

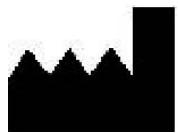


Thermal Balloon Endometrial Ablation System

This Operator's Manual is designed for use with the Thermablate EAS
Endometrial Ablation System

Read all directions, cautions, and warnings prior to use.

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Idoman Teoranta,
Killateeau, Tourmakeady,
Co. Mayo, Ireland.

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1. Device Description

The Thermablate EAS system is a software-controlled device designed to ablate uterine tissue with thermal energy. The Thermablate EAS system includes the following components:

1.1 TREATMENT CONTROL UNIT (TCU)



Figure 1. Thermablate EAS Treatment Control Unit, TCU (REF. No. 22001)

This handheld unit, weighing approximately 830g, controls the treatment settings (time, pressure, and temperature) through a computerized system that operates the electromechanical heating and pumping/draining subsystems of the Thermablate EAS device. The TCU has an LCD that provides pertinent information to the user: warm-up cycle, leak checks, treatment cycle, and completion of treatment are all clearly indicated. The TCU (REF. No. 22001) is reusable, requiring only cleaning between uses over its working lifetime. The TCU is not user serviceable, see Section 5 for details.

1.2 DISPOSABLE CARTRIDGE



Figure 2. Thermablate EAS Disposable Cartridge (REF. No. 21004)

The catheter-balloon Disposable Cartridge (REF. No. 21004) is the actual treatment component of the Thermablate EAS device. Its pre-shaped silicone balloon directly contacts the endometrial tissue to perform thermal ablation. The Disposable Cartridge is a SINGLE-USE device. It is designed for use with the Thermablate EAS TCU only.

1.3 POWER SUPPLY

Figure 3. Thermablate TCU Power Supply (Réf. 23001)

The Power Supply (REF. No. 23001) converts 100-240VAC to 24VDC for the TCU. It is supplied with a relevant power cord. Class I ME Equipment WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with a protective earth.

1.4 TCU STAND

Figure 4. TCU Thermablate Stand (Réf. 24001)

The Stand (REF. No. 24001) provided with the Thermablate EAS device is a stable support that holds the TCU in the horizontal position during the warm-up cycle of the system. It also offers a sanitary rest when the unit is not in use.

1.5 CARRYING CASE

Figure 5. Thermablate EAS Carrying Case (Réf. 25001)

The Thermablate EAS TCU Kit is supplied in a Carrying Case (REF. No. 25001) to facilitate its transportation, handling, and storage. This TCU Kit (REF. No. 22101) comprises the TCU, its Power Supply, Stand, and Carrying Case.

2. PRINCIPLES OF OPERATION

The ablating heat source of the Thermablate EAS system is the treatment liquid, which is supplied inside the diaphragm of the Disposable Cartridge. This diaphragm, surrounded by an aluminum shield, is inserted into the heating chamber of the TCU. Once the treatment liquid is heated up to approximately 173°C, the balloon is inserted into the uterine cavity. The physician formally initiates the ablation treatment by holding the treatment button. Using a controlled pneumatic pressure with set point of approximately 220 mmHg, the treatment liquid is forced into the balloon. The treatment liquid cools as it travels through the catheter and into the balloon to approximately 150°C. Temperatures at the endometrial lining in uterine models are approximately 100°C.

During treatment, the TCU performs a series of pressurization and depressurization cycles to homogenize the temperature of the liquid in the balloon. This ensures a uniform endometrial remodelling throughout most of the uterine lining. The total treatment takes less than 3 minutes to complete, a nominal 4-5 mm treatment depth is achieved.

3. SAFETY INFORMATION

3.1 INDICATIONS FOR USE

The Thermablate EAS System is a thermal ablation device intended to ablate the endometrial lining of the uterus in women suffering from excessive uterine bleeding due to benign causes for whom childbearing is complete.

3.2 PATIENT SELECTION

Excessive uterine bleeding can be caused by a variety of underlying problems including but not limited to endometrial cancer, myomas, polyps, and drugs. Patients should always be evaluated to determine if there are underlying causes of their excessive uterine bleeding before any treatment option is initiated.

The patient selection criteria are:

- Documented diagnosis of excessive uterine bleeding with no underlying causes
- Completed childbearing
- Pre-menopausal
- Normal uterine cavity with sounding between 8 cm and 12 cm, inclusive
- Normal Pap Smear and endometrial biopsy
- Does not present any of the contraindications below.

3.3 CONTRAINDICATIONS

The device is contraindicated for use in:

- A patient with a uterine sounding less than 8 cm or in excess of 12 cm (external os to fundus)
- A patient with active pelvic inflammatory disease
- A patient with known or suspected endometrial carcinoma (uterine cancer) or premalignant change of the endometrium, such as unresolved complex (adenomatous) hyperplasia
- A patient with history of pelvic malignancy within the past 5 years
- A patient with submucous / intramural myomas greater than 3.0 cm such that the uterine cavity is significantly distorted
- A patient with intracavitary lesions (Type 0 or 1 myoma or polyps of any size) as documented by hysteroscopy, contrast infusion sonohysterogram (CIS), or MRI performed in the last 6 months. Ablation can be performed if polyp is removed prior to procedure.
- A patient with a septate uterus
- A patient with any anatomic or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical caesarean sections or transmural myomectomy
- A patient that has had three or more, lower segment C sections and where the linear scar thickness in those patients is less than 8mm
- A patient who is pregnant or who wants to become pregnant in the future
- A patient with active genital or urinary tract infection at the time of procedure (e.g.cervicitis, vaginitis, endometritis, salpingitis, or cystitis)
- A patient with an IUD (Intra-Uterine Device) currently in place
- A patient less than 6 months post-partum.

3.4 WARNINGS

Only medical professionals who have experience in performing procedures within the uterine cavity, such as IUD insertions or dilation and curettage, and adequate familiarity with the Thermablate EAS system, should perform endometrial ablation using this device.

Read all directions, cautions, and warnings prior to use. This manual provides directions for using the Thermablate EAS system. Failure to follow any instructions or to heed any warnings or precautions could result in serious injury to the patient and/or the user.

This device is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following this procedure.

Endometrial ablation using the Thermablate EAS system is not a sterilization procedure. Pregnancies after ablation can be dangerous for both mother and foetus.

Endometrial ablation procedures do not eliminate the potential for endometrial hyperplasia or adenocarcinoma of the endometrium, and may diminish the physician's ability to detect or make a diagnosis of such pathology.

The Thermablate EAS Disposable Cartridge is for SINGLE-USE only – do not reuse, or re-sterilize.

Use caution not to perforate the uterine wall during dilation, sounding, or curettage (if performed). If a perforation is suspected, a hysteroscopy **must be performed**.

Do not initiate the procedure if perforation of the uterine wall or the creation of a false passage is confirmed during the hysteroscopy performed just prior to the insertion of the balloon.

If you suspect that the treatment liquid is leaking from the balloon during treatment, turn the "POWER SWITCH" to the "OFF" position and then to the "ON" position again, which will cause the TCU to apply a vacuum to withdraw any remaining liquid from the balloon. Withdraw the balloon from the patient only when the LCD of TCU indicates to do so. Place a gauze sponge into the vagina to absorb any liquid that may have collected there, and remove the sponge. Evaluate the patient for evidence of thermal injury to cervix, vagina and perineum. Instruct the patient regarding signs or symptoms of thermal injury to bowel or bladder. The Thermablate EAS TCU, Disposable Cartridge, Power Supply, and TCU Stand are designed as a system. To ensure proper function, never use other components with the Thermablate EAS device. After each use, follow the TCU cleaning procedure thoroughly.

REPEAT BALLOON ABLATIONS ARE CONTRAINDICATED

As the endometrial cavity following any kind of endometrial ablation is most likely distorted, repeat ablation should not be attempted with Thermablate EAS. Patients requiring further treatment after thermal balloon ablation should be treated medically, by resectoscopic endometrial ablation, or by hysterectomy. Repeat resectoscopic ablation / resection should be attempted only by experienced hysteroscopists since the complications may be severe.

3.5 POTENTIAL ADVERSE EFFECTS

The following adverse events are potentially associated with endometrial ablation:

- Pelvic cramping
- Nausea and vomiting
- Perforation of the uterus
- Rupture of the uterus
- Thermal injury to adjacent tissue/organs
- Heated liquid escaping into the cervix, vagina, or fallopian tubes
- Infection
- Post-ablation tubal sterilization syndrome (PATSS)
- Haematometra.

3.6 PATIENT COUNSELLING

As with any procedure, the physician needs to discuss the risks, benefits, and alternatives with the patient prior to performing endometrial ablation.

The device is intended for use in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following this procedure.

Patients of childbearing capability should be counselled that endometrial ablation is not a sterilization procedure and should be provided with an appropriate birth control method. These patients should be cautioned of the potential complications that may ensue if they should become pregnant.

Vaginal discharge is typically experienced during the first few days following ablation and may last as long as a few weeks. Generally, the discharge is described as: bloody during the first few days; serosanguineous by approximately one week; then profuse and watery thereafter. Excessive pain, heavy bleeding, foul smelling discharge or fever should be reported to the physician.

3.7 PREPARATION OF THE PATIENT

Appropriate sterile technique should be used to prepare the patient for procedure. Upon discretion of the physician, thinning of the endometrium can be performed either with hormonal agents administered prior to treatment, by timing the treatment to the early proliferative phase of the menstrual cycle, or by a gentle suction curettage performed immediately prior to the procedure. It is recommended that a non-steroidal anti-inflammatory drug (NSAID) be given at least one hour prior to the procedure. Antibiotics can be prescribed as per the physician's practice.

Anaesthesia may include a paracervical or intracervical block, intravenous sedation, or light general anaesthesia at the physician's discretion.

3.8 RECOMMENDED PRE TREATMENT OF ENDOMETRIUM

- Oral Contraceptives (Recommended for minimum 21 days until day of treatment)
- NuvaRing ®
- Timing of the menstrual Cycle
- Suction Curettage (if necessary)
- GnRH analogues minimum four weeks recommended only for patients with a uterine sounding ≥ 10 cm

4. DIRECTIONS FOR USE

4.1 SET-UP

1. CHECK THAT THE FOLLOWING ITEMS ARE PRESENT WITH THE THERMABLADE EAS DEVICE :

- One (1) Sterile Disposable (Single-Use) Cartridge
 - One (1) Treatment Control Unit (TCU)
 - One (1) Universal-Input Power Supply
 - One (1) Power Cord (to match local AC power receptacles)
 - One (1) TCU Stand
2. Place TCU in Stand.
 3. Ensure the "POWER SWITCH" is in the "OFF" position.
 4. Connect the Power Supply to TCU. Plug the Power Cord into both the Power Supply and the wall power outlet. Ensure that all connections are firmly connected. Ensure that the "POWER SWITCH" and connector can be easily accessed.

4.2 OPENING AND INSTALLING THE THERMABLADE EAS STERILE DISPOSABLE CARTRIDGE

1. The Disposable Cartridge is inside a pouch (Pouch made of clear film and Tyvek webs). The pouch is inside a tube with lids. The tube is inside a foil vacuum bag designed to be peeled open. ONLY THE CONTENTS OF THE FOIL BAG ARE DEEMED TO BE IN A STERILE STATE. The foil bag is inside a cardboard box.
2. Check expiry date. DO NOT USE the Disposable Cartridge if it has expired.
3. Open cardboard box.
4. Remove foil vacuum bag from cardboard box.
5. Ensure vacuum is intact. If it is not, DO NOT USE the Disposable Cartridge. Get another Disposable Cartridge instead.
6. Peel open foil vacuum bag.
7. Remove tube from the foil vacuum bag.
8. Remove the lid with "OPEN AT THIS END" label attached from the tube.
9. Remove sterile bag. DO NOT USE the Disposable Cartridge if the sterile bag is open or damaged. Peel open sterile bag to remove cartridge using standard aseptic technique.
10. Install Disposable Cartridge in the TCU, by lining up the 2 pins on the cartridge with the 2 slots in the TCU, and rotating it clockwise, as shown in the figure below.
Ensure that "This Side Up" and the guidance markings are visible on the top side of the catheter. Leave the plastic balloon cover on.

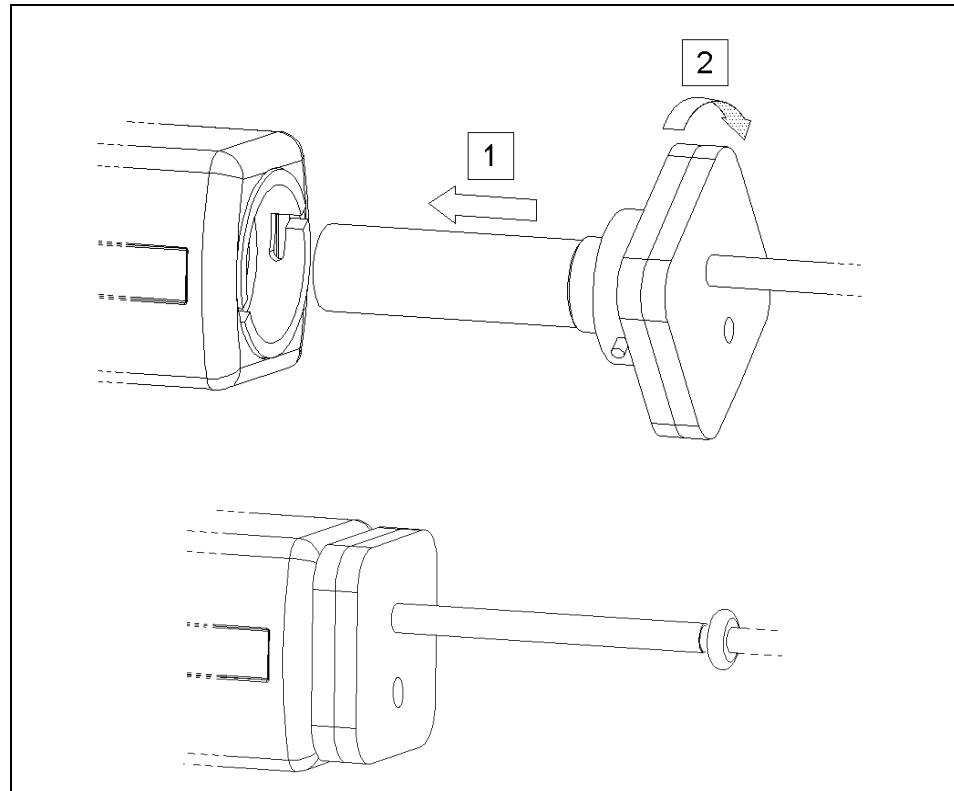


Figure 6. Installation of Disposable Cartridge

4.3 WARM-UP

1. Turn the "POWER SWITCH" to the "ON" position, the LCD will show the following message:

WELCOME TO
THERMABLADE

Both LED's should be OFF (see below right-bottom corner of LCD). (If the number of treatments remaining before servicing is less than 50, the TCU will issue a beeping sound and the LCD will show the following message for 10 seconds:

X TREATMENT(S)
BEFORE SERVICING

where "X" is number of remaining uses of the TCU.)

2. THE UNIT AUTOMATICALLY PERFORMS A SELF-TEST, AND, IF NO TECHNICAL PROBLEMS ARE ENCOUNTERED, THE INITIAL MESSAGE IS REPLACED BY THE FOLLOWING MESSAGE:

Device OK

(If the TCU encounters a technical problem, an error number will be displayed on the LCD. Please refer to page 21, "7. ERROR MESSAGES AND TROUBLESHOOTING".)

3. THE FOLLOWING MESSAGE IS THEN DISPLAYED:

HEATING – Wait ...
Fluid Temp XXX °C

where "XXX" is the measured temperature of the treatment liquid.

The "Heating" LED will turn ON, indicating that the pre-heating of the treatment liquid has begun. The "Ready" LED should be OFF. Before entering the "READY FOR TREATMENT" state the TCU performs a leak test. If this test is not passed ("ERROR # 19 will appear on LCD), turn the "POWER SWITCH" to the "OFF" position, and verify that:

- A) The Disposable Cartridge has been installed properly into the TCU, and
- B) No fluid is leaking out from the Disposable Cartridge, particularly from the balloon.

In case of a leaking Disposable Cartridge that has not spilled treatment fluid into the TCU, replace it with a new one. USE EXTRA CAUTION, AS THE METALLIC PART OF THE DISPOSABLE CARTRIDGE MAY BE VERY HOT.

Turn the "POWER SWITCH" back to the "ON" position. Wait until the TCU reaches the "READY FOR TREATMENT" state.

If treatment liquid leaked into the TCU, it will need to be repaired.

4.4 PATIENT PREPARATION

1. Provide patient with adequate analgesia.
2. During and/or prior to the warm up of the treatment fluid, patient preparation may be performed. Appropriate sterile technique for vaginal/ cervical preparation should be used.

4.5 TREATMENT

After approximately 8 to 12 minutes, the LCD will show "READY FOR TREATMENT" (see below) and the TCU will beep, indicating that the liquid has been heated up to treatment temperature (approximately 173°C) and the treatment procedure can be initiated. The "Heating" LED turns OFF and the "Ready" LED turns ON. The LCD Display reads:

READY
FOR TREATMENT

NOTICE :

If the system is left unused, the treatment temperature will be maintained for 35 minutes. After this period , the system will automatically turn OFF. To re-initiate Warm-Up, turn the « POWER SWITCH » to the « OFF » position, and ON again to restart the process. The Disposable Cartridge must not be used if it has been heated up and cooled down more than twice or exposed to ambient air for more than 2 hours.

WARNING

IF THE BALLOON IS NOT COMPLETELY DEFLATED AND LIQUID AND / OR GAS IS SEEN IN BALLOON DURING "READY FOR TREATMENT" STATE, DO NOT PROCEED WITH THE TREATMENT. Instead, turn "POWER SWITCH" to the "OFF" position, substitute the Disposable Cartridge, and restart the process

WARNING

IF THE BALLOON COVER CANNOT BE EASILY REMOVED FROM THE BALLOON, DUE TO PRESSURE IN THE BALLOON, DO NOT DETACH CARTRIDGE FROM TCU. Instead, turn the "POWER SWITCH" to the "OFF" position and cool down both TCU and Cartridge together until Balloon Cover can be easily removed. Remove Cartridge carefully from TCU, verify no fluid leaking out to the TCU, substitute Disposable Cartridge, and restart the process

CAUTION

Patients with either acutely anteverted or retroverted uterus, or a fixed uterus (e.g. due to significant endometriosis or adhesions), or those that have had previous uterine surgery are at a higher risk.

Particular attention should be paid to the angulation of the uterine sound, cervical dilator and Thermablate catheter during insertion.

1. Conduct pelvic examination to confirm position of the uterus.
2. Insert Speculum.
3. Apply tenaculum.
4. Measure sounding length of uterus from the external os to the fundus using a uterine sound. Confirm that measurement is between eight (8) and twelve (12) cm.
5. Use dilators to gradually dilate the cervix to seven (7) mm. Dilators should pass easily through the cervix with minimal discomfort to the patient. Dilators should not be advanced greater than the predetermined uterine depth.
6. Measure length of uterus a second time using the uterine sound. Confirm that sounding length of the uterus after dilation is the same as sounding length obtained prior to dilation. If there is a discrepancy of more than 0.5cm between the first and second measurements a false passage or perforation of the uterus may have been created during the dilation.
7. **Perform hysteroscopy prior to balloon insertion to ensure that the uterus has not been perforated or a false passage has not been created during dilatation, sounding or curettage (if performed).**

CAUTION

A PERFORATION OF THE UTERUS OR CREATION OF A FALSE PASSAGE, IF UNDETECTED, CAN LEAD TO THERMAL INJURIES OF ADJACENT ORGANS OR TISSUE

Hysteroscopy should reveal both tubal ostia clearly before proceeding with the treatment. If distension of uterus during hysteroscopy cannot be maintained, it is possible that the uterus has been perforated and treatment should not proceed.

Should the hysteroscopy reveal an excessively thick endometrial lining, a gentle curettage of the uterus may be performed. A second hysteroscopy should be performed immediately following curettage to ensure that the curettage has not created a perforation of the uterus.

8. Alternatively, use ultrasound surveillance during the treatment to check for correct balloon position inside the uterine cavity.
9. Slide the balloon cover off the balloon. Do NOT DISPOSE OF BALLOON COVER AS IT IS REQUIRED FOR LATER USE. Remove the Thermablate EAS system from the TCU Stand.
10. Slowly insert the Thermablate balloon until balloon tip touches the fundus. Tap the tip of catheter gently against the fundus to confirm placement of the catheter within the uterus.
11. Ensure that the depth marking on the balloon catheter matches the previously obtained sounding measurements. Should there be a discrepancy of more than 0.5 cm between the sounding measurements obtained and depth marking on the cartridge, a repeat hysteroscopy should be performed.
12. Activate the treatment cycle by holding the device trigger for 5 seconds. After hearing five (5) short and one (1) long beeping sounds, the treatment will automatically begin. The Finger can be removed from the trigger at this point. The LCD will show the following message:

Performing
System Check

Both LED's will turn OFF.

13. After 15 seconds, if the TCU passes the system check, the actual treatment cycle will start, and the LCD will show the following message:

TREATING...
Starting...

Followed shortly after by:

Pressure:XXXX
Time Left: Z:ZZ

where: "X" is the sign (+ or -) for positive or negative pressure "YYY" is the actual pressure value reached during procedure (mmHg) "Z:ZZ" is the treatment time remaining (min:sec).

If the system check fails, the TCU will issue an alarm and stop operating. In this case, turn the "POWER SWITCH" to the "OFF" position, remove the Disposable Cartridge from the patient, and verify that:

- A) The Disposable Cartridge has been installed properly into the TCU, and;
- B) No fluid is leaking out from the Disposable Cartridge, particularly from the balloon.

In case of a leaking Disposable Cartridge that has not spilled treatment liquid into the TCU, replace with a new one. USE EXTRA CAUTION, AS THE METALLIC PART OF THE DISPOSABLE CARTRIDGE MAY BE VERY HOT.

Turn the "POWER SWITCH" back to the "ON" position and follow the instructions until reaching the system check.

If treatment liquid has leaked into the TCU, it will need to be repaired.

14. As the balloon deploys, it may push the catheter slightly backward (Up to 0.5 cm is normal). Do not push the catheter forward during treatment.

CAUTION

At no time during the treatment should the catheter advance beyond the pre-determined sounding length. Should this occur, abort the procedure by turning the power switch off and then on again. Wait for the message: "FINISHED V :XXI Withdraw Balloon" to appear on the LCD screen and slowly remove the Thermablate catheter from the uterus. Perform hysteroscopy to ensure that the uterus has not been perforated.

15. Observe the LCD screen on the TCU as it automatically performs system checks and completes the treatment cycle. Automatic operation of the System inflates the balloon, controls the pressure, and pulses the treatment liquid, maintaining uniform temperature in the balloon. During this time, the pump is clearly audible. This is not a malfunction – it is part of the normal operation of the unit.

CAUTION

IN THE EVENT OF POWER LOSS DURING TREATMENT

*If the power is lost during treatment, wait for thirty (30) seconds. If, after this 30-second period, the power has not come on again, withdraw the balloon quickly but carefully since some liquid may still be contained in the balloon. Turn the "POWER SWITCH" to the "OFF" position, and then go to Section "Post-Treatment" below. If the power has come on again within this 30-second period, **DO NOT WITHDRAW THE BALLOON**. The TCU will automatically recognize that the "previous" treatment did not finish correctly and will proceed to actively withdraw the liquid from the balloon. **REMOVE THE BALLOON FROM THE UTERUS ONLY AFTER THE "FINISHED V: XX ml Withdraw Balloon" MESSAGE APPEARS ON THE LCD SCREEN***

INTERRUPTION / TERMINATION OF TREATMENT

IF INTERRUPTION/TERMINATION OF TREATMENT IS REQUIRED OR IF LIQUID IS NOTED LEAKING THROUGH THE CERVIX, DO NOT IMMEDIATELY REMOVE THE BALLOON FROM THE UTERUS. First, turn off the power to TCU. Then proceed to turn the TCU on. In doing so, the TCU will automatically recognize that the "previous" treatment did not finish correctly. The TCU will proceed to actively withdraw the liquid from the balloon.

REMOVE THE BALLOON FROM THE UTERUS ONLY AFTER "FINISHED V: XX ml Withdraw Balloon" MESSAGE APPEARS ON the LCD screen.

WARNING

If the TCU encounters a technical problem during the procedure, it will issue a "TREATMENT FAILED" message. REMOVE THE BALLOON FROM THE UTERUS ONLY AFTER THE "FINISHED V: XX ml Withdraw Balloon" MESSAGE APPEARS ON THE LCD Screen.

If no problems are encountered, the treatment will proceed as follows.

16. After completion of the treatment cycle, the LCD will show the following message:

FINISHING...
Do NOT Remove

WARNING

If the TCU encounters a technical problem during the deflation procedure, it will issue a "DEFLATION FAILED" message. DO NOT REMOVE THE BALLOON FROM THE UTERUS. Instead, wait until the device withdraws the liquid from the balloon. REMOVE THE BALLOON FROM THE UTERUS ONLY FATER THE "FINISHED V:XX ml Withdraw Balloon" MESSAGE APPEARS ON THE LCD screen.

17. After 10 seconds of deflation time the LCD will show the following message:

FINISHED V: XX ml
Withdraw Balloon

where "XX" is the estimated uterus volume.

This message indicates that the treatment is complete and that the balloon can be withdrawn. Withdraw the balloon carefully from the uterus.

4.6 POST-TREATMENT

- 1. Place the TCU in the TCU Stand.** REPLACE BALLOON COVER ONTO THE BALLOON (To prevent blood splatter during disposal of cartridge).
- 2. After 50 seconds, the TCU will beep and its LCD will alternate the two following messages, continuously:**

DISCARD
USED CARTRIDGE

WARNING
*Metal End *HOT*

- 3. Turn the "POWER SWITCH" to the "OFF" position.**

WARNING

The Disposable Cartridge IS HOT and should be removed from the TCU and returned to the tube carefully

4. Remove Disposable Cartridge from TCU.
5. Return the Disposable Cartridge into its original tube by holding the blue connector and inserting it **ALUMINIUM SHIELD END FIRST** (so that the hot metal end of the cartridge will be toward the metal reinforced cap) and cover with the cap containing holes. Allow it to cool, and dispose of it in biohazard-labelled containers or per facility policy.

WARNING

The Disposable Cartridge is a SINGLE-USE component. Do not reuse it as this could result in serious injuries to the patient and/or the user.

6. Post treatment hysteroscopy is recommended.
7. Repeat balloon ablations are contraindicated.

5. CLEANING, MAINTENANCE, STORAGE AND TRANSPORTATION

5.1 CLEANING

After each use, the TCU must be cleaned according to the following procedure.

1. Disconnect the TCU from the power supply.
2. Wipe down the outside of TCU housing with an approved disinfectant wipe as per the infection control protocols of your facility.

CAUTION

This unit contains electronic components. DO NOT soak, flush, spray or use excessive free liquid on the TCU

5.2 MAINTENANCE

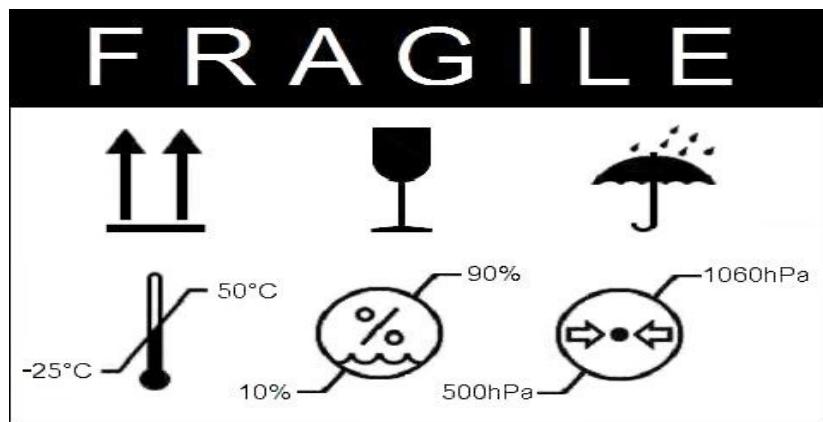
There are no user serviceable parts within the TCU. Opening the device will void the warranty.

WARNING

No modification of this equipment is allowed. Unauthorised modifications or access may result in electrical shock or leave the unit in a hazardous condition.

5.3 STORAGE AND TRANSPORT

1. Store the TCU in the Carrying Case. The storage temperature should never exceed 50°C.
2. Store Disposable Cartridge in dry place at room temperature..
3. For storage and transport environmental conditions, see the label with graphical representations and Technical Specifications table, below.



6. TECHNICAL INFORMATION

6.1. TECHNICAL SPECIFICATIONS

Item	Specification		
Temperature of treatment liquid during ablation	Initial: 150°C, approx.; Final: 110°C, approx		
Treatment pressure	220 mmHg		
Heat-up time	20 minutes maximum		
Treatment time	Less than 3 minutes		
Maximum stand-by time in "Ready" state	35 minutes		
Input power requirements to regulated power supply	Input Voltage 100-240VAC 50/60HZ Input Power 400-480 VA		
Output power of regulated power supply	24 volts, 5.5 amp		
Environmental Conditions for Operation	<ul style="list-style-type: none"> Temperature is between +10°C and +40°C. Humidity is between 15% and 70%. Atmospheric pressure between +690 hPa and +1060 hPa. 		
Environmental Conditions for Storage and Transport	 <ul style="list-style-type: none"> Temperature is between -25°C and +50°C Humidity is between 10% and 90%. Atmospheric pressure is between +500 hPa and +1060 hPa. Vibration 8 hour limit of 2.5m/s² Pollution Degree 2 		
Handling	Fragile - Medical devices		
Classification	Equipement Classe I ME Type BF Applied Part		
Mode of Operation	Non-Continuous Operation Disposable Cartridge is for Single Use Only		
Device Lifetime	TCU Software requires manufacturer maintenance after 600 procedures. The Disposable Cartridge is for SINGLE USE ONLY and has a shelf life of 2 Years.		
Physical Dimensions	TCU	Length	27,1 cm (27,18cm)
		Width	8,9 cm (8,89cm)
		Height	10,5 cm (10,49cm)
	Disposable Cartridge	Total Length	31,3cm (31,24cm)
		Connector Height	5,5cm (5,59 cm)
		Connector Width	5,5cm (5,59 cm)
Weight	Insertion Length		12 cm (11,99 cm) From insertion stop to balloon tip maximum
	TCU		830g (1lb 13oz)
Disposable Cartridge		110g (4oz)	
Protection	IP Rating		IPX2

6.2. STANDARDS

The Thermablate EAS device complies with:

- CAN/CSA C22.2 No. 601.1-M90 (with Supplement 1:1994 & Amendment 2:1998) Medical Electrical Equipment, Part 1, General Requirements for Safety.
Reference document:
IEC601-1:1988 (with Amendment 1:1991 & Amendment 2:1995) Medical Electrical Equipment, Part 1, General Requirements for Safety
- IEC60601-1-2:2007, IEC60601-1-2:2001, IEC60601-1-2:1993 Medical Directive Emissions and Immunity Standard.

The Thermablate *EAS* conforms to the EN60601-1-2:2007 standard for both immunity and emissions.

Note: This device is not intended for use in a residential installation.

The Emissions and Immunity limits are designed to provide reasonable protection against harmful interference in a typical medical environment installation. The device generates and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference with other devices, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between devices.
- Connect the device into an outlet on a circuit different from that to which the other device(s) is (are) connected.

The Thermablate *EAS* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The users of the Thermablate *EAS* can help prevent electromagnetic interference by maintaining a maximum distance between portable and mobile RF communications equipment (transmitters) and the Thermablate *EAS*.

7. ERROR MESSAGES AND TROUBLESHOOTING

During either the warm-up or the treatment cycles, the TCU may issue an error message on the LCD, due to either a malfunction or incorrect use of the device. The following list indicates the types of errors that the unit may issue, and the corresponding corrective actions to be taken:

WARNING

If any of the following errors occur during the treatment cycle, the treatment is considered as failed. It is CONTRAINDICATED TO RE-TREAT a patient with the Thermablate EAS device, as unintended burn may occur. Except as noted.

Error No.	Hardware Failure	Corrective Action
1	Ambient temperature sensor failure (output shorted to +5V)	Unit requires repairing.
2	Ambient temperature sensor failure (output shorted to ground)	Unit requires repairing.
3	Ambient temperature is too high	<u>If the error occurs before starting the treatment cycle:</u> • Turn TCU off and wait until room cools down below 40°C or perform the treatment in an A/C-equipped room. • Restart the unit and proceed with treatment as indicated.
4	Liquid temperature thermocouple failure	Unit requires repairing.
5	Heater temperature thermocouple failure	Unit requires repairing.
6	Heaters connection failure	Unit requires repairing.
7	Heater overheated	<ul style="list-style-type: none">• Turn TCU off.• Wait for 30-40 minutes.• Restart TCU.
8	Pressure sensor failure	<u>If the error occurs before starting the treatment cycle:</u> Unit requires repairing. <u>If the error occurs during the treatment cycle:</u> <ul style="list-style-type: none">• Wait for the unit to withdraw the liquid from the balloon.• Remove the balloon from the patient only when the unit indicates to do so.
9	Positive overpressure	<ul style="list-style-type: none">• Wait for the unit to withdraw the liquid from the balloon.• Remove the balloon from the patient only when the unit indicates to do so.

Error No.	Hardware Failure	Corrective Action
10	Negative overpressure	<p><u>If the error occurs before starting the treatment cycle:</u> Restart the unit.</p> <p><u>If the error occurs after treatment cycle completion:</u></p> <ul style="list-style-type: none"> • DO NOT REMOVE BALLOON FROM PATIENT. Instead, restart TCU. • If the error occurs again, turn the TCU off and withdraw the balloon quickly but carefully since some liquid may still be contained in the balloon. • If the error DOES NOT occur again, wait for the unit to withdraw the liquid from the balloon, and remove the balloon from the patient only when the unit indicates to do so.
11	Pump cannot reach test vacuum value	<ul style="list-style-type: none"> • Turn the unit off. • Ensure the cartridge is properly installed in the TCU, and the O-Ring is in good condition and properly installed. • Restart the unit. • If the problem persists, turn the unit off, replace the cartridge with a new one, and restart the unit.
12	ADC channel 8 is not grounded	Unit requires repairing.
13	Liquid temperature does not rise monotonically	Unit requires repairing.
14	Overtime for HEATING state	<ul style="list-style-type: none"> • Restart the unit, proceed with treatment as indicated. • If error persists, unit requires repairing.
15	Wrong air flow direction during treatment cycles	Unit requires repairing
16	Unable to hold vacuum	<p><u>If the error occurs before starting the treatment cycle:</u></p> <ul style="list-style-type: none"> • Turn the unit off. • Ensure the cartridge is properly installed in the TCU, and the O-Ring is in good condition and properly installed. • Restart the unit. • If the problem persists, turn the unit off, replace the cartridge with a new one, and restart the unit. <p><u>If the error occurs after treatment cycle completion:</u></p> <ul style="list-style-type: none"> • Turn the TCU off and withdraw the balloon quickly but carefully since some liquid may still be contained in the balloon.
17	Unable to reach vacuum for balloon leak tests	<ul style="list-style-type: none"> • Turn the unit off. • Ensure the cartridge is properly installed in the TCU, and the O-Ring is in good condition and properly installed. • Restart the unit. • If the problem persists, turn the unit off, replace cartridge with a new one, and restart the unit. <p>NOTE: At the time the second balloon leak test is performed the balloon has already been inserted into the uterus, but actual ablation HAS NOT commenced. It is thus safe to attempt the treatment again.</p>
18	Unable to reach and hold vacuum during liquid removal	Turn the TCU off and withdraw the balloon quickly but carefully since some liquid may still be contained in the balloon.
19	First leak test failure	Possible leak in the balloon. Replace cartridge with new one, and restart the unit.

Error No.	Hardware Failure	Corrective Action
20	Second leak test failure	Possible leak in the balloon. Replace cartridge with new one, and restart the unit. NOTE: At the time this balloon leak test is performed the balloon has already been inserted into the uterus, but actual ablation HAS NOT commenced. It is thus safe to attempt the treatment again.
21	Comparative leak test failure	Possible leak in the balloon. Replace cartridge with new one, and restart the unit. NOTE: At the time this balloon leak test is performed the balloon has already been inserted into the uterus, but actual ablation HAS NOT commenced. It is thus safe to attempt the treatment again.
22	Time out for reaching positive pressure	<u>If the error occurs before starting the treatment cycle:</u> <ul style="list-style-type: none">• Wait for the unit to withdraw the liquid from the balloon.• Remove the balloon from the patient only when the unit indicates to do so.
24	Liquid temperature is too low	<ul style="list-style-type: none">• Restart the unit. Initiate treatment as soon as the unit displays the "Ready for Treatment" message.• If the problem persists, turn the unit off, replace cartridge with a new one, and restart the unit.
25	Liquid temperature is too high	<ul style="list-style-type: none">• Turn the unit off.• CAREFULLY remove cartridge from TCU and allow it to cool down for 30-40 minutes.• Install cartridge back into TCU.• Restart the unit and initiate the treatment as soon as the unit displays the "Ready for Treatment" message.• If the problem persists, turn the unit off, replace cartridge with a new one, and restart again.
26	Value read from RAM cell do not match that was stored	The unit requires repairing.
27	Data stack overflow	The unit requires repairing.

8. LIMITED WARRANTY

IDOMAN TEORANTA warrants to the original purchaser that the **Thermablate™ EAS™ TCU** and all accessories provided with it (collectively, the "Thermablate") will be free from defects in material and workmanship for two (2) years from the date of the original purchase from an Idoman Teoranta authorized reseller. This limited warranty is nontransferable. If the Thermablate is defective during the warranty period, the purchaser's sole and exclusive remedy, and Idoman Teoranta's sole obligation, will be to (at Idoman Teoranta's option): repair the Thermablate to conform with its specifications; replace the Thermablate with a comparable product; or refund to the purchaser the original purchase price paid for the Thermablate. Repaired or replaced products or parts may be new or reconditioned, and are subject to this limited warranty through the end of the original warranty period. To obtain warranty service, the purchaser must: contact Idoman Teoranta during the warranty period; provide Idoman Teoranta with a dated proof of original purchase from an Idoman Teoranta-authorized reseller; and ship the Thermablate to Idoman Teoranta by prepaid delivery and packaged appropriately for safe shipment. The purchaser is responsible for shipping costs. This warranty does not apply if the defect or malfunction in the Thermablate was caused by misuse, neglect, unauthorized attempts to open, repair or modify the Thermablate, use of the Thermablate with accessories or other products that are not authorized by Idoman Teoranta, or any cause other than the intended normal use of the Thermablate. Non-warranty work is charged at the minimum repair rate effective at the time the Thermablate is returned to Idoman Teoranta, repairs include a complete functional test using factory test fixtures.

EXCLUSIONS: TO THE FULL EXTENT ALLOWED BY LAW, THIS LIMITED WARRANTY IS THE PURCHASER'S SOLE AND EXCLUSIVE REMEDY, AND NO OTHER WARRANTIES, CONDITIONS OR GUARANTEES OF ANY KIND SHALL APPLY, WHETHER STATUTORY, WRITTEN, ORAL, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES, CONDITIONS OR GUARANTEES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, PERFORMANCE, QUALITY, OR DURABILITY, ALL OF WHICH ARE DISCLAIMED. IN NO EVENT WILL IDOMAN TEORANTA BE LIABLE FOR ANY SPECIAL, EXTRAORDINARY, INDIRECT OR CONSEQUENTIAL DAMAGES OF ANY KIND WHATSOEVER, INCLUDING WITHOUT LIMITATION DAMAGES FOR LOSS OF DATA, LOST PROFITS, LOSS OF OPPORTUNITY, BUSINESS INTERRUPTION, PERSONAL INJURY OR DEATH, OR ANY OTHER LOSS ARISING OUT OF, RELATING TO, OR IN CONNECTION WITH, THE THERMABLADE, EVEN IF IDOMAN TEORANTA IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

LIABILITY LIMITATIONS: IF, AS A RESULT OF OR IN CONNECTION WITH ANY USE OF THE THERMABLADE, IDOMAN TEORANTA BECOMES LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY DAMAGES, LOSSES, COSTS, EXPENSES, OR OTHER LIABILITIES WHATSOEVER, AND REGARDLESS OF THE FORM OF ACTION (IN CONTRACT, TORT OR PURSUANT TO STATUTE), THEN IDOMAN TEORANTA's AGGREGATE LIABILITY TO ALL SUCH PERSONS WILL BE LIMITED TO AN AMOUNT EQUAL TO THE PURCHASE PRICE PAID FOR THE THERMABLADE.

The exclusion of certain conditions and warranties and the limitation of certain liabilities is prohibited in some jurisdictions, so these limitations and exclusions may not apply to some purchasers.

8. SYMBOLES USED ON LABELLING

Symbol	Symbol definition	Symbol	Symbol definition
	Method of Sterilization – Gamma Irradiation		Correct upright position
	Do not reuse		Fragile, handle with care
	Do not resterilize		Keep dry
	Read Instruction/Operators Manual		Temperature limitation
	Caution – Hot Surface		Humidity limitation
	Latex-free		Atmospheric pressure limitation
	Expiry Date		Date of Manufacture
	Classification according to the degree of protection against electric shock: Type BF		Do not use if package is damaged
	Product must be disposed of as per WEEE Directive 2002/96/EC		Power Supply Green Energy Level Rating
	Power Supply ROHS Compliant		The CE mark is a protected conformity mark of the European Community. The products herewith comply with the Medical Directive 93/42/EEC

	<p><i>Idoman Teoranta Killateeau, Tourmakeady, Co Mayo Ireland</i> <i>Tel No: +353 94 95 44726 Fax No: +353 94 95 44725 E-mail: info@thermablate-eas.com Web Site: www.thermablate-eas.com</i></p>
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	<p>CE 0120</p>

10. NOTES:

DISTRIBUTORS :

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