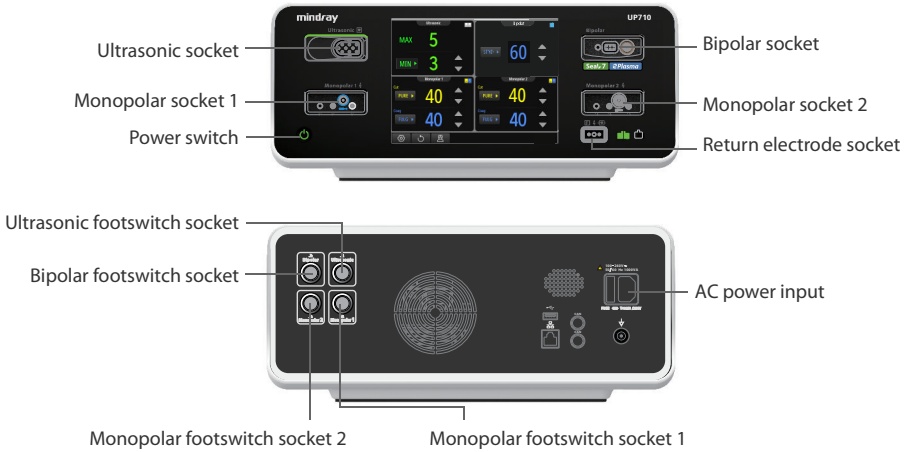
Tone Enhancement mode R



Tone Enhancement mode G

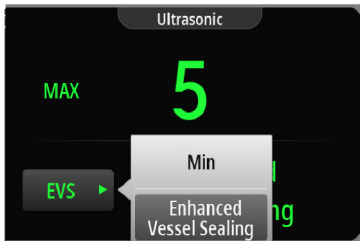
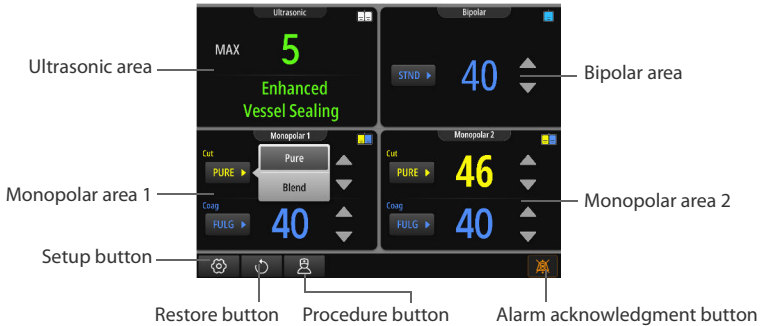
UP710 Series Generator Quick Start Guide

Product Overview



Note: Multiple instruments can be connected to the generator at the same time, but they cannot be activated simultaneously.

Using the Touchscreen



Using the EVS Function


When using an ultrasonic assembly, you can switch between the EVS function and the MIN mode in the ultrasonic area. **EVS(Enhanced Vessel Sealing)** is switched on by default.

Press the MIN button on the ultrasonic surgical instrument or press the left pedal of footswitch to activate the EVS function.



Enabling Neonatal Return Electrode Monitoring

When using a monopolar instrument, you can switch on **Neonatal Return Electrode Monitoring** in the setup menu.

Then the neonate symbol  is displayed in the monopolar area, indicating that the return electrode monitoring for neonate is enabled.

Setting Procedure

Select the Procedure button  on the touchscreen to display the **Select Procedure** page.

On the **Select Procedure** page, you can either add a Procedure, or edit or select a saved one.

A maximum of 500 Procedures can be added.



Setting Seal 7 Mode

Connect the electrode surgical instrument for Seal 7 to the generator. The generator automatically identifies the instrument and enter the Seal 7 mode.

The prompt tone will change when the sealing is finished.



Using Plasma Electrode

Connect the plasma electrode to the generator. The generator automatically identifies the instrument and display the operation area.

Select the plasma bipolar cutting mode or bipolar coagulation mode.














Set power level and effect for the mode.

Troubleshooting

Symptom	Attemptable Solution
There is no energy output when the instrument is activated.	Set the power level and reactivate the instrument.
	Properly connect the instrument to the generator. Make sure that the relevant instrument tests have been performed according to the on screen prompts.
When the generator is activated, the operation of other devices is interfered.	Keep the generator and cords connected to the generator away from other electronic devices.

Note: If the problem persists, remove the system from use immediately. Contact your service personnel.

Recommended Power Levels

<p>GI Surgery</p>  <p>Monopolar: Blend 40W Monopolar: Fulgurate 40W</p>	<p>Hepatobiliary Surgery</p>  <p>Monopolar: Blend 40W Monopolar: Fulgurate 40W Monopolar: Spray 80W (Optional) Bipolar: Standard 50W</p>	<p>Gynecological Surgery</p>  <p>Monopolar: Blend 40W Monopolar: Fulgurate 40W Bipolar: Standard 50W SalineCut: 200W SalineCoag: 120W Vaporization: 300W</p>	<p>Thyroid Surgery</p>  <p>Monopolar: Blend 30W Monopolar: Fulgurate 30W Bipolar: Precise 10W</p>
<p>Breast Surgery</p>  <p>Monopolar: Blend 40W Monopolar: Fulgurate 40W</p>	<p>Esophageal and Lung Surgery</p>  <p>Monopolar: Blend 30W Monopolar: Fulgurate 35W</p>	<p>Spine Surgery</p>  <p>Monopolar: Blend 40W Monopolar: Fulgurate 40W Bipolar: Standard 12W</p>	<p>Brain Surgery</p>  <p>Monopolar: Pure 30W Bipolar: Precise 8W</p>
<p>Arthroscopic Surgery</p>  <p>Monopolar: Blend 25W Monopolar: Fulgurate 25W</p>	<p>ENT Surgery</p>  <p>ENT (Needle Electrode) Monopolar: Fulgurate 15W ENT (Blade Electrode) Monopolar: Fulgurate 30W</p>	<p>Cardiothoracic Surgery</p>  <p>Cardiothoracic (Heart Surface) Monopolar: Fulgurate 10W</p> <p>Cardiothoracic (Coronary Artery Bypass) Monopolar: Fulgurate 20W</p>	
<p>Ophthalmic Surgery</p>  <p>Bipolar: Precise 2W</p>	<p>Surgery</p>  <p>SalineCut: 200W SalineCoag: 120W Vaporization: 300W</p>	<p>Cardiothoracic (Vessels) Monopolar: Blend 30W Monopolar: Fulgurate 25W</p> <p>Cardiothoracic (Sternum) Monopolar: Spray 75W</p>	

Note: The listed recommended power levels were derived from clinical feedback for reference only. The actual power level applied may vary significantly due to the surgery situation, patient differences, or electrode type. You are advised start with a low power level and increase it cautiously for optimal effect.

To obtain more maintenance information:



046-028633-00(1.0)

X S042600R/X S292200R/X S042601R/X S292201R/

X W042601R/X W292201R/X W042600R/X W292200R/

X W042610R/X W292210R/X W042620R/X W292220R/

X C042600R/X C292200R/X C042652R/X C292252R/X C042601R

Resectoscope Outer Sheaths, Resectoscope Inner Sheaths, Obturators, Working Elements

Operator's Manual



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- Release time: 2026-1
- Revision: 2.0

2.8 Applied Part

The applied part of the product is the rigid endoscope.

2.9 Product Models

Type	Product Name	Model
Sheath	Resectoscope outer sheath	X S042600R/X S292200R
	Resectoscope inner sheath	X S042601R/X S292201R
Working element	Active working element	X W042601R/X W292201R
	Passive working element	X W042600R/X W292200R
	Working element with channel	X W042610R/X W292210R/X W042620R/X W292220R
Obturator	Standard obturator	X C042600R/X C292200R
	Visual obturator	X C042652R/X C292252R
	Deflecting obturator	X C042601R

NOTE

- Hereinafter, "resectoscope outer sheath" will be referred to as "outer sheath", and "resectoscope inner sheath" will be referred to as "inner sheath".

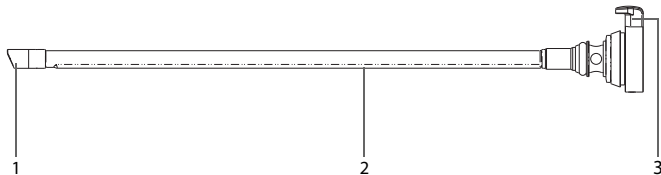
- Your product may not contain all of these components. For details about availability of components, contact Mindray.
-

2.10 System Components

2.10.1 Sheaths

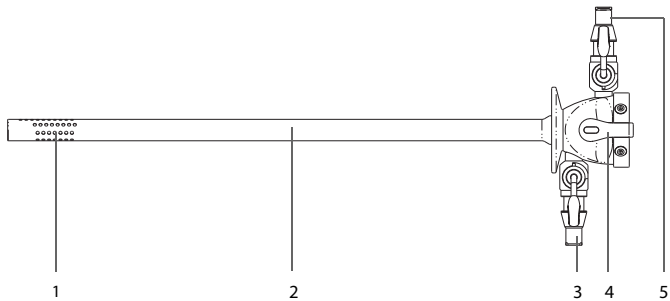
The sheaths consist of an inner sheath and an outer sheath, including inlet and outlet valves.

2.10.1.1 Inner Sheath



- (1) Insulation tip
- (2) Working channel
- (3) Unlocking button: used to unlock the connection between the inner sheath and the obturator or working element.

2.10.1.2 Outer Sheath

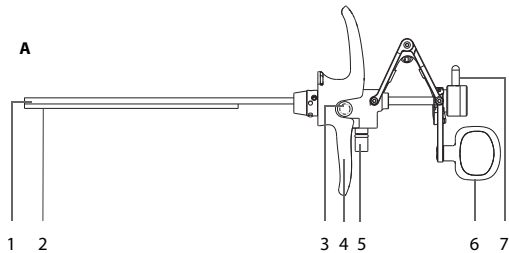


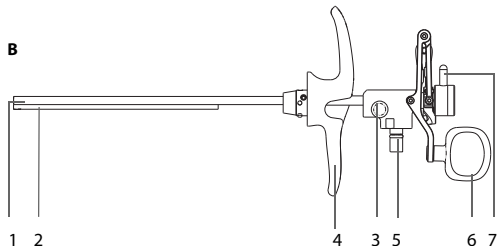
- (1) Outlets
- (2) Insertion portion
- (3) Outlet valve: used to open or close the outlet channel.
- (4) Unlocking button: used to unlock the connection between the inner sheath and the outer sheath.
- (5) Inlet valve: used to open or close the inlet channel

2.10.2 Working Elements

The working elements include active working element, passive working element, and working element with channel.

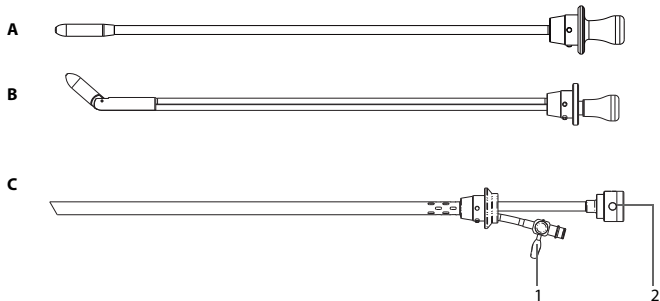
2.10.2.1 Active and Passive Working Elements





- A Active working element: In stationary state, the working tip of the plasma electrode extends beyond the electrode channel.
- B Passive working element: In stationary state, the working tip of the plasma electrode stays inside the electrode channel.
- (1) Endoscope channel
 - (2) Electrode channel
 - (3) Electrode unlocking button: used to unlock the connection between the working element and the plasma electrode.
 - (4) Handle: a black part, used for gripping.

2.10.3 Obturator



A Standard obturator

B Deflecting obturator: with a flexible tip.

C Visual obturator

(1) Instrument valve lever

(2) Endoscope locking lever: used to lock or unlock the connection between the visual obturator and the endoscope.

Rigid Endoscope

Operator's Manual

(M 00430A/G 00430A/M 00412A/G 00412A/M 02930A/
G 02930A/M 02912A/G 02912A/M 00430PA/G 00430PA/
M 00412PA/G 00412PA/M 02930PA/G 02930PA/M 02912PA/
G 02912PA)



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- Release time: 2026-1
- Revision: 2.0

4.7.2 Packaging Before Sterilization

Place the equipment in a proper container and double wrap the container with sterile sheets or any other sterile packing materials, preventing equipment contamination during storage and transportation.

Recommended specifications of the sterile sheet are as follows:

Dimension	Gram Weight	Materials
1.2m x 1.2m	45g	100% polypropylene, 5-layer SMMMS laminates

4.7.3 Autoclave Sterilization

NOTE

- **As the sterilizer and its operating conditions may affect sterilization, it is recommended that the sterilization process be reconfirmed and monitored before sterilization in accordance with related international standards (for example, ISO 17665), national standards, or hospital management rules.**
-

To perform autoclave sterilization, follow the procedure below:

1. Place the packaged container into the sterilizer.
2. Sterilize the equipment following the instructions for use of the sterilizer.

Sterilization parameters of autoclave sterilizer are as follows:

Device	Temperature	Required Minimum Time
Pre-vacuum	132°C	4min
	134°C	

CAUTION

- **After autoclave sterilization, do not use liquid to forcibly cool the equipment. Otherwise, the equipment may be damaged.**
-

CAUTION

- Use the equipment only in environment that meets the specific requirements. Otherwise, the equipment may not meet the performance specifications or unexpected consequences, e.g. damage to the equipment, could result. If the performance of the equipment is degraded due to aging or environmental conditions, contact your service personnel.
-

A.3 Basic Parameters

Model	Field of View	Direction of View	Working Length	Max. Width of Insertion Portion
M 00430A/M 00430PA/G 00430A/ G 00430PA	70° ± 15%	30° ± 10°	302mm ± 3%	4mm
M 02930A/M 02930PA/G 02930A/ G 02930PA	80° ± 15%	30° ± 10°	302mm ± 3%	2.9mm
M 00412A/M 00412PA/G 00412A/ G 00412PA	70° ± 15%	12° ± 10°	302mm ± 3%	4mm
M 02912A/M 02912PA/G 02912A/ G 02912PA	70° ± 15%	12° ± 10°	302mm ± 3%	2.9mm

NOTE

- There is no guarantee that instruments selected solely using maximum insertion portion width and working length will be compatible in combination.
-

LC0005S/LC0003S Light Cable

Instructions for Use

Statement

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. (hereinafter called Mindray) owns the intellectual property rights to this product and this manual. Disclosure of the information in this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden.

This manual provides the instructions necessary to operate the product in accordance with its function and intended use. Observance of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety.

Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

- (1) this product is used in accordance with the instructions for use.
- (2) this product is not damaged by human factors. Human factors refer to unintentional falling, intentional damaging, etc.

In the event that it becomes necessary to return a unit to Mindray, please contact the Mindray Service Department and obtain a Mindray Customer Service Authorization Number. The Mindray Customer Service Authorization Number must appear on the outside of the shipping container. Return shipments will not be accepted if the Mindray Customer Service Authorization Number is not clearly visible. Please provide the model number, serial number, and a brief description of the reason for return. The customer is responsible for freight charges when this product is shipped to Mindray for service (including any relevant customs fees or other freight related charges).

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The issue date of this manual is 2021-5.

Notification of Adverse Events

As a health care provider, you may report the occurrence of certain events to SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD., and possibly to the competent authority of the Member state in which the user and/or patient is established.

These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. provides only the highest quality products.

Important Information

1. It is the customer's responsibility to maintain and manage the product after delivery.
2. The warranty does not cover the following items, even during the warranty period:
 - (1) Damage or loss due to misuse or abuse.
 - (2) Damage or loss caused by force majeure such as fires, earthquakes, floods, and lightning.
 - (3) Damage or loss involving the product purchased from a channel other than Mindray or its authorized agency.
3. This product shall not be modified without permission.
4. In no event shall Mindray be liable for the damage caused by alteration, modification, or repair performed by personnel other than those designated by Mindray.
5. At the end of the service life of the product, please contact Mindray or its agency. Mindray shall not be liable for the result if you do not consult Mindray or its agency about disposal of the product.
6. This manual contains warnings regarding foreseeable potential dangers, but you shall always be alert to dangers other than those indicated as well.
7. Mindray shall not be liable for damage or loss that results from negligence or from ignoring the precautions and operating instructions described in this manual.
8. This manual shall always be kept properly so that it can be obtained conveniently as needed.

I. Intended Use

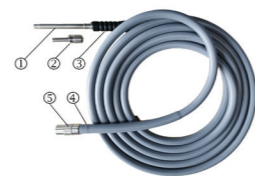
The light cable is used to transmit light during the endoscopic diagnosis and treatment. In the medical field, it is used with the cold light source of endoscopes.

NOTE
<ul style="list-style-type: none"> According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Thus, no residual risk associated with using the medical device should be disclosed due to the risk management report.

II. Specifications

Model	LC0005S	LC0003S
Length of light cable	3000 mm ± 10%	
Diameter of exit optical fiber	Φ4.8 mm ± 0.1mm	Φ3.5 mm ± 0.1mm
Minimum bending radius	50mm	

III. Introduction



1. Connector (to light source)
2. Light source adapter
3. Connector sleeve
4. Anti-bending device
5. Connector (to endoscope)

IV. Safety Precautions

<p>⚠ WARNING</p> <p>Risk of patient injury</p> <ul style="list-style-type: none"> Ensure that all endoscopic equipment is properly connected and functioning before inserting the endoscope into a patient. Use this product only along with the endoscopic device specified by Mindray.
<p>⚠ CAUTION</p> <p>Risk of patient injury</p> <p>Light source produces a lot of heat, causing a high temperature at the connector and front end of the endoscope. It may result in the following risk:</p> <ul style="list-style-type: none"> Scalding the patient (for example, when the small cavity of the lumen is exposed to excessive lighting, or the front end of the endoscope is close to the tissue). Burn of the patient or user's skin. Combustion or burning-out of surgical instruments (such as surgical drapes, and plastic materials). <ul style="list-style-type: none"> It is forbidden to place the endoscopic equipment on the patient's skin, flammable materials, or temperature-sensitive materials. Adjust the output power of the light source to make the minimum brightness required to illuminate the target area. Avoid excessive exposure to strong light.
<p>⚠ CAUTION</p> <p>Risk of user injury</p> <p>When the light source is on, do not look straight at the endoscopic connector of the light cable because that may cause eye injury.</p>

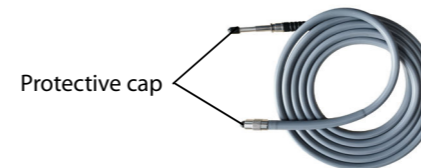
V. Removal After Use

<p>⚠ CAUTION</p> <p>Risk of user injury</p> <p>Touching the light cable connector when its temperature is high may cause scalding.</p> <ul style="list-style-type: none"> Cool the light cable after use.

INSTRUCTION
<p>Risk of product damage</p> <p>Sudden change in temperature may cause damage to the product.</p> <ul style="list-style-type: none"> Cool the light cable after use. It is forbidden to use liquid to cool the light cable.
INSTRUCTION
<p>Risk of product damage</p> <p>Pulling the cable may damage the product.</p> <ul style="list-style-type: none"> To unplug the light cable from the light source, grasp the plastic shell of the connector.

VI. Cleaning, Disinfection, and Sterilization

Clean, disinfect and sterilize this product regularly based on the local or hospital's regulations related to cleaning, disinfection, and sterilization. A protective cap is provided together with the product before delivery, as shown in the following figure. Remove the protector before cleaning, disinfection, and sterilization.



1. Cleaning and Disinfection

- (1) Disconnect the light cable from the devices, including light source and endoscope.
- (2) Use a soft cloth dipped in an appropriate amount of water to remove leftover on the surface of the light cable.
- (3) Use a clean soft cloth dipped in an appropriate amount of ethanol (75%) to wipe the surface of the light cable.
- (4) Use a dry soft cloth to wipe off detergent on the surface of the light cable, and place the light cable in a ventilated and cool environment to air dry it.

2. Sterilization

The recommended sterilization method is pressure steam sterilization. For loading method of pressure steam sterilization, please refer to the corresponding sterilizer operation instructions.

The procedure is as follows:

- (1) Remove the light source adapter from the light cable.
- (2) Put the product in a sterilization box, and wrap two layers of sterile sheets to prevent contamination during storage and transportation after sterilization.
- (3) Perform pressure steam sterilization as instructed in the manual for using the sterilizer.

The pressure steam sterilization parameters are as follows:

Sterilization process	Temperature	Minimum required time
Pulsation vacuum	132°C - 134°C	4min

<p>⚠ WARNING</p> <p>Risk of patient/medical staff injury</p> <p>Improper or inadequate cleaning, disinfection, and sterilization may result in infection of the patient or medical staff or product damage.</p> <ul style="list-style-type: none"> Clean, disinfect, and sterilize the product for the first use and before each use. Clean, disinfect and sterilize the product properly according to this manual.
--

VII. Warranty

If a user or unauthorized person repairs or modifies the product privately, the warranty of the Mindray becomes invalid. The product damage caused by improper use is not covered by the warranty.

VIII. Operating Environment

1. Temperature: 0°C - +35°C
2. Humidity: 30% - 85% RH, non-condensing
3. Atmospheric pressure: 70 kPa - 106 kPa

IX. Storage and Transportation Environment

1. Temperature: -20°C - +60°C
2. Humidity: 30% - 95% RH, non-condensing
3. Atmospheric pressure: 70 kPa - 106 kPa

Put clean and disinfected products in packages capable of isolating the products from bacteria, and store them in a dark, cool, and well-ventilated room.

X. Equipment Symbols

Symbol	Description
	Medical Device
	Manufacturer
	Date of manufacture
	TYPE CF APPLIED PART
	Batch code
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive. Note: The product complies with the Council Directive 2011/65/EU.
	Refer to instruction manual/booklet
	Authorized representative in the European community
	Comply with the requirements of Directive 2012/19/EU Waste Electrical & Electronic Equipment

Company Contact

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Address:	Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen 518057, P.R.China
Website:	www.mindray.com
E-mail Address:	service@mindray.com
Tel:	+86 755 81888998
Fax:	+86 755 26582680
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe)
Address:	Eiffestraße 80, 20537 Hamburg, Germany
Tel:	0049-40-2513175
Fax:	0049-40-255726



LC0005S/LC0003S

导光束 使用说明书

Light Cable Instructions for Use



声明

本产品及其使用说明书的知识产权属于深圳迈瑞生物医疗电子股份有限公司（以下简称迈瑞公司）。

迈瑞公司拥有本使用说明书的最终解释权。未经迈瑞公司书面许可，任何个人或组织不得复制、修改或翻译本使用说明书。

本说明书详细地介绍了产品的用途、功能和操作使用。使用本产品之前，请认真阅读并理解本说明书中的内容，以保证能够正确地使用本产品，并确保病人和操作者安全。在下列条件都满足的情况下，迈瑞公司将对产品的安全性、可靠性和性能负责：

- 按照《使用说明书》使用本产品。
- 非人为因素造成的产品损坏。人为因素是指不小心摔落、蓄意破坏等。

确实需要向迈瑞公司退货时，请联系迈瑞公司售后服务部，告知产品型号和系列号，并简述原因。若产品的系列号模糊不可辨认，退货请求将不予接受。

说明书编制日期：2021年5月

mindray和**迈瑞**是迈瑞公司的注册商标或者商标。

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重要信息

- 购买本产品后，客户对产品的维护和管理负全部责任。
- 即使在保修期内，对下列情况迈瑞将不负责保修：
 - 由于操作不当或故意损坏造成的损坏。
 - 由于不可抗力如火灾、地震、洪水、闪电等造成的损坏。
 - 不是从迈瑞公司或指定的分销商手中购买的迈瑞产品，如果发生损坏，将不予保修。
- 禁止擅自对本产品做任何改动。
- 非迈瑞公司指定人员对设备进行的重新改装、改动或维修造成的损坏，迈瑞将不负任何责任。
- 产品报废处理前请联系迈瑞公司或其代理机构。未向迈瑞公司或其代理机构咨询而对产品进行处理，迈瑞公司不对其所产生的后果负责。
- 本说明书对可以预见的危险做出了警告。但请在任何时间保持警惕以防出现其他危险。
- 由于疏忽没有按照说明书中的指引而产生的问题，迈瑞公司将不对此负责。

8. 请妥善保管本说明书，以确保管理和操作人员可以随时查阅。

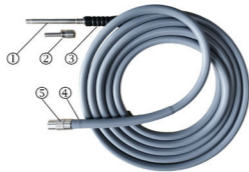
一、预期用途

导光束用于在内窥镜诊断和治疗中传输光线。医学领域中，它与医用内窥镜冷光源配套使用。

二、主要技术参数

型号	LC0005S	LC0003S
导光束长度	3000 mm ± 10%	
出射端光纤直径	Φ4.8 mm，允差 ±0.1mm	Φ3.5 mm，允差 ±0.1mm
最小可弯曲半径	50mm	

三、导光束结构



- 导光束接头（光源侧）
- 导光束光源适配套
- 接头套管
- 防折弯装置
- 导光束接头（内窥镜侧）

四、安全注意事项

警告
患者受伤的风险 <ul style="list-style-type: none"> 将内窥镜插入患者体内之前，应始终正确连接内窥镜设备。 本产品仅可与迈瑞指定的内窥镜设备配合使用。
小心
患者受伤的风险 光源会产生大量热量，导致内窥镜接头与先端部温度升高。可能会存在以下风险： <ul style="list-style-type: none"> 患者组织烫伤（例如，管腔较小的腔隙暴露在过强的照明下，或内镜先端部与组织距离过近）。 患者或用户皮肤烧伤。 手术器械燃烧或烧毁（例如，手术铺巾，塑料材料等）。 <ul style="list-style-type: none"> 禁止将内窥镜设备放置在患者皮肤、可燃性材料或对温度敏感的材料上。 调节光源的输出功率，达到照亮目标区域所需的最低亮度。避免强光的过度暴露。
小心
用户受伤的风险 在光源打开的情况下，直视导光束的内镜接头可能导致眼睛损伤。因此，光源打开的情况下，禁止直视导光束的内镜接口。

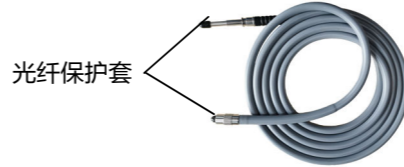
五、使用后拆卸

小心
用户受伤的风险 导光束上的接头温度过高时，触摸接头可能会导致烫伤。 <ul style="list-style-type: none"> 使用后应使导光束冷却。
说明
产品损坏的风险 高温导光束的温度急剧变化会损伤产品。 <ul style="list-style-type: none"> 使用后应使导光束冷却。 禁止使用液体冷却导光束。
说明
产品损坏的风险 拉拽缆线会损坏产品。 <ul style="list-style-type: none"> 从光源上拔下导光束时，应拉动接头的塑料外壳。

六、清洗、消毒和灭菌

请根据当地或医院关于医疗设备清洁消毒的规定定期对本产品进行清洁、消毒和灭菌。

本产品出厂时配送光纤保护套，如下图所示，清洁消毒及灭菌前请先取下保护套。



1. 清洁和消毒

- 断开导光束与光源、内窥镜等设备的连接。
- 使用一块软布蘸取适量的水除去导光束表面的残留物。
- 使用干净的软布蘸取适量乙醇（75%）擦拭导光束表面。
- 用干的软布擦去导光束表面的清洁剂，并将导光束置于通风阴凉的环境下风干。

2. 灭菌

推荐使用经验证过的灭菌方法：压力蒸汽灭菌。

压力蒸汽灭菌的装载方法，请参照相应灭菌器的操作说明。

步骤如下：

- 卸下导光束光源适配套。
- 将产品放置在灭菌盒中，并包裹两层无菌单，以防止灭菌后在存放、运输过程中染菌。
- 参照灭菌器的使用说明书执行压力蒸汽灭菌。

压力蒸汽灭菌器灭菌参数如下：

设备类别	温度	所需最短时间
预真空式	132°C ~ 134°C	4min

警告
患者 / 医务人员受伤的风险 清洗、消毒和灭菌不当或不充分可能导致患者或医务人员感染和产品损坏。 <ul style="list-style-type: none"> 首次及此后每次使用产品之前，应该进行清洗、消毒和灭菌。 按照本说明书，正确进行产品清洗、消毒和灭菌。

七、保修

如果用户或未经授权的人员私自维修或改造产品，则迈瑞公司的保修将失效。因使用不当导致的产品损坏不在保修范围之内。

八、工作环境

- 温度：0°C ~ +35°C
- 湿度：30% ~ 85% RH（无凝露）
- 大气压：70 kPa ~ 106 kPa

九、存储和运输环境

- 温度：-20°C ~ +60°C
- 湿度：30% ~ 95% RH（无凝露）
- 大气压：70 kPa ~ 106 kPa

将清洗和消毒处理后的产品置于能隔离细菌的包装中，存放在避光、阴冷、通风良好的室内。

十、符号

符号	说明
	注意！查阅随机文件
	生产日期
	CF 型应用部分
	批次代码
	温度极限

符号	说明
	湿度极限
	大气压力极限
	电子产品环保使用年限（20年）

售后服务单位

单位名称：深圳迈瑞生物医疗电子股份有限公司
 单位地址：深圳市南山区高新技术产业园区科技南十二路迈瑞大厦
 邮政编码：518057
 网址：www.mindray.com
 24小时服务热线：4007005652
 电话：+86 755 81888998
 传真：+86 755 26582680



EU-Representative: Shanghai International Holding Corp. GmbH (Europe)
 Address: Eiffestraße 80, 20537 Hamburg, Germany
 Tel: +49-40-2513175
 Fax: +49-40-255726

X A00002R HF cable

Instructions for Use



046-030305-00(1.0)

Notification of Adverse Events

As a health care provider, you may report the occurrence of certain events to WUHAN MINDRAY SCIENTIFIC CO., LTD., and possibly to the competent authority of the Member state in which the user and/or patient is established.

These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, WUHAN MINDRAY SCIENTIFIC CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that WUHAN MINDRAY SCIENTIFIC CO., LTD. provides only the highest quality products.

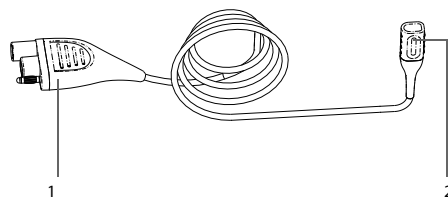
1 Safety

CAUTION

- Use only working elements and other endoscopic devices specified by Mindray. Using accessory or device that is not compatible with the cable may cause injury to the patient, damage to the cable, or deterioration in performance. Contact us in case of any questions concerning equipment compatibility.
- Prior to putting the cable into clinical operation and inspection, read this instructions for use carefully and make sure all contents are fully understood, to ensure the correct operation of the cable and safety of the patients and operators.
- Before the endoscopic surgery, prepare a backup HF cable to avoid surgery interruption due to possible system failure.
- Do not excessively bend, pull, or twist the cable.
- Dispose of the package material as per the applicable waste control regulations. Keep the packing material out of children's reach.
- At the end of its service life, the cable, as well as its accessories, must be disposed of in compliance with the local or hospital's guidelines regulating the disposal of such products, to avoid contaminating or infecting the environment, other persons, or equipment.

2 Product Introduction

2.1 HF Cable



- Generator connector: connects the generator.
- Working element connector: connects the HF connector of the working element.

2.2 Intended Purpose

HF cable is intended for electrosurgical use in endoscopic and open surgery in combination with compatible active accessories and compatible electrosurgical generators.

NOTE

- According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations.

2.3 Intended Users

It may only be used by physicians and medical assistants who have a corresponding specialized qualification and who have been instructed in use of the listed product.

2.4 Intended Patient Populations

There are no restrictions in terms of patient groups for this product.

2.5 Intended Environment

It is used in professional healthcare facility environment.

2.6 Contraindications

There are no known contraindications.

2.7 Applied Part

The HF cable is the applied part of the Ultrasonic Surgical & Electrosurgical Energy Platform.

3 Inspection Before Use

To inspect the cable before use, follow the procedure below:

- Check the product appearance for any damage. Ensure that they are clean and intact.
- Check the connectors of the HF cable for residual moisture. Ensure that they are dry.
- Check the product models to avoid connecting to incompatible equipment.

If any damage is detected, do not use the cable, and contact your service personnel.

4 Routine Maintenance

The HF cable is not intended to come into contact with the patient. Thus, it is not disinfected before leaving the factory. Clean, disinfect, and sterilize the device before the first use and after each use.

4.1 Initial Treatment at the Point of Use

Immediately after surgery, remove the blood, mucus, and protein residues from the surface of the cable with running water, or with a lint-free cloth soaked with purified water. This prevents the residues from coagulating and forming stubborn stains, affecting subsequent use.

4.2 Preparation Before Cleaning

4.2.1 Pretreatment

Flush the surface of the cable with running water, and then clean it with a lint-free cloth soaked with purified water.

4.3 Manual Cleaning

4.3.1 Flushing

To flush the cable, follow the procedure below:

- Flush the cable with running water for 1 to 2 minutes to remove contaminations from the cable surface.
- Use a pressure washing gun to flush the gaps.

CAUTION

- The water temperature during flushing shall be 15°C to 30°C, and the maximum temperature shall not exceed 45°C. High temperature may cause denaturation and coagulation of blood or protein, increasing cleaning difficulty.

4.3.2 Washing

To wash the cable, follow the procedure below:

- Fully immerse the cable in enzyme-containing cleanser. For requirements about immersing time, temperature, and concentration, refer to the instructions for use of the cleanser. Below are enzyme-containing cleansers of which the efficacy has been tested:

Product Name	Manufacturer	Concentration	Immersing Time
neodisher® MediClean forte	Dr. Weigert	5-20 mL/1L water	10 - 30 min
neodisher® Medizym (neutral)	Dr. Weigert	5-20 mL/1L water	10 - 30 min

- Use a syringe with a volume of at least 10 ml to aspirate the enzyme-containing cleanser and thoroughly wash the gaps. Repeat this step 5 to 10 times.
- While immersing the cable, use a surface cleaning brush to clean all accessible outer surfaces. Brush the surfaces for 1 to 2 minute until no residue remains.
- Put the cable in the ultrasonic cleaning machine, and add the enzyme-containing cleanser. Perform ultrasonic cleaning for at least 5 minutes.

NOTE

- Use one of the enzyme-containing cleansers on the same equipment. Mixing different cleansers may reduce the cleaning effect.

4.3.3 Rinsing

After preliminary cleaning, follow the procedure below to rinse the cable:

- Rinse all accessible surfaces of the cable thoroughly with running water or brush them. Repeat this step 3 times.
- Flush all surfaces of the cable, especially the gaps, with a pressure washing gun. Repeat this step 3 times.

For rinsing, use purified water.

4.3.4 Disinfection

Disinfect the cable as required in the local or your hospital's servicing schedule. Clean the cable before disinfection.

You can use the following tested disinfectant for disinfection:

Disinfectant	Method	Disinfection Time
Ethanol, 75%	Wiping	1 - 3 min

NOTE

- After disinfection, the cable still needs to be sterilized before use.

4.3.5 Drying

Dry the cable with a disinfected lint-free cloth or an air gun.

NOTE

- After machine cleaning and disinfection, check the cable surface for stains. Repeat the cleaning procedure if necessary.

4.4 Automated Cleaning

You can also use an automatic cleaning and disinfection machine to clean and disinfect the cable. The tested machine is as follows:

Brand	Model	Manufacturer
Steris	AMSCO 3052	STERIS Corporation

Fix and place the cable in the basket of the machine.

4.4.1 Automated Cleaning Parameters

Before starting the automated cleaning, refer to the instructions for use of the machine to set the cleaning parameters. Enzyme-containing cleansers are recommended for automatic cleaning.

The tested cleaning parameters are as follows:

Procedure	Temperature	Time	Concentration	Water Quality	Cleanser
Pretreating	Room temperature	2 min	/	Tap water	/
Cleaning	55°C	10 min	5 mL/1L water	Purified water	Dr. Weigert neodisher® MediClean forte
	45°C	10 min	10 mL/1L	Purified water	Dr. Weigert neodisher® Medizym (neutral)
Rinsing 1	Room temperature	2 min	/	Purified water	/
Rinsing 2	Room temperature	2 min	/	Purified water	/
Rinsing 3	Room temperature	1 min	/	Purified water	/
High temperature disinfection	90°C	5 min	/	Purified water	/
Drying	82.2°C (Low Mode)	25 min	/	/	/

NOTE

- Select an automatic cleaning and disinfection machine that is certified to meet local regulations.
- Maintain and inspect the cleaning and disinfection machine regularly.
- Use one of the enzyme-containing cleansers on the same equipment. Mixing different cleansers may reduce the cleaning effect.
- After automated cleaning and disinfection, check the cable surface for stains. Repeat the cleaning procedure if necessary.
- After disinfection, the cable still needs to be sterilized before use.
- For moist heat disinfection, use purified water.

4.5 Sterilization

Recommended sterilization methods that have been verified are as follows:

- Autoclave sterilization
- Low temperature plasma sterilization
- Ethylene oxide (EO) sterilization

CAUTION

- Perform sterilization in accordance with the methods described in this section. Otherwise, the sterilization may fail.
- Autoclave sterilization must be performed with purified water that meets the requirements of the medical institution and relevant standards.
- After autoclave sterilization, allow the cable to naturally cool down to room temperature. Quick cooling down may damage the cable.
- After each reprocessing, make sure that the cable has been taken out of the sterilizer. In other cases, the cable in the sterilizer shall not be considered sterilized.

4.5.1 Maintenance, Inspection and Testing Before Sterilization

Before sterilization, follow the method in 3 *Inspection Before Use* to check the equipment. Ensure the equipment is intact and functions normally.

4.5.2 Packaging Before Sterilization

Place the cable in a proper container and double wrap the container with sterile sheets or any other sterile packing materials, preventing equipment contamination during storage and transportation.

Recommended specifications of the sterile sheet are as follows:

Dimension	Gram Weight	Materials
1.2m x 1.2m	45g	100% polypropylene, 5-layer SMMMS laminates

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This manual provides the instructions necessary to operate the product in accordance with its function and intended use. Observance of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety.

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4.5.3 Autoclave Sterilization

NOTE

- As the sterilizer and its operating conditions may affect sterilization, it is recommended that the sterilization process be reconfirmed and monitored before sterilization in accordance with related international standards (for example, ISO 17665), national standards, or hospital management rules.

To perform autoclave sterilization, follow the procedure below:

- Place the packaged container into the sterilizer.
- Sterilize the cable following the instructions for use of the sterilizer.

Sterilization parameters of autoclave sterilizer are as follows:

Device	Temperature	Required Minimum Time
Pre-vacuum	132°C	4min
	134°C	

4.5.4 Low Temperature Plasma Sterilization

You are advised to use the following low temperature hydrogen peroxide plasma sterilizer that has been tested:

Manufacturer	Product	Cycle Mode
Advanced Sterilization Products (ASP)	STERRAD® 100NX System	Standard cycle

To perform low temperature plasma sterilization, follow the procedure below:

- Place the packaged container into the sterilizer, and ensure:
 - The container is adequately exposed in the hydrogen peroxide plasma.
 - Do not allow any object to contact the inner sides of the sterilizer.
- Set the sterilizer to standard cycle and sterilize the cable following the instructions for use of the sterilizer.

For detailed instructions and precautions, refer to the instructions for use of the sterilizer.

4.5.5 EO Sterilization

- Place the packaged container into the sterilizer.
- Sterilize the cable following the instructions for use of the sterilizer. You are advised to apply the following EO sterilization parameters that have been tested:

EO Concentration	Temperature	Relative Humidity	Sterilization Time
About 760 mg/L	55°C	40% - 85%	60 min

- To ensure the EO residues remain at a level that does no harm to the human body, the sterilized equipment should go through a 12-hour aeration or longer in a well-ventilated room at 55°C before reuse.

4.6 Consequences Caused by Inappropriate Cleaning, Disinfection and Sterilization

Using detergents or methods other than those recommended might cause the following consequences:

- Color change on the surface of the device
- Corrosion of metal parts
- Reduced service life of cords
- Equipment malfunction

5 Service Life

The service life of the HF cable is 2 years.

6 Storage

After sterilization and before next use, store the equipment in a pollution-free environment where bacteria are not easy to breed, for example, a dark, cool and, well ventilated room.

7 Disposal

At the end of its service life, the device must be disposed of in compliance with the local or hospital's guidelines regulating the disposal of such products. Clean and disinfect the device before disposal.

A Environmental Condition

Item	Temperature (°C)	Relative Humidity (Non-condensing)	Barometric (kPa)
Operating condition	+5 - +40	30% - 80%	70 - 106
Storage/transportation condition	-40 - +70	10% - 95%	70 - 106

B Physical Specifications

Minimum insulation voltage	1000Vp
Cable length	4m ± 0.1m

C Equipment Symbols

Symbol	Description	Symbol	Description	Symbol	Description
	Date of manufacture		Manufacturer		Temperature limit
	Medical Device		Humidity limitation		Atmospheric pressure limitation

Symbol	Description	Symbol	Description	Symbol	Description
	Unique device identifier		Refer to instruction manual/ booklet		Non-sterile
	Serial number		Authorized representative in the European Union		Dispose of in accordance to your country's requirements
	The product bears CE mark indicating its conformity with the provisions of the REGULATION (EU) 2017/745 on medical devices and fulfills the general safety and performance requirements of Annex I of this regulation. Note: The product complies with the Council Directive 2011/65/EU, amended by Directive 2015/863/EU.				

The general meaning assigned to geometric shapes, safety colors and contrast colors for safety signs are as follows:

Geometric Shape	Meaning	Safety Color	Contrast Color	Graphical Symbol Color
	Mandatory action	Blue	White	White

D EMC

The HF cable complies with the EMC standard IEC60601-1-2:2020.

WARNING

- The use of unapproved accessories may diminish product performance.
- Use of components, accessories, probes, and cables other than those specified may result in increased emission or decreased immunity of HF cable.
- Use of this HF cable adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Other devices may interfere with this equipment even though they meet the requirements of CISPR.
- Use of portable or mobile communications devices can degrade the performance of the equipment.
- This equipment is not intended for use in residential environments and can possibly not provide adequate protection to radio reception in such environments.
- This HF cable is intended for use in professional healthcare environment. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.
- The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.
- If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM, shielding the location or stopping using the ME EQUIPMENT or ME SYSTEM and contact the service personnel.

If the HF cable is operated within the electromagnetic environment listed in TABLE EMC-2, TABLE EMC-3 and TABLE EMC-4, the system will remain safe and will provide the following basic performances:

To use with the working elements powered by Ultrasonic Surgical & Electrosurgical Energy Platform and keep the power output within the specification range.

TABLE EMC-1

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS		
The HF cable is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.		
EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIROMENT – GUIDANCE

RF Emissions CISPR 11	Group 1	The HF cable uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The HF cable is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not applicable	

TABLE EMC-2

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY			
The HF cable is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIROMENT – GUIDANCE
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact; ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact; ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient / burst IEC 61000-4-4	±1 kV for input/output lines	±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

TABLE EMC-3

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY			
The HF cable is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIROMENT – GUIDANCE
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM bands ⁹ between 0,15 MHz and 80 MHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM bands ⁹ between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \times \sqrt{P}$
			$d = 2 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz - 2.7GHz	3 V/m 80MHz - 2.7GHz	$d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.7GHz Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ⁵ , should be less than the compliance level in each frequency range ⁶ . Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

⁹The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

⁶ Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

⁵ Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m.

TABLE EMC-4

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY			
The HF cable is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIROMENT – GUIDANCE
Proximity magnetic fields IEC 61000-4-39	65 A/m 134,2 kHz Pulse modulation 2,1 kHz	65 A/m 134,2 kHz Pulse modulation 2,1 kHz	/
	7,5 A/m 13,56 MHz Pulse modulation 50 kHz	7,5 A/m 13,56 MHz Pulse modulation 50 kHz	

TABLE EMC-5- Test specifications and minimum distances

Recommended separation distances between portable and mobile RF communications equipment and this HF cable

The HF cable is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this HF cable can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this HF cable as recommended below, according to the maximum output power of the communications equipment. Portable and mobile radio communications equipment (e.g. two-way radio, cellular/ cordless telephones and similar equipment) should be used no closer to any part of this system, including cables, than determined according to the following method:

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 - 470	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/ 900, tetra 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3,4,25,UMT S	Pulse modulation 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/ n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN, 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

TABLE EMC-6

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND THE HF CABLE

The HF cable is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and system as recommended below, according to the maximum output power of the communication equipment.

Rated Maximum Output power of Transmitter (W)	Separation Distance According to Frequency of Transmitter			
	150kHz - 80MHz Out ISM bands $d = 1.2 \times \sqrt{P}$	150kHz - 80MHz in ISM bands $d = 2 \times \sqrt{P}$	80MHz-800MHz $d = 1.2 \times \sqrt{P}$	800MHz-2.7GHz $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.2	0.12	0.23
0.1	0.38	0.64	0.38	0.73
1	1.2	2	1.2	2.3
10	3.8	6.4	3.8	7.3
100	12	20	12	23

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



X A00050R Ellik Evacuator

Instructions for Use



046-033680-00(2.0)

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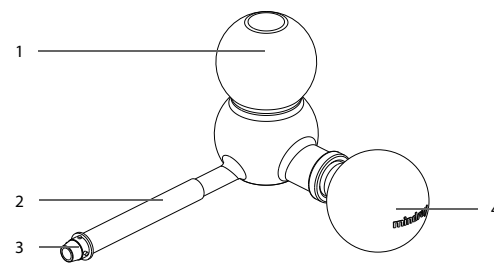
Notification of Adverse Events

As a health care provider, you may report the occurrence of certain events to WUHAN MINDRAY SCIENTIFIC CO., LTD., and possibly to the competent authority of the Member state in which the user and/or patient is established.

These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, WUHAN MINDRAY SCIENTIFIC CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that WUHAN MINDRAY SCIENTIFIC CO., LTD. provides only the highest quality products.

1 Product Introduction

1.1 Product Components



- (1) Ellik bulb
- (2) Flexible tube
- (3) Evacuator connector: connects to sheath.
- (4) Silicon bulb

1.2 Intended Purpose

Ellik Evacuator is intended for evacuation of the bladder during cystoscopic and resectoscopic procedures.

NOTE

- According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations.

1.3 Intended Users

It may only be used by physicians and medical assistants who have a corresponding specialized qualification and who have been instructed in use of the listed product.

1.4 Intended Patient Populations

There are no restrictions in terms of patient groups for this product.

1.5 Intended Environment

It is used in professional healthcare facility environment.

1.6 Contraindications

There are no known contraindications.

2 Safety

CAUTION

- Use only resectoscope outer sheaths, resectoscope inner sheaths, and other endoscopic devices specified by Mindray. Using accessory or device that is not compatible with the equipment may cause injury to the patient, damage to the equipment, or deterioration in performance. Contact us in case of any questions concerning equipment compatibility.
- Before the endoscopic surgery, prepare a backup Ellik evacuator to avoid surgery interruption due to possible system failure.
- This equipment contains no user serviceable parts. In case of any equipment failure, contact the service personnel.
- Mindray shall not be responsible for personal injury and equipment damage caused by maintenance attempts of service personnel not authorized by Mindray.
- Dispose of the package material as per the applicable waste control regulations. Keep the packing material out of children's reach.

3 Using the Ellik Evacuator

3.1 Inspection Before Use

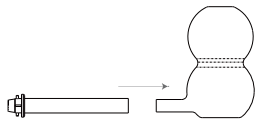
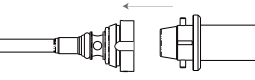
To inspect the equipment before use, follow the procedure below:

- Check the bulbs and flexible tube for any damage. Ensure that they are intact.
- Check the interior of the equipment for any foreign objects. Ensure that they are clean.
- Check all moving parts and sealed parts for intact function.
- Check the product models to avoid connecting to incompatible cables or equipment.

If any damage is detected, do not use the equipment, and contact your service personnel. Otherwise, the risk of patient injury and equipment damage may be caused.

3.2 Assembling the Ellik Evacuator

Before use, follow the procedure below to assemble the Ellik evacuator:

1. Connect the flexible tube to the Ellik bulb. Ensure that the evacuator connector is parallel to the flexible tube connector of the Ellik bulb, as shown in the following figure:
- 
2. Remove the silicon bulb and inject the irrigation fluid into the Ellik bulb and silicon bulb.
 3. Connect the silicon bulb to the silicon bulb connector of the Ellik bulb.
 4. Connect the evacuator connector of the flexible tube to the sheath, as shown in the following figure:
- 

4 Reprocessing the Ellik Evacuator

The Ellik evacuator is not intended to come into contact with the patient. Thus, it is not disinfected before leaving the factory. Clean, disinfect, and sterilize the device before the first use and after each use.

WARNING

- Cleaning, disinfection, and sterilization of the equipment may induce risks of infection. Follow the requirements in this chapter or the instructions of the cleaning, disinfection, and sterilization procedure of the hospital.

- Mindray is not liable for the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's infection control officer or epidemiologist.
- Wear appropriate protective equipment, for example eye protection and gloves, during cleaning, disinfection, or sterilization.
- The duration from the end of surgery to cleaning and disinfection should not exceed 2 hours. Otherwise stubborn stains may make cleaning more difficult.
- After being cleaned, disinfected, and sterilized, the equipment shall be cooled down before use to avoid the risk of burns.

4.1 Initial Treatment at the Point of Use

Immediately after surgery, remove the blood, mucus, and protein residues from the surface of the equipment with running water, or with a lint-free cloth soaked with purified water. This prevents the residues from coagulating and forming stubborn stains, affecting subsequent use.

4.2 Preparation Before Cleaning

4.2.1 Cleaning Tools

During the cleaning process, cleaning brushes, lint-free clothes, a pressure washing gun, a syringe, and other tools are required. You are advised to select an appropriate lumen cleaning brush according to the following requirements:

- The brush should be at least 50 mm longer than the lumen of the instrument to be cleaned.
- The brush diameter should exceed the inner diameter of the lumen to be cleaned.

4.2.2 Disassembling the Ellik Evacuator

Prior to cleaning, disinfection and sterilization, make sure that the equipment is intact and disassemble it. If the equipment is cleaned, disinfected, and sterilized without disassembly, it may fail to reach the desired effect. Take care to avoid equipment damage during disassembly.

To disassemble the Ellik evacuator, follow the procedure below:

1. After irrigation, remove the evacuator from the sheaths and empty the Ellik bulb and silicon bulb.
2. Remove the rubber bulb from the Ellik bulb.
3. Remove the flexible tube from the Ellik bulb.

4.2.3 Pretreatment

Flush the surface of the disassembled equipment with running water, and then clean them with a lint-free cloth soaked with purified water.

4.3 Manual Cleaning

4.3.1 Flushing

To flush the equipment, follow the procedure below:

1. Flush the equipment with running water for 1 to 2 minutes to remove contaminations from the equipment surface.
2. Use a pressure washing gun to flush the equipment parts with complex structures, such as screw threads and gaps.

CAUTION

- The water temperature during flushing shall be 15°C to 30°C, and the maximum temperature shall not exceed 45°C. High temperature may cause denaturation and coagulation of blood or protein, increasing cleaning difficulty.

4.3.2 Washing

To wash the equipment, follow the procedure below:

1. Fully immerse the equipment in enzyme-containing cleanser. For requirements about immersing time, temperature, and concentration, refer to the instructions for use of the cleanser. Below are enzyme-containing cleansers of which the efficacy has been tested:

Product Name	Manufacturer	Concentration	Immersing Time
neodisher® MediClean forte	Dr. Weigert	5-20 mL/1L water	10 - 30 min
neodisher® Medizym (neutral)	Dr. Weigert	5-20 mL/1L water	10 - 30 min

2. Use a syringe with a volume of at least 10 ml to aspirate the enzyme-containing cleanser and thoroughly wash the equipment parts with complex structures, such as screw threads and gaps. Repeat this step 5 to 10 times.
3. While immersing the equipment, use a surface cleaning brush to clean all accessible outer surfaces, especially parts with complex structures, such as

screw threads, gaps, and springs. Brush the surfaces for 1 to 2 minute until no residue remains.

- Use a lumen cleaning brush to clean the instrument lumens for at least 1 minute. For instrument lumens open at one end, pull out the cleaning brush after brushing. For instrument lumens open at both ends, scrub through them with the brush. Before cleaning the next part, remove the contaminants on the cleaning brush.

NOTE

- Use one of the enzyme-containing cleansers on the same equipment. Mixing different cleansers may reduce the cleaning effect.

4.3.3 Rinsing

After preliminary cleaning, follow the procedure below to rinse the equipment:

- Rinse all accessible surfaces of the equipment thoroughly with running water or brush them. Repeat this step 3 times.
- Flush all surfaces of the equipment, especially parts with complex structures, such as screw threads and gaps, with a pressure washing gun. Repeat this step 3 times.

For rinsing, use purified water.

4.3.4 Disinfection

Disinfect the equipment as required in the local or your hospital's servicing schedule. Clean the equipment before disinfection.

You can use the following tested disinfectant for disinfection:

Disinfectant	Method	Disinfection Time
Ethanol, 75%	Wiping	1 - 3 min

NOTE

- After disinfection, the equipment still needs to be sterilized before use.

4.3.5 Drying

Dry the equipment with a disinfected lint-free cloth or an air gun.

NOTE

- After machine cleaning and disinfection, check the equipment surface for stains. Repeat the cleaning procedure if necessary.

4.4 Automated Cleaning

You can also use an automatic cleaning and disinfection machine to clean and disinfect the equipment. The tested machine is as follows:

Brand	Model	Manufacturer
Steris	AMSCO 3052	STERIS Corporation

Disassemble the equipment before putting it into the cleaning and disinfection machine. Fix the disassembled equipment and place small parts in the basket of the machine.

Before starting the automated cleaning, refer to the instructions for use of the machine to set the cleaning parameters. Enzyme-containing cleansers are recommended for automatic cleaning.

The tested cleaning parameters are as follows:

Procedure	Temperature	Time	Concentration	Water Quality	Cleanser
Pretreating	Room temperature	2 min	/	Tap water	/
Cleaning	55°C	10 min	5 mL/1L water	Purified water	Dr. Weigert neodisher® MediClean forte
	45°C	10 min	10 mL/1L	Purified water	Dr. Weigert neodisher® Medizym (neutral)
Rinsing 1	Room temperature	2 min	/	Purified water	/
Rinsing 2	Room temperature	2 min	/	Purified water	/
Rinsing 3	Room temperature	1 min	/	Purified water	/

Procedure	Temperature	Time	Concentration	Water Quality	Cleanser
High temperature disinfection	90°C	5 min	/	Purified water	/
Drying	82.2°C (Low Mode)	25 min	/	/	/

NOTE

- Select an automatic cleaning and disinfection machine that is certified to meet local regulations.
- Maintain and inspect the cleaning and disinfection machine regularly.
- Put the product in a meshed tray to ensure all parts can be flushed.
- Place the rubber bulb of the Ellik evacuator in the cleaning and disinfection machine with its opening facing down, to avoid liquid residue after cleaning, which could cause patient infection.
- Use one of the enzyme-containing cleansers on the same equipment. Mixing different cleansers may reduce the cleaning effect.
- After automated cleaning and disinfection, check the equipment surface for stains. Repeat the cleaning procedure if necessary.
- After disinfection, the equipment still needs to be sterilized before use.
- For moist heat disinfection, use purified water.

4.5 Sterilization

Recommended sterilization methods that have been verified are as follows:

- Autoclave sterilization
- Low temperature plasma sterilization
- Ethylene oxide (EO) sterilization

CAUTION

- Perform sterilization in accordance with the methods described in this section. Otherwise, the sterilization may fail.
- Autoclave sterilization must be performed with purified water that meets the requirements of the medical institution and relevant standards.
- After autoclave sterilization, allow the equipment to naturally cool down to room temperature. Quick cooling down may damage the equipment.
- The equipment is sensitive to impacts at high temperature. Therefore, avoid impacting and vibrating the equipment at high temperature.
- After each reprocessing, make sure that the equipment has been taken out of the sterilizer. In other cases, the equipment in the sterilizer shall not be considered sterilized.

4.5.1 Maintenance, Inspection and Testing Before Sterilization

Before sterilization, follow the method in 3.1 *Inspection Before Use* to check the equipment. Ensure the equipment is intact and functions normally.

4.5.2 Packaging Before Sterilization

Place the equipment in a proper container and double wrap the container with sterile sheets, preventing equipment contamination during storage and transportation.

Recommended specifications of the sterile sheet are as follows:

Dimension	Gram Weight	Materials
1.2m x 1.2m	45g	100% polypropylene, 5-layer SMMMS laminates

4.5.3 Autoclave Sterilization

NOTE

- As the sterilizer and its operating conditions may affect sterilization, it is recommended that the sterilization process be reconfirmed and monitored before sterilization in accordance with related international standards (for example, ISO 17665), national standards, or hospital management rules.

To perform autoclave sterilization, follow the procedure below:

- Place the packaged container into the sterilizer.
- Sterilize the equipment following the instructions for use of the sterilizer.

Sterilization parameters of autoclave sterilizer are as follows:

Device	Temperature	Required Minimum Time
Pre-vacuum	132°C	4min
	134°C	

4.5.4 Low Temperature Plasma Sterilization

You are advised to use the following low temperature hydrogen peroxide plasma sterilizer that has been tested:

Manufacturer	Product	Cycle Mode
Advanced Sterilization Products (ASP)	STERRAD® 100NX System	Standard cycle

To perform low temperature plasma sterilization, follow the procedure below:

- Place the packaged container into the sterilizer, and ensure:
 - The container is adequately exposed in the hydrogen peroxide plasma.
 - Do not allow any object to contact the inner sides of the sterilizer.
- Set the sterilizer to standard cycle and sterilize the equipment following the instructions for use of the sterilizer.

For detailed instructions and precautions, refer to the instructions for use of the sterilizer.

NOTE

- After long time sterilization, the color of the silicon parts may fade, which is a normal phenomenon. It will not affect the sealing performance and the whole machine function.

4.5.5 EO Sterilization

- Place the packaged container into the sterilizer.
- Sterilize the equipment following the instructions for use of the sterilizer. You are advised to apply the following EO sterilization parameters that have been tested:

EO Concentration	Temperature	Relative Humidity	Sterilization Time
About 760 mg/L	55°C	40% - 85%	60 min

- To ensure the EO residues remain at a level that does no harm to the human body, the sterilized equipment should go through a 12-hour aeration or longer in a well-ventilated room at 55°C before reuse.

4.6 Consequences Caused by Inappropriate Cleaning, Disinfection and Sterilization

Using detergents or methods other than those recommended might cause the following consequences:

- Color change on the surface of the device
- Corrosion of metal parts
- Cracks or distortion of connectors and the housing of the device
- Equipment malfunction

5 Storage

After sterilization and before next use, store the equipment in a pollution-free environment where bacteria are not easy to breed, for example, a dark, cool and well ventilated room.

6 Disposal

At the end of its service life, the equipment, as well as the accessories, must be disposed of in compliance with the local or hospital's guidelines regulating the disposal of such products. Clean and disinfect the device and accessories before disposal.

A Product Specifications












A.1 Environmental Condition

Item	Temperature (°C)	Relative Humidity (Non-condensing)	Barometric (kPa)
Operating condition	+5 - +40	30% - 80%	70 - 106
Storage/transportation condition	-40 - +70	10% - 95%	70 - 106


A.2 Physical Specifications

Inner diameter of flexible tube	φ10 ± 1mm
Volume of the Ellik bulb	270ml±30ml

B Equipment Symbols

Symbol	Description	Symbol	Description
	Date of manufacture		Manufacturer
	Medical Device		Temperature limit
	Humidity limitation		Atmospheric pressure limitation
	Unique device identifier		Authorized representative in the European Union
	Serial number		Consult instructions for use
	The product bears CE mark indicating its conformity with the provisions of the REGULATION (EU) 2017/745 on medical devices and fulfills the general safety and performance requirements of Annex I of this regulation. Note: The product complies with the Council Directive 2011/65/EU, amended by Directive 2015/863/EU.		

The general meaning assigned to geometric shapes, safety colors and contrast colors for safety signs are as follows:

Geometric Shape	Meaning	Safety Color	Contrast Color	Graphical Symbol Color
	Mandatory action	Blue	White	White