



*Thermal Balloon Endometrial Ablation System*

This Instructions For Use is designed for use with the Thermablate EAS  
Endometrial Ablation System

**NOTE: Please contact Idoman for extra or spare copies of the Thermablate EAS  
system instructions for use**

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

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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 non-sterile device, weighing less than 1Kg, controls the treatment settings (time, pressure, and temperature) through a computerized system that operates the electromechanical heating and pumping/draining subsystems. 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

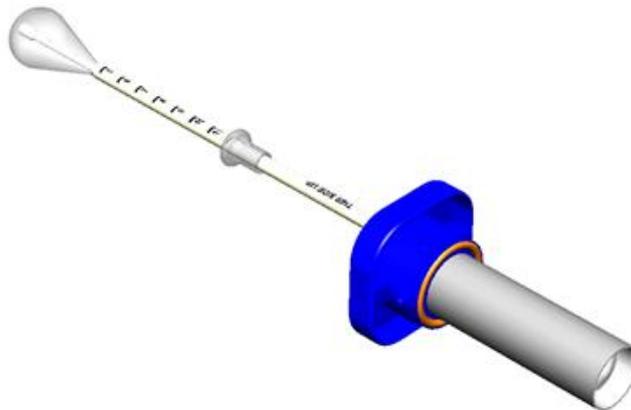


Figure 2. Thermablate EAS Disposable Cartridge (REF. No. 21004)

The sterilised catheter-balloon Disposable Cartridge (REF. No. 21004) is the actual treatment component (applied part) 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. Thermablade 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 which consists of IEC C13 connector, H05VV-F3G 1.0mm<sup>2</sup> cable and suitable plug for country. (Please consult distributor).

**Class I ME Equipment WARNING: To avoid the risk of electric shock, this equipment must only be connected to a mains supply with a protective earth.**

### 1.4 TCU STAND



Figure 4. TCU Thermablade Stand (Réf. 24001)

The Stand (REF. No. 24001) provided with the Thermablade 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. Thermablade EAS Carrying Case (Réf. 25001)

The Thermablade 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 aluminium 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 (menorrhagia) can be caused by a variety of underlying problems including but not limited to endometrial cancer, myomas, polyps, and hormonal disorders. Patients should always be evaluated, using the FIGO classification system (PALM-COEIN) for causes of abnormal uterine bleeding in nongravid women of reproductive age, to determine the underlying causes of their excessive uterine bleeding before any treatment option is initiated.

The patient selection criteria, as assessed by a physician, are.

- Documented diagnosis of excessive uterine bleeding with benign causes
- Completed childbearing
- Pre-menopausal
- Normal uterine cavity with sounding between 8 cm and 12 cm, inclusive
- Normal Cervical Screening sample performed in accordance with established clinical guidelines.
- Normal endometrial biopsy results within last 6 months.
- Does not present any of the contraindications below.

#### 3.3 PRE-ASSESSMENT OF UTERUS AND CAVITY

##### **Assessment of the Endometrium**

Assessment of the Endometrium to be carried out by endometrial biopsy within the last 6 months to exclude endometrial neoplasia (Hyperplasia or Cancer)

##### **Assessment of the Endometrial Cavity**

Assessment of the Endometrial Cavity should be performed by uterine sound, Transvaginal or Transabdominal Ultrasound, Saline / Gel Infusion Sonography (SIS)/(GIS), Hysterosalpingography (HSG) or Hysteroscopy.

### 3.4 CONTRAINDICATIONS

Thermablate EAS 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 or bicornate 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, T-Incision Caesarean or transmural myomectomy
- A patient who has had three or more, lower segment C sections and where the linear scar thickness in these 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.
- A patient who has had hysteroscopic tubal occlusion/sterilization performed in the last 3 months and in whom the 3-month tubal occlusion confirmatory test has not been performed.

### 3.5 WARNINGS

- Only medical professionals who have experience in performing procedures within the uterine cavity, such as IUD insertions or dilation and curettage, are suitably trained (including Thermablate User Training), have adequate knowledge and familiarity with the Thermablate EAS system should perform endometrial ablation using this device.
- Like every surgical intervention, endometrial ablation procedure may require access to emergency surgery premises which should be in proximity to the facility conducting the Thermablate procedure
- Read all directions, cautions, and warnings prior to use. This IFU 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 are not planning on having further/any children.
- Endometrial ablation using the Thermablate EAS system is not a sterilization procedure. Pregnancies after ablation can be dangerous for both mother and foetus. An effective form of contraception is required following Thermablate procedure.
- 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). A hysteroscopy must be performed prior to balloon insertion to ensure uterus has not been perforated during dilation, sounding or curettage  
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.
- Do not perform same day Thermablate EAS procedure and hysteroscopic tubal occlusion/sterilization.  
Thermablate EAS procedure can be safely and effectively performed with nickel titanium inserts in place, however the procedure should only be performed after the 3 month tubal occlusion confirmation test.
- If you suspect that the treatment liquid is leaking from the balloon during treatment, activate the "Emergency Stop" button or 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.
- If you are unable to see the LCD display messages or the unit loses power, turn the power switch to the off position and wait for thirty (30) seconds. After this 30-second period, withdraw the balloon quickly but carefully since some liquid may still be contained in the balloon.
- 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.
- Medical Equipment should not be placed against exposed flesh during treatment.

**(WARNINGS continued)**

**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, or by hysteroscopic endometrial ablation / resection only by experienced physicians.
- The outside temperature measured on the disposable cartridge sheath can reach a maximum of 80°C during treatment cycle. It has been confirmed, in a clinical study carried out by Idoman in 2010 and historical PMS data, that the temperature of the disposable cartridge sheath lacks sufficient energy to cause any heat transfer to surrounding area.

**3.6 POTENTIAL ADVERSE EFFECTS**

As with all endometrial ablation procedures, serious injury or death can occur.

The following adverse events have been potentially associated with endometrial ablation:

- Pelvic cramping
- Nausea and vomiting
- Perforation of the uterus
- Perforation of the Bowel
- Rupture of the uterus
- Thermal injury to adjacent tissue/organs, resulting in emergency surgery, and patient requiring a colectomy and creation of a stoma
- Heated liquid escaping into the cervix, vagina, or fallopian tubes
- Infection
- Post-ablation tubal sterilization syndrome ( PATSS)
- Haematometra.
- Pelvic Abscess
- Peritonitis
- Tubovarian abscess
- Salpingectomy

Based on current post market surveillance data the following incident rates are applicable

<b>Intra-operative Adverse Events</b>	<b>Incidence</b>
Uterine Perforation	<0.1%
Thermal Injury	<0.1%
Uterus Rupture	<0.1%
Bowel resection	<0.1%
Bowel Perforation	<0.1%
Pelvic Abscess	<0.1%
Perotinitis	<0.1%
Tuboovarian abscess	<0.1%
Salpingectomy	<0.1%

<b>Post-operative Adverse Events</b>	<b>Incidence</b>
Pain (Abdominal)	<0.1%
Pelvic (pain)/cramping	<0.1%
(Post-Op) Nausea and vomiting	<0.1%
Infection	<0.1%
Post-Ablation Tubal Sterilization Syndrome (PATSS)	<0.1%
Haematometra	<0.1%

### 3.7 PATIENT COUNSELLING

As with any procedure, the physician needs to discuss the risks, benefits, and alternatives with the patient prior to performing endometrial ablation. Endometrial ablation may be considered where bleeding is having a severe impact of the patient's quality of life and where the patient does not wish to conceive in the future.

Ablation should only be considered where first line treatment (e.g. NSAIDs, oral contraceptives, hormonal therapies) has failed or where patients have refused first line treatment. In addition the physician should discuss with the patient signs and symptoms such as bleeding, excessive pain, fever and nausea that may indicate potential complications of endometrial ablation such as infection, thermal injury or complications associated with uterine perforation. These symptoms should be reported to their physician immediately

It is important for clinicians to be aware of their patients' health literacy, which refers to the way in which information is assimilated, decisions made and the likelihood of the patient correctly following the treatment plan. Written information on the causes, investigations, treatment options and potential side-effects of treatment should be available to patients presenting with menorrhagia. Adequate time should be allowed to review information, discuss treatment options and answer questions. The avoidance of medical jargon, use of simple illustrations and confirming that patients understand how to use the prescribed treatment increases the likelihood of treatment success. First line treatments for menorrhagia, such as the oral contraceptive pill, should be discussed with the patient where applicable.

Patients should also be counselled about the inability to have a minimally invasive, yet adequate assessment of the endometrial cavity in the event of recurrence of AUB. These women may also be at risk for inability to adequately assess for endometrial hyperplasia or malignancy in the future.

This device is intended for use only in women who are not planning on having further/any children. 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 arise if they should become pregnant.

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

**CLINICAL STUDIES**

Two studies that have evaluated the safety and effectiveness of the Thermablate are presented here.

**Patient Acceptability<sup>1</sup>**

Acceptability and feasibility of Thermablate Endometrial ablation System (TEAS) as an outpatient procedure, was evaluated in a single arm prospective observational study in 70 patients.

Results

<b>Table 1A. Patient Questionnaire on pain, nausea and vomiting*</b>					
	<b>No Pain/Nausea (Score 0)</b>	<b>Mild Pain /Nausea(score 1-4)</b>	<b>Moderate Pain/ Nausea (Score 5-7)</b>	<b>Severe Pain/Nausea (Score 8-10)</b>	
<b>Preoperative pain, abdominal or pelvic</b>	55(78%)	13	2	0	
<b>Perioperative pain 1min</b>	37	18	12	3	
<b>Perioperative pain 2 min</b>	41	11	15	3	
<b>Postoperative pain 1min</b>	47	15	7	1	
<b>Postoperative pain 30 min</b>	30	30	8	2	
<b>Nausea 1 min</b>	58 (No Nausea)	9		3	1 vomited
<b>Nausea 30 min</b>	60 (No Nausea)	8		2	1 vomited

\*70 patients

<b>Table 1B. Patient satisfaction with the procedure as an outpatient procedure</b>			
	<b>Yes</b>	<b>No</b>	<b>Unsure</b>
<b>Preoperative analgesia*</b>	37(53%)	33 (47%)	
<b>Needing additional pain relief during procedure</b>	13 (18.5%)	57 (81.5%)	
<b>Patient satisfaction with procedure/pain relief</b>	62 (88%) <sup>‡</sup>	5 (7%) <sup>Σ</sup>	3 (4%) (neither satisfied nor dissatisfied)
<b>Would they have this procedure again?</b>	65 (93%)	5 (7%)	
<b>Would they recommend this procedure to a friend?</b>	62 (88%)	5 (7%)	3 (4%) (not sure whether to recommend or not)

\*Patients did/did not take oral analgesia prescribed

<sup>‡</sup> Scoring 8-10 = very satisfied to satisfied

<sup>Σ</sup> Scoring 1- 4 = very unsatisfied to unsatisfied

The TEAS was successfully used as an outpatient procedure for global EA in this group of 70 patients. No procedure was abandoned because of technical difficulties or patient intolerance. During the

thermablation, both at 1 minute and 2 minutes after starting the procedure, less than half (42%) the patients had mild to moderate pain and only 3 said the pain was severe. Postoperatively at 1 minute and 30 minutes these figures were 33% and 57%, respectively; in most the pain was said to be mild to moderate and only 2 had severe pain at 30 minutes after surgery (Table 1A). Nausea occurred in 12 (17%) patients during and after the procedure. When asked about their general satisfaction with the procedure as an outpatient treatment 88% (62 of 70) scored it as high, either very satisfied or satisfied.

### Patient Outcomes<sup>2</sup>

A comparative retrospective review of patient outcomes was performed on 180 patients with menorrhagia who underwent either; Radiofrequency Ablation (RFA) (n=50), Thermablate (n=40), Microwave Endometrial Ablation (MEA) (n=50) or Intrauterine device (IUS) insertion (n=40).

Data was collected by telephone questionnaire and chart review. Subjective menstrual loss and pain were rated pre and post procedure. Amenorrhoea, subsequent hysterectomy, satisfaction, recommendation rates and complications were recorded.

### Results

<b>Table 2A. Patient Improvement in Menorrhagia</b>				
	<b>RFA</b>	<b>Thermablate</b>	<b>MEA</b>	<b>IUS</b>
<b>Menstrual loss improvement</b>	90% (45/50)	95% (38/40)	72% (36/50)	88% (35/40)
<b>Dysmenorrhea Improvement</b>	74%	76%	57% (25/44)	74% (26/35)
<b>Amenorrhea Rate</b>	36% (18/50)	30% (12/40)	10% (5/50)	28% (11/40)

<b>Table 2B. Post Procedure Intervention</b>				
	<b>RFA</b>	<b>Thermablate</b>	<b>MEA</b>	<b>IUS</b>
<b>Hysterectomy Rates</b>	6%	2.5%	16%	2.5%

### References :

1. Prasad P, Powell MC. Prospective Observational Study of Thermablate Endometrial Ablation System as an Outpatient Procedure. J Minim Invasive Gynecol 2008 Jul-Aug; 15(4):476 – 479
2. O’Kane C, Chinnadurai A, Beirne J et al. A Retrospective Review of Patient Outcomes Comparing Novosure, Thermablate, Microwave Endometrial Ablation (MEA) and the Mirena Intrauterine System (IUS). Abstracts / J Minim Invasive Gynecol 2010 17 S109-S127

### **3.8 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.

### **3.9 RECOMMENDED PRE TREATMENT OF ENDOMETRIUM**

- Oral Contraceptives (Recommended for a minimum 21 days until day of treatment)
- An estrogen/progestin combined preparation may be administered daily by mouth or monthly per vagina
- Timing of the menstrual Cycle
- Curettage (if necessary)
- GnRH analogues minimum four weeks recommended only for patients with a uterine sounding  $\geq 10$  cm

## 4. DIRECTIONS FOR USE

### 4.1 SET-UP

4.1.1. 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

#### **Frequently used Functions:**

Operator should make themselves aware of the following functions.

On / Of Power switch located on TCU

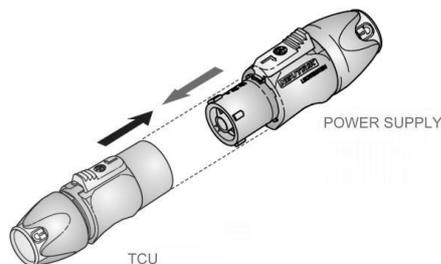
Emergency Stop Button located on LCD overlay on top of TCU

Blue Treatment Trigger Switch located on front of TCU handle.

4.1.2. Place TCU in Stand.

4.1.3. Ensure the "POWER SWITCH" is in the "OFF" position.

4.1.4. Connect the Power Supply to TCU (as shown below). 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 mains plug can be easily accessed to disconnect power to the TCU.



To make connection line up the two power connectors as shown above and twist to lock. To disconnect unit slide yellow buttons on connectors to unlock and twist connectors in direction shown by arrows on yellow buttons.

4.1.5. Ensure that the device is positioned to allow ease of access to the patient during treatment, avoiding any hindrances, stretching or obstructions. Also ensure that no cables or accessories are placed in a dangerous manner or position.

## 4.2 OPENING AND INSTALLING THE THERMABLATE EAS STERILE DISPOSABLE CARTRIDGE

- 4.2.1. The disposable cartridge is packaged inside a foil vacuum bag designed to be peeled open. ONLY THE CONTENTS OF THE FOIL VACUUM BAG ARE DEEMED TO BE IN A STERILE STATE. The foil vacuum bag is inside a cardboard box.
- 4.2.2. Check expiry date. DO NOT USE the Disposable Cartridge if it has expired.
- 4.2.3. Open cardboard box.
- 4.2.4. Remove foil vacuum bag from cardboard box.
- 4.2.5. Ensure vacuum is intact. If it is not, DO NOT USE the Disposable Cartridge, use another Disposable Cartridge instead.
- 4.2.6. Peel open foil vacuum bag where indicated by  label.
- 4.2.7. Remove disposable cartridge from the foil vacuum bag. Do not discard packaging but place aside for use in the safe disposal of disposable cartridge after use.
- 4.2.8. Remove disposable cartridge from packaging using standard aseptic technique.
- 4.2.9. 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 balloon cover on.

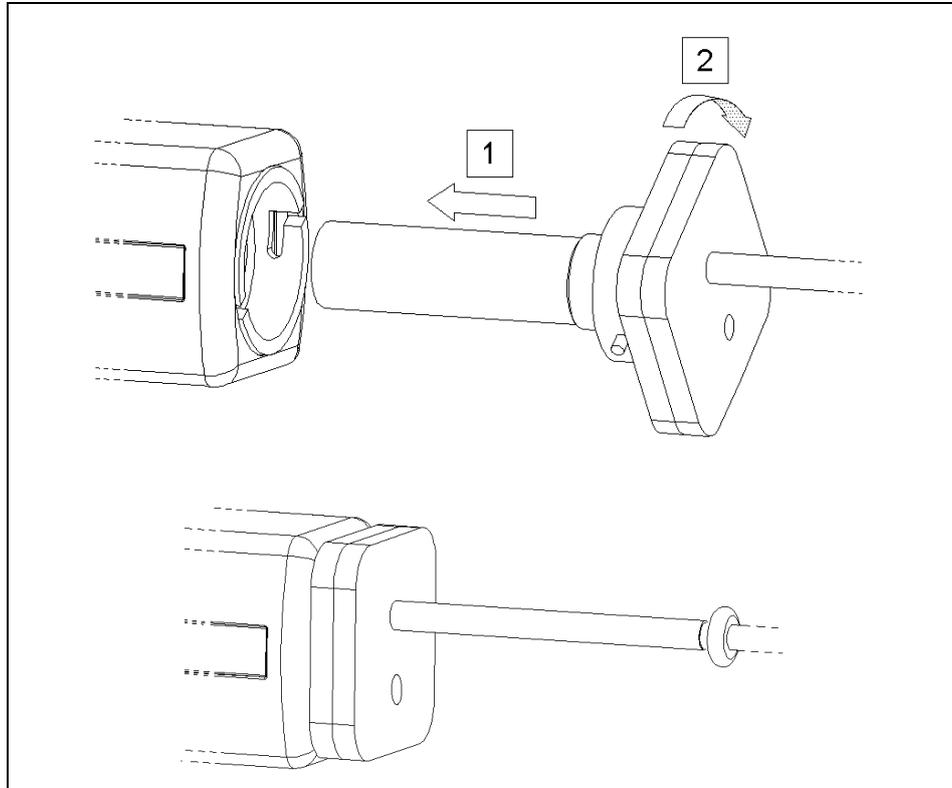


Figure 6. Installation of Disposable Cartridge

### 4.3 WARM-UP

- 4.3.1. Turn the "POWER SWITCH" to the "ON" position, the LCD will show the following message: **If no display is present then do not continue with procedure.**

WELCOME TO  
THERMABLATE

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.)

- 4.3.2. 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 or message will be displayed on the LCD. Please refer to section 7 "ERROR MESSAGES AND TROUBLESHOOTING".)

- 4.3.3. 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.

After approximately 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 and the treatment procedure can be initiated. The "Heating" LED will turn OFF and the "Ready" LED will turn 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, disconnect the power cord and 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, disconnect the power cord 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 the Disposable Cartridge, and restart the process*

#### **4.4 PATIENT PREPARATION**

- 4.4.1. Provide patient with adequate analgesia.
- 4.4.2. 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.
- 4.4.3. Place patient in dorsal lithotomy position.

#### **4.5 TREATMENT**

**CAUTION**

*Patients with either an 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.*

- 4.5.1. Conduct pelvic examination to confirm position of the uterus.
- 4.5.2. Insert Speculum.
- 4.5.3. Apply Tenaculum.
- 4.5.4. 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.
- 4.5.5. 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.
- 4.5.6. 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.

- 4.5.7. **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.**

- 4.5.8. **Alternatively, use ultrasound surveillance during the treatment to check for correct balloon position inside the uterine cavity.**
- 4.5.9. 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.
- 4.5.10. 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.
- 4.5.11. 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 balloon catheter, a repeat hysteroscopy should be performed.
- 4.5.12. Activate the treatment cycle by holding the Blue Treatment Trigger Switch 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 switch at this point. The LCD will show the following message:

Performing  
System Check

Both LED's will turn OFF.

- 4.5.13. 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:YYYY  
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).

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 activating the "Emergency Stop" button, observe the "Treatment Stop" message, while the fluid is actively withdrawn from the balloon and 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.

- 4.5.14. 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.

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

FINISHING...  
Do NOT Remove

- 4.5.15. 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.

**After every treatment the TCU carries out a test on the Filter Quality and if it has deteriorated beyond a set point the following message will be displayed along with audible indication.**

Filter Change is  
Due Right NOW

**If this message is displayed the TCU MUST be returned to Distributor for IMMEDIATE Servicing**

## 4.6 POST-TREATMENT

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

DISCARD  
USED CARTRIDGE

\*\*\*WARNING\*\*\*  
\*Metal End \*HOT\*

- 4.6.3. Turn the "POWER SWITCH" to the "OFF" position.

**WARNING**

*The Disposable Cartridge IS HOT and should be removed from the TCU and returned to its packaging carefully*

- 4.6.4. Remove Disposable Cartridge from TCU.
- 4.6.5. Return the Disposable Cartridge into its original packaging by holding the blue connector and inserting it ALUMINIUM SHIELD END FIRST (where packaging tube is used ensure that the hot metal end of the cartridge is towards the metal reinforced cap) and place it aside allowing to cool before disposing 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.***

- 4.6.6. Post treatment hysteroscopy is recommended.
- 4.6.7. 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 validated infection control procedure.

- 5.1.1. Disconnect the TCU from the power supply.
- 5.1.2. Wipe down the outside of the TCU housing with warm water using a soft bristle brush until it is clean. DO NOT SOAK OR IMMERSE
- 5.1.3. Subsequently, wipe down the outside of the TCU housing with warm water using a clean wipe. DO NOT SOAK OR IMMERSE.
- 5.1.4. Disinfect the outside of the TCU housing with a clean wipe and 50%IPA/ water solution. DO NOT SOAK OR IMMERSE.

**CAUTION**

*This unit contains electronic components. DO NOT soak, flush, spray or use excessive free liquid on the TCU. Any units that have been subjected to excessive free liquids during operation or cleaning should not be used and must be returned to Idoman.*

## 5.2 Maintenance

**There are no user serviceable parts within the TCU. Opening the device will void the warranty. Return unit to Idoman via Distributor for service or repair.**

It is recommended that the TCU and its accompanying power supply are subjected to annual local inspection to ensure the safety of the device for both patient and user.

This inspection should include the following:

- Power connecting cords and power supply for signs of damage or wear.
- TCU housing for signs of damage which may leave it in an unsafe or contaminated state.
- Presence and legibility of all Safety related markings and Labels.
- Copy of Instructions For Use (IFU) present.  
(Please contact Idoman for most recent version.)

Testing (If Required)

- Protective earth resistance
- Equipment leakage current
- Patient leakage current
- Insulation resistance.
- Functional Test of Device

**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.**

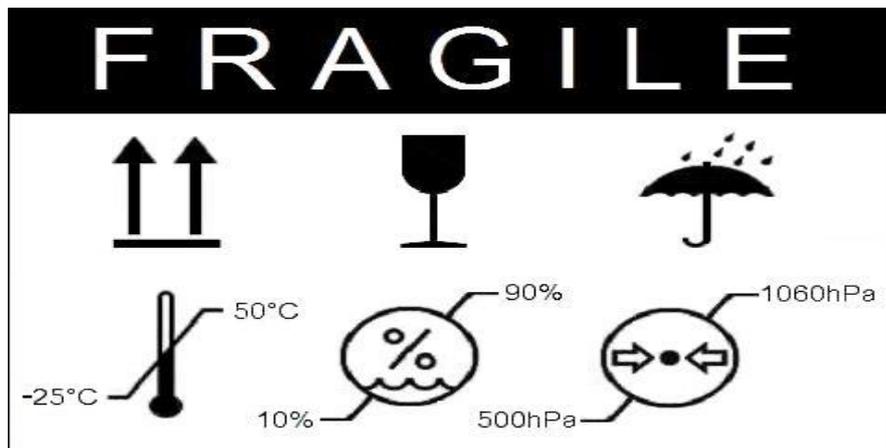
All TCU units that have reached their end of service life should be returned to manufacturer for disposable as per WEEE Directive 2002/96/EC or disposed of as per relevant national guidelines and regulations.

## 5.3 STORAGE AND TRANSPORT

5.3.1. Store the TCU in the Carrying Case. The storage temperature should never exceed 50°C.

5.3.2. Store Disposable Cartridge in dry place as per label.

5.3.3. For storage and transport environmental conditions, see the label with graphical representations and Technical Specifications table, below.



## 6. TECHNICAL INFORMATION

### 6.1. Technical Specifications

<u>Item</u>	<u>Specification</u>		
Temperature of treatment liquid during ablation	Initial: 150°C, approx.; Final: 100°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 4-2A		
Output power of regulated power supply	24 volts, 6 Amp		
Environmental Conditions for Operation	<ul style="list-style-type: none"> <li>Indoor Use only</li> <li>Temperature is between <b>10°C</b> and <b>30°C</b>.</li> <li>Humidity is between <b>15%</b> and <b>70%</b>.</li> <li>Atmospheric pressure between <b>690 hPa</b> and <b>1060 hPa</b>.</li> </ul>		
Environmental Conditions for Storage and Transport	<div style="text-align: center;">  </div> <ul style="list-style-type: none"> <li>Temperature is between <b>-25°C</b> and <b>50°C</b></li> <li>Humidity is between <b>10%</b> and <b>90%</b>.</li> <li>Atmospheric pressure is between <b>500 hPa</b> and <b>1060 hPa</b>.</li> <li>Tested for transportation in accordance with ASTM 4619-09</li> <li>Pollution Degree 2</li> <li>Ultraviolet Protection: Indoor use only</li> </ul>		
Handling	Fragile - Medical devices		
Classification	TCU Degree of protection Electrical Equipment Class II ME Disposable Cartridge is Type BF Applied Part		
Mode of Operation	Continuous Operation following cleaning / disinfection. 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	27.3 cm
		Width	11.1 cm
		Height	17.8 cm
	Disposable Cartridge	Total Length	30.7cm
		Connector Height	5.5cm
		Connector Width	5.5cm
Insertion Length	12 cm From insertion stop to balloon tip		
Weight	TCU	Less than 1Kg	
	Disposable Cartridge	110g (4oz)	
Protection	The TCU does not have any degree of protection against direct and prolonged ingress of liquids and should be handled accordingly		

**The Thermablade EAS device is not suitable for use in an Oxygen rich or hazardous substances environment.**

## 6.2. STANDARDS

The Thermablade EAS device complies with:

- IEC60601-1:2005 Edition 3.0 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.
- CAN/CSA C22.2 No. 60601.1:08 (with Supplement 1:1994 & Amendment 2:1998) Medical Electrical Equipment, Part 1, General Requirements for Safety.
- ANSI/AAMI ES60601-1:2005 Medical electrical equipment—Part 1: General requirements for basic safety and essential performance

Guidance and manufacturer's declaration-electromagnetic emissions		
The Thermablade EAS Treatment Control Unit (TCU) is intended for use in the electromagnetic environment specified below. The customer or the user of the Thermablade EAS Treatment Control Unit (TCU) should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CSPR 11	Group 1	The Thermablade EAS Treatment Control Unit (TCU) 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 CSPR 11	Class A	The Thermablade EAS Treatment Control Unit (TCU) is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded.  <b>Warning:</b> This equipment/system is intended for use by healthcare professionals only. This equipment /system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orientating or relocating the Thermablade EAS Treatment Control Unit (TCU) or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

<b>Guidance and manufacturer's declaration-electromagnetic immunity</b>			
The Thermablade EAS Treatment Control Unit (TCU) is intended for use in the electromagnetic environment specified below. The customer or the user of the Thermablade EAS Treatment Control Unit (TCU) should assure that it is used in such an environment			
<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 seconds	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 seconds This condition causes the Treatment Control Unit to enter power interruption mode.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Thermablade EAS Treatment Control Unit (TCU) requires continued operation during power mains interruptions, it is recommended that the Thermablade EAS Treatment Control Unit (TCU) be powered from an uninterruptible power supply or a battery.
Power frequency 50/60Hz Magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

<b>Guidance and manufacturer's declaration-electromagnetic immunity</b>			
The Thermablade EAS Treatment Control Unit (TCU) is intended for use in the electromagnetic environment specified below. The customer or the user of the Thermablade EAS Treatment Control Unit (TCU) should assure that it is used in such an environment			
<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Thermablade EAS Treatment Control Unit (TCU), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b>  $d=1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz  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, are determined by an electromagnetic site survey, <sup>1</sup> should be less than the compliance level in each frequency range. <sup>2</sup>  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.			
<p><sup>1</sup>. 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 Thermablade EAS Treatment Control Unit (TCU) is used exceeds the applicable RF compliance level above, the Thermablade EAS Treatment Control Unit (TCU) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Thermablade EAS Treatment Control Unit (TCU).</p> <p><sup>2</sup>. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m</p>			

**Recommended separation distances between portable and mobile RF communications equipment and the Thermablade EAS Treatment Control Unit (TCU)**

The Thermablade EAS Treatment Control Unit (TCU) is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Thermablade EAS Treatment Control Unit (TCU) can help prevent electromagnetic interference by maintaining a minimum distance between portables and mobile RF communications equipment (transmitters) and the Thermablade EAS Treatment Control Unit (TCU). As recommended below, according to the maximum output power of the communication equipment.

Rated Maximum output power of transmitter <b>W</b>	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated 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 separation distance for 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

## 7. ERROR MESSAGES AND TROUBLESHOOTING

### 7.1 EMERGENCY STOP

#### **EMERGENCY INTERRUPTION / TERMINATION OF TREATMENT**

IF EMERGENCY INTERRUPTION/TERMINATION OF TREATMENT IS REQUIRED OR IF LIQUID IS NOTED LEAKING THROUGH THE CERVIX, DO NOT IMMEDIATELY REMOVE THE BALLOON FROM THE UTERUS.

If fitted, first Activate the red "Emergency Stop" button on the LCD Overlay which will activate the emergency routine and display the "TREATMENT STOP" message on the LCD and then proceed to actively withdraw the liquid from the balloon.

OR

Turn off the power to the TCU. Then proceed to turn power back on to the TCU. In doing so, the TCU will automatically recognize that the "previous" treatment did not finish correctly. The TCU will display the "TREATMENT STOP" message on the LCD and then proceed to actively withdraw the liquid from the balloon.

TREATMENT STOP

Do Not Remove

REMOVE THE BALLOON FROM THE UTERUS ONLY AFTER "FINISHED , Withdraw Balloon" MESSAGE APPEARS ON the LCD screen.

### 7.2 INITIAL HEAT UP

If you observe any liquid or gas in the balloon during "Heat Up" or "Ready For Treatment" state, or the balloon cover cannot be easily removed, do not proceed with the treatment. Turn the power switch to the off position, disconnect the power cord, substitute the disposable cartridge and restart the process.

### 7.3 SYSTEM CHECK FAILURE

If the system check fails, the TCU will issue an error code or message and stop operating. In this case, turn the "POWER SWITCH" to the "OFF" position, disconnect the power cord, and 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.

**Note: The Treatment Control Unit will register an Error 11 when powered on if the disposable cartridge is not fitted or not fully fitted.**

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.

### 7.4 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

### **7.5 LOSS OF TCU DISPLAY DURING TREATMENT**

If you are unable to see the LCD display messages during treatment, turn the power switch to the off position and wait for thirty (30) seconds. After this 30-second period, withdraw the balloon quickly but carefully since some liquid may still be contained in the balloon

### **7.6 SYSTEM FAILURE DURING TREATMENT**

If the TCU encounters a technical problem during the procedure, it will issue a "TREATMENT FAILED" message. Do not attempt to remove the disposable from the uterus as the device will then actively withdraw any fluid that is in the disposable. Remove the disposable from the uterus only after the "FINISHED, Withdraw Balloon" message appears on the LCD screen.

### **7.7 SYSTEM FAILURE DURING DEFLATION**

If the TCU encounters a technical problem during the deflation procedure, it will issue a "DEFLATION FAILED" message. Do not remove the disposable from the uterus. Instead, wait until the device withdraws the liquid from the balloon. Remove the disposable from the uterus only after the "FINISHED, Withdraw Balloon" message appears on the LCD screen.

### **7.8 ERROR CODES**

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 or messages that the unit may issue, and the corresponding corrective actions to be taken:

**WARNING**

*If any errors occur after ablation has started, the treatment is considered as failed. It is CONTRAINDICATED TO RE-TREAT a patient with the Thermablate EAS device, as unintended burn may occur.*

<b>Error No.</b>	<b>Hardware Failure</b>	<b>Corrective Action</b>
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> <ul style="list-style-type: none"> <li>• Turn TCU off and wait until room cools down below 40°C or perform the treatment in an A/C-equipped room.</li> <li>• Restart the unit and proceed with treatment as indicated.</li> </ul>
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"> <li>• Turn TCU off.</li> <li>• Wait for 30-40 minutes.</li> <li>• Restart TCU.</li> </ul>

Error No.	Hardware Failure	Corrective Action
8	Pressure sensor failure	<p><u>If the error occurs before starting the treatment cycle:</u> Unit requires repairing.</p> <p><u>If the error occurs during the treatment cycle:</u></p> <ul style="list-style-type: none"> <li>• Wait for the unit to withdraw the liquid from the balloon.</li> <li>• Remove the balloon from the patient only when the unit indicates to do so.</li> </ul>
9	Positive overpressure	<ul style="list-style-type: none"> <li>• Wait for the unit to withdraw the liquid from the balloon.</li> <li>• Remove the balloon from the patient only when the unit indicates to do so.</li> </ul>
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"> <li>• DO NOT REMOVE BALLOON FROM PATIENT. Instead, restart TCU.</li> <li>• 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.</li> <li>• 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.</li> </ul>
11	Pump cannot reach test vacuum value	<ul style="list-style-type: none"> <li>• Turn the unit off.</li> <li>• Ensure the cartridge is properly installed in the TCU, and the O-Ring is in good condition and properly installed.</li> <li>• Restart the unit.</li> <li>• If the problem persists fit disposable in second TCU, (if available).</li> <li>• If error occurs again then replace disposable cartridge.</li> </ul> <p>If error does not occur again, original unit may require servicing.</p>
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"> <li>• Restart the unit, proceed with treatment as indicated.</li> <li>• If error persists, unit requires repairing.</li> </ul>
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"> <li>• Turn the unit off.</li> <li>• Ensure the cartridge is properly installed in the TCU, and the O-Ring is in good condition and properly installed.</li> <li>• Restart the unit.</li> <li>• If the problem persists, turn the unit off, replace the cartridge with a new one, and restart the unit.</li> </ul> <p><u>If the error occurs after treatment cycle completion:</u></p> <ul style="list-style-type: none"> <li>• Turn the TCU off and withdraw the balloon quickly but carefully since some liquid may still be contained in the balloon.</li> </ul>
17	Unable to reach vacuum for balloon leak tests	<ul style="list-style-type: none"> <li>• Turn the unit off.</li> <li>• Ensure the cartridge is properly installed in the TCU, and the O-Ring is in good condition and properly installed.</li> <li>• Restart the unit.</li> <li>• If the problem persists, turn the unit off, replace cartridge with a new one, and restart the unit.</li> </ul> <p><b>NOTE:</b> 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>

Error No.	Hardware Failure	Corrective Action
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. Ensure the cartridge is properly installed in the TCU, and the O-Ring is in good condition and properly installed. If the problem persists fit disposable in second TCU (if available). If error occurs again then replace disposable cartridge. If error does not occur again, original unit may require servicing.
20	Second leak test failure	Possible leak in the balloon. Replace cartridge with new one, and restart the unit. <b>NOTE:</b> 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. <b>NOTE:</b> 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"> <li>• Wait for the unit to withdraw the liquid from the balloon.</li> <li>• Remove the balloon from the patient only when the unit indicates to do so.</li> </ul>
24	Liquid temperature is too low	<ul style="list-style-type: none"> <li>• Restart the unit. Initiate treatment as soon as the unit displays the "Ready for Treatment" message.</li> <li>• If the problem persists, turn the unit off, replace cartridge with a new one, and restart the unit.</li> </ul>
25	Liquid temperature is too high	<ul style="list-style-type: none"> <li>• Turn the unit off.</li> <li>• CAREFULLY remove cartridge from TCU and allow it to cool down for 30-40 minutes.</li> <li>• Install cartridge back into TCU.</li> <li>• Restart the unit and initiate the treatment as soon as the unit displays the "Ready for Treatment" message.</li> <li>• If the problem persists, turn the unit off, replace cartridge with a new one, and restart again.</li> </ul>
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 **Thermablade™ EAS™ TCU** and all accessories provided with it (collectively, the "Thermablade") 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 Thermablade 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 Thermablade to conform with its specifications; replace the Thermablade with a comparable product; or refund to the purchaser the original purchase price paid for the Thermablade. 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 Thermablade 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 Thermablade was caused by misuse, neglect, unauthorized attempts to open, repair or modify the Thermablade, use of the Thermablade with accessories or other products that are not authorized by Idoman Teoranta, or any cause other than the intended normal use of the Thermablade. Non-warranty work is charged at the minimum repair rate effective at the time the Thermablade 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 THERMABLATE, 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 THERMABLATE, 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 THERMABLATE.

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.

**9. SYMBOLS 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 Instructions For Use		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		Open Here
	On position of power switch		Off position of power switch
	Class II Method of protection against electric shock		EMERGENCY STOP
	Power Supply ROHS Compliant		Power Supply Green Energy Level Rating
	Manufactured By		CE Mark and Identification Number of Notified Body. Product conforms to the essential requirements of the Medical Devices Directive 93/42/EEC
	ETL Mark and Control Number. Conforms to ANSI/AAMI ES60601-1:2005 Medical Electrical Equipment—Part 1 Certified to CAN/CSA C22.2 No. 60601.1:08 Medical Electrical Equipment, Part 1		

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