# MINITOUCH 3.8 ERA SYSTEM

# (MINITOUCH SYSTEM)

# INSTRUCTIONS FOR USE

**Caution: US Federal Law restricts this device to sale by or on the order of a physician trained in the use of the Minitouch System.**

PN 5091 Rev A-6, CLEAN VERSION, 21 Jul 2023

# CLINICAL INFORMATION

## Indications for Use

The Minitouch System is intended for ablation of the endometrial lining of the uterus for the treatment of menorrhagia (heavy menstrual bleeding) due to benign causes in premenopausal women for whom childbearing is complete.

## Contraindications

The Minitouch System is contraindicated for the patient:

a. who is pregnant or desires to retain fertility. **Pregnancy following the ablation can be dangerous for both mother and fetus.**
b. who has known/suspected uterine cancer or pre-malignant conditions of the endometrium, such as unresolved adenomatous hyperplasia.
c. with any anatomic condition (e.g., history of previous classical cesarean section or transmural myomectomy, including hysteroscopic and/or laparoscopic myomectomy performed immediately prior to the Minitouch procedure) or pathologic condition (e.g., requiring long- term medical therapy) that could lead to weakening of the myometrium
d. with a history of endometrial ablation and/or resection (including endometrial ablation/resection performed immediately prior to the Minitouch procedure), regardless of the modality by which it was performed. Repeat ablation may result in serious patient injury.
e. who has active genital or urinary tract infection, or pelvic inflammatory disease.
f. who has abnormal, obstructed, or perforated cavity. **Ablation in such cavities could result in serious injury.**
g. who has intrauterine implant, such as intrauterine device (IUD) currently in place.
h. who has undiagnosed vaginal bleeding
i. who has uterine cavity length of less than 4 cm. The Handpiece may not deploy adequately and system may not initiate energy delivery.
j. who has abnormal uterine/pelvic anatomy, such as frozen pelvis.

## Warnings

a. User must be experienced in transcervical intra-uterine procedures and have clinical knowledge of endometrial ablation procedures.
b. User must have completed the Minitouch Training Program.
c. Carefully read the “Instructions for Use". Failure to follow it diligently could result in serious injury.
d. Minitouch Procedure is not for female sterilization. Post-procedure contraception and prevention of pregnancy are essential.
e. Do not use if the Handpiece or its sterile pouch is damaged. It can expose the patient to non-sterile components.
f. Handpiece is for a single procedure use only. Do not reuse or re-sterilize Handpiece. It could result in unsafe treatment.
g. To reduce and/or avoid the risk of a uterine perforation, do not plan additional procedures that require dilation or can cause significant trauma to the uterus. Ablations performed in the presence of perforations increase the risk of non-target tissue damage. Energy must never be delivered if a perforation is suspected.
h. Accurately determine the Reference Sounding Depth S1 at the time of the scheduled Minitouch Procedure right before the Handpiece is placed in the uterine cavity. It is essential for safe and proper positioning of the Handpiece in the cavity, and for identifying any undetected perforation or false passage.
i. Ensure that Leaf is properly deployed and positioned within the cavity by diligently following the procedural steps listed under “Minitouch Procedure – Part 1”. A warning screen displayed during this phase indicates a possible contraindicated cavity. In that event, use clinical judgment and decide to either end the procedure or restart it beginning from the section A under “Before the Minitouch Procedure”. Failure to comply could result in serious injury.
j. Instruct the patient to contact appropriate medical staff immediately in case of unexpected symptoms, such as increasing pain or fever, as it may indicate unanticipated injury to the pelvic anatomy and risk of a serious adverse condition.
k. End the procedure and perform checks per standard clinical practice if an equipment malfunction or other abnormal situation is suspected at any time. Failure to comply could result in serious injury.
l. Do not perform the Extension and Main Treatment steps at the same Leaf position to mitigate the risk of unintended thermal injury.

## Precautions

a. Clear all Generator checks prior to use.
b. Inter-connecting cable (ICC) is not sterile. Do not sterilize it. Insert in a provided sterile cover before use.
c. Do not connect the mains power if Generator is wet.
d. Use only a “Hospital Grade” mains power receptacle for grounding reliability.
e. Do not use Generator near flammable materials or in an oxygen enriched environment. Spark generation is possible.
f. The Minitouch procedure has not been evaluated in patients with cardiac pacemakers or metallic implants.
g. Caution should be used in treating patients with small sized uteri. Please refer to the ex vivo ablation depth information in GI-2 Patient Safety.

## Anticipated Post-Procedural Symptoms

The following post-procedural symptoms are commonly reported for all global endometrial ablation procedures, including Minitouch.

Uterine cramping, nausea, vomiting, vasovagal reaction, vaginal discharge, bleeding, or spotting.

## Other Adverse Events

The following adverse events are rare but have been reported with other endometrial ablation procedures and may occur with the Minitouch Procedure.

Pelvic pain, hemorrhage, endometritis, infection, fever, sepsis, cervical stenosis, uterine necrosis, adhesions, hematometra, pelvic inflammatory disease, post-ablation tubal sterilization syndrome, hydrosalpinx, unintended thermal/mechanical injury to uterus and other organs, cardiac complications, death.

## References

American College of Obstetricians and Gynecologists Practice Bulletin No. 128: Diagnosis of Abnormal Uterine Bleeding in Reproductive-aged Women. *Obstet Gynecol.* 2012:120(1):197-206.

American College of Obstetricians and Gynecologists FAQ134: Endometrial Ablation. *Frequently Asked Questions.* 2022.

## Clinical Study

**Purpose.** To evaluate the safety and effectiveness of the Minitouch System in premenopausal women with heavy menstrual bleeding due to benign causes for whom childbearing is complete.

**Pretreatment.** Endometrial thinning was not used.

**Period Timing.** Period timing was not used.

**Study Endpoints.** The primary safety endpoint was incidence of device or procedure-related serious adverse events at 12 months post-procedure. The primary effectiveness endpoint was reduction in menstrual bleeding at Month 12. Success was defined as a Pictorial Blood Loss Assessment Chart (PBLAC) score of ≤ 75.[1,2]

**Methods.** A prospective, multi-center, single-arm, open-label, non-randomized clinical trial was conducted at 5 US Physician's Office sites by investigators with experience in transcervical procedures and knowledge of endometrial ablation. The investigators had no prior exposure to the Minitouch System. Outcomes incorporate the learning curve cases as the protocol did not allow for practice cases.

**Key Inclusion Criteria**

a. Excessive menstrual bleeding due to benign causes.
b. Premenopausal women 30 to 50 years of age.
c. Willing to use reliable contraception.
d. Uterine sounding depth measurement of 6.0 – 12.0cm.
e. Minimum uterine cavity length of 4.0cm; no upper limit.
f. Menstrual blood loss with a PBLAC score of ≥150.

**Key Exclusion Criteria**

a. Pregnant or desires to retain fertility.
b. Endometrial hyperplasia.
c. Abdominal, pelvic, or gynecological malignancy.
d. Known clotting defects or bleeding disorders.
e. Active genital/urinary/systemic infection or sexually transmitted disease.
f. Clinically significant or suspected adenomyosis.
g. Presence of an IUD.
h. Previous medical/surgical treatments that could lead to anatomic/pathologic weakness or thinning of the myometrium.

[1] The PBLAC is a self-administered instrument that allows the subject to record the number of menstrual products she used during her menstrual period. A PBLAC score is calculated from the number, type, and saturation level of menstrual products recorded on the diary.
[2] The effectiveness of the Minitouch System was compared to an FDA established objective performance criterion (OPC) and therefore, did not have an active Control Group in the study. The OPC was developed by FDA with input from industry and members of the Obstetrics and Gynecology Devices Panel.

i. Abnormal, obstructed, or perforated cavity.
j. Intramural or subserosal myomas >3cm, or any myoma that distorts the uterine cavity.

**Patient Population.** A total of 114 subjects who were treated comprise the Intent-to-Treat (ITT) population. At maximum, the sounding depth was 11 cm, cavity length was 7.8 cm, and endometrial thickness was 23.4 mm. The number of low transverse C-Sections ranged from 1 to 5.

| | N | Mean | SD | Median | Min | Max | Unit |
|---|---|---|---|---|---|---|---|
| Age | 114 | 41.8 | 4.7 | 42.0 | 30.0 | 50.0 | years |
| BMI | 114 | 29.7 | 6.2 | 28.9 | 17.8 | 50.3 | $kg/m^2$ |
| Sounding Depth | 114 | 8.6 | 0.9 | 8.5 | 7.0 | 11.0 | cm |
| Cavity Length | 114 | 5.2 | 0.8 | 5.1 | 4.0 | 7.8 | cm |
| Endometrial Thickness | 114 | 9.5 | 4.2 | 8.9 | 3.0 | 23.4 | mm |
| PBLAC Score at Baseline | 114 | 265 | 161 | 204 | 152 | 1070 | |
| FSH | 75 | 7.3 | 5.7 | 6.2 | 0.6 | 35.9 | IU/L |
| *Obstetric History* | | | | | | | |
| Nulligravida | 6 | | | | | | |
| Gravida | 108 | 2.9 | 1.2 | 3 | 1 | 6 | |
| Para | 108 | 2.4 | 1.0 | 2 | 0 | 5 | |
| C-Section (Low Transverse) | 43 | 1.7 | 0.8 | 2 | 1 | 5 | |

| | N | N % |
|---|---|---|
| *Ethnicity* | | |
| Hispanic or Latino | 14 / 114 | 12% |
| Not Hispanic or Latino | 100 / 114 | 88% |
| *Race* | | |
| American Indian or Alaska Native | 0 / 114 | 0% |
| Asian | 2 / 114 | 2% |
| Black or African American | 3 / 114 | 3% |
| Native Hawaiian or Other Pacific Islander | 0 / 114 | 0% |
| White | 108 / 114 | 95% |
| Other | 2 / 114 | 2% |

## *Results*

**Subject Accountability.** All ITT subjects (100%, 114/114) were available for evaluation at the Month 12 postoperative visit.

## *Primary Endpoints*

**Safety.** There were no reported device or procedure related serious adverse events.

**Effectiveness.** *The success rate was 89.5% (102/114)* with a 95% confidence interval of 82.3% to 94.4%. There were no additional interventions or treatments for bleeding during the 12-month follow-up period.

| PBLAC Score | N | N % |
|---|---|---|
| ≤ 75 | 102 / 114 | 89.5% |

## *Secondary Outcome Measures*

**Safety.** The table below lists the device or procedure related non-serious adverse events.

| | Day 0 | | Day 1 | | Day 2 to Week 2 | | Week 3 to Month 12 | |
|---|---|---|---|---|---|---|---|---|
| | No. of Events | % Subjects with Events | No. of Events | % Subjects with Events | No. of Events | % Subjects with Events | No. of Events | % Subjects with Events |
| Total | 69 | 41.2% (48/114) | 2 | 1.8% (2/114) | 7 | 6.1% (7/114) | 3 | 2.6% (3/114) |
| | | | | | | | | |
| Abdominal distension | 1 | 0.9% (1/114) | | | 1 | 0.9% (1/114) | | |
| Chills | 2 | 1.8% (2/114) | | | | | | |
| Bacterial vaginosis | | | | | 1 | 0.9% (1/114) | 1 | 0.9% (1/114) |
| Procedural nausea | 6 | 5.3% (6/114) | | | | | | |
| Procedural pain | 2 | 1.8% (2/114) | | | | | 1 | 0.9% (1/114) |
| Procedural vomiting | 5 | 4.4% (5/114) | | | | | | |
| Dizziness | 1 | 0.9% (1/114) | | | | | | |
| Presyncope | 1 | 0.9% (1/114) | | | | | | |
| Somnolence | 1 | 0.9% (1/114) | | | | | | |
| Pollakiuria | 1 | 0.9% (1/114) | | | | | | |
| Uterine pain | 2 | 1.8% (2/114) | | | | | | |
| Uterine spasm | 44 | 38.6% (44/114) | 2 | 1.8% (2/114) | 3 | 2.6% (3/114) | 1 | 0.9% (1/114) |
| Vaginal discharge | 2 | 1.8% (2/114) | | | 1 | 0.9% (1/114) | | |
| Vaginal odour | | | | | 1 | 0.9% (1/114) | | |
| Hot flush | 1 | 0.9% (1/114) | | | | | | |

**Effectiveness.** *The Amenorrhea rate was 51.8% (59/114).*

| PBLAC Score | N | N % |
|---|---|---|
| 0 | 59 / 114 | 51.8% |

**Dysmenorrhea NRS Scores.** (scale of 0 to 10). Dysmenorrhea burden reduced in 98% of the subjects who had dysmenorrhea. A majority (67%) reported no dysmenorrhea at Month 12. Mean dysmenorrhea score reduced from 6.1 at baseline to 0.9 at Month 6 and 0.8 at Month 12.

| NRS Score Level | Baseline | | Month 12 | |
|---|---|---|---|---|
| | N | N% | N | N% |
| 0 | 5 / 114 | 4.4% | 76 / 114 | 66.7% |
| 1 | 5 / 114 | 4.4% | 12 / 114 | 10.5% |
| 2 | 5 / 114 | 4.4% | 11 / 114 | 9.6% |
| 3 | 4 / 114 | 3.5% | 6 / 114 | 5.3% |
| 4 | 2 / 114 | 1.8% | 4 / 114 | 3.5% |
| 5 | 20 / 114 | 17.5% | 3 / 114 | 2.6% |
| 6 | 15 / 114 | 13.2% | 2 / 114 | 1.8% |
| 7 | 19 / 114 | 16.7% | 0 / 114 | 0.0% |
| 8 | 16 / 114 | 14.0% | 0 / 114 | 0.0% |
| 9 | 19 / 114 | 16.7% | 0 / 114 | 0.0% |
| 10 | 4 / 114 | 3.5% | 0 / 114 | 0.0% |

| NRS Score | N | N % | NRS Score – Mean | |
|---|---|---|---|---|
| | | | *Baseline* | *Month 12* |
| Reduced | 107 / 109 | 98% | 6.4 | 0.7 |
| Same | 3 / 114 | 3% | 0.7 | 0.7 |
| Increased | 4 / 114 | 4% | 1.3 | 3.3 |
| ALL | 114 | 100% | 6.1 | 0.8 |

| N = 114 | Baseline | Month 3 | Month 6 | Month 12 |
|---|---|---|---|---|
| NRS Score – Mean | 6.1 | 1.4 | 0.9 | 0.8 |

**Menorrhagia Impact Questionnaire (MIQ).** 93% of the subjects reported no limitations in work/physical/social/leisure activities at Month 12.

| | Baseline | | Month 12 | |
|---|---|---|---|---|
| | **N** | **N%** | **N** | **N%** |
| **Perception of Amount of Blood Loss** | | | | |
| None | 0 / 114 | 0.0% | 47 / 114 | 41.2% |
| Spotting | 0 / 114 | 0.0% | 14 / 114 | 12.3% |
| Light | 1 / 114 | 0.9% | 29 / 114 | 25.4% |
| Moderate | 4 / 114 | 3.5% | 18 / 114 | 15.8% |
| Heavy | 39 / 114 | 34.2% | 4 / 114 | 3.5% |
| Very Heavy | 70 / 114 | 61.4% | 2 / 114 | 1.8% |
| **Limitations in Work Outside or Inside the Home** | | | | |
| Not at all | 9 / 114 | 7.9% | 108 / 114 | 94.7% |
| Slightly | 17 / 114 | 14.9% | 3 / 114 | 2.6% |
| Moderately | 34 / 114 | 29.8% | 3 / 114 | 2.6% |
| Quite a bit | 34 / 114 | 29.8% | 0 / 114 | 0.0% |
| Extremely | 20 / 114 | 17.5% | 0 / 114 | 0.0% |
| **Limitations in Physical Activity** | | | | |
| Not at all | 2 / 114 | 1.8% | 106 / 114 | 93.0% |
| Slightly | 20 / 114 | 17.5% | 5 / 114 | 4.4% |
| Moderately | 27 / 114 | 23.7% | 2 / 114 | 1.8% |
| Quite a bit | 40 / 114 | 35.1% | 1 / 114 | 0.9% |
| Extremely | 25 / 114 | 21.9% | 0 / 114 | 0.0% |
| **Limitations in Social or Leisure Activities** | | | | |
| Not at all | 7 / 114 | 6.1% | 108 / 114 | 94.7% |
| Slightly | 20 / 114 | 17.5% | 4 / 114 | 3.5% |
| Moderately | 30 / 114 | 26.3% | 1 / 114 | 0.9% |
| Quite a bit | 36 / 114 | 31.6% | 1 / 114 | 0.9% |
| Extremely | 21 / 114 | 18.4% | 0 / 114 | 0.0% |
| **Activities that were Limited by Excessive Bleeding** | | | | |
| None | 6 / 114 | 5.3% | 104 / 114 | 91.2% |
| Access to Bathroom | 17 / 114 | 14.9% | 1 / 114 | 0.9% |
| Exercise/Physical Activity | 67 / 114 | 58.8% | 5 / 114 | 4.4% |
| School | 1 / 114 | 0.9% | 0 / 114 | 0.0% |
| Sex | 7 / 114 | 6.1% | 0 / 114 | 0.0% |
| Sitting | 3 / 114 | 2.6% | 0 / 114 | 0.0% |
| Sleeping | 12 / 114 | 10.5% | 1 / 114 | 0.9% |
| Socializing | 30 / 114 | 26.3% | 4 / 114 | 3.5% |
| Swimming | 26 / 114 | 22.8% | 1 / 114 | 0.9% |
| Work | 22 / 114 | 19.3% | 0 / 114 | 0.0% |
| Other | 15 / 114 | 13.2% | 1 / 114 | 0.9% |
| **Global Assessment of Change in Blood Loss** | | | | |
| About the same | | | 2 / 114 | 1.8% |
| Better | | | 112 / 114 | 98.2% |
| *Meaningful Change* | | | *106 / 112* | *94.6%* |
| Worse | | | 0 / 114 | 0.0% |
| *Meaningful Change* | | | *0 / 0* | *0.0%* |

**Patient Global Evaluation (PGE).** 94% of the subjects would recommend the treatment to a friend or relative.

| N = 114 | N | N % |
|---|---|---|
| Very Satisfied or Satisfied with procedure | 104 | 91% |
| Recommend treatment to a friend or relative | 107 | 94% |

**Investigator Global Evaluation (IGE).** Investigators were Satisfied or Very Satisfied in treatment of 94.8% of the subjects.

| | N | N% |
|---|---|---|
| **Investigator Satisfaction with Treatment** | | |
| Very Satisfied | 80 / 114 | 70.2% |
| Satisfied | 28 / 114 | 24.6% |
| Not Sure | 2 / 114 | 1.8% |
| Dissatisfied | 3 / 114 | 2.6% |
| Very Dissatisfied | 1 / 114 | 0.9% |
| **Menstrual Status** | | |
| No Bleeding (Amenorrhea) | 48 / 114 | 42.1% |
| Spotting | 22 / 114 | 19.3% |
| Light Bleeding (Hypomenorrhea) | 25 / 114 | 21.9% |
| Medium or Normal Bleeding (Eumenorrhea) | 15 / 114 | 13.2% |
| High or Heavy Bleeding (Menorrhagia) | 4 / 114 | 3.5% |

**Procedure Details.** All procedures were performed at physician's office sites.

Cervical dilation was not required in 92% of the subjects.

Total Procedure Energy delivered per subject is listed below.

| N = 114 | Joules |
|---|---|
| Mean ± SD | 5768 ± 719 |
| Median (Min, Max) | 6000 (3000, 7200) |

Each of the five sites used their own pre-determined pain management protocol. 70% (80/114) of the procedures were performed without IV sedation or general anesthesia. No procedures were abandoned for any reason.

| | N | N % |
|---|---|---|
| *Site of Procedure* | | |
| Physician's Office | 114 / 114 | 100% |
| *Cervical Dilation* | | |
| No | 105 / 114 | 92% |
| Yes | 9 / 114 | 8% |
| *Pain Management* | | |
| Analgesia Only | 11 / 114 | 10% |
| Local + Analgesia | 69 / 114 | 61% |
| Multiple + Analgesia | 26 / 114 | 23% |
| General | 8 / 114 | 7% |

Median and mean procedure times were 7 minutes each. Median and mean recovery times are 13 and 21 minutes respectively.

| N = 114 | Mean | SD | Median | Min | Max | Unit |
|---|---|---|---|---|---|---|
| Procedure Time | 7 | 2 | 7 | 4 | 16 | minutes |
| Treatment Time | 220 | 36 | 218 | 142 | 341 | seconds |
| Recovery Time | 21 | 23 | 13 | 5 | 177 | minutes |

**Procedure-related Pain** (scale of 0 to 10). The average pain level at 24-hour was low and similar to the pre-procedure level.

| N -= 114 | Pre-Procedure | Discharge | 24-Hour |
|---|---|---|---|
| NRS Score - Mean | 0.6 | 2.6 | 1.2 |

# GENERAL INFORMATION

### *GI-1 Minitouch System*

The Minitouch System consists of a reusable Generator and a sterile, single use Handpiece, both connected via an Inter-connecting Cable.

Handpiece is slim, flexible, and atraumatic. It is brought into Closed State for passage through the cervix and into Open State for performing the procedure.

Generator is a line-powered energy source. It consists of 4 main non-sterile modular components – Keypad, Display, Inter-connecting Cable, and Central Unit. User operates Generator by selecting menu items on Display via hand-held Keypad. Generator is all electronic, powers on instantly and does not require any gas, fluid, or other consumables, or preparation prior to the procedure.

Refer to the sections on Minitouch System, Minitouch Handpiece and Minitouch Generator for full description.

### *GI-2 Patient Safety*

Carefully read the “Instructions for Use". Contact a Minitouch representative for questions related to the IFU. Note that they are not authorized to assist in patient care.

To reduce and/or avoid the risk of a uterine perforation, do not plan additional procedures that require dilation or can cause significant trauma to the uterus.

Accurately determine the Reference Sounding Depth S1 at the time of the scheduled Minitouch Procedure right before the Handpiece is placed in the uterine cavity. It is used for safe and proper positioning of Leaf in the uterine cavity. Distal end of Handpiece should never be beyond the Sounding Depth S1.

The Reference Sounding Depth S1 is matched with two additional sounding depth measurements, S2 and S3, measured using the Handpiece. Important steps are specified in “Deploy Leaf’ and “Position Leaf” sections to assist in proper deployment and positioning of Leaf into the cavity.

Throughout the procedure, remain mindful of Handpiece State, Leaf Position, and associated cmScale readings to ensure a safe, normal, and efficient procedure.

Preclinical benchtop testing was conducted in ex vivo non-perfused porcine tissue where the Extension and Main Treatment steps were performed at the same Leaf position to simulate the worst-case thermal injury in the mid-corpus region. Thermal injury depth in the simulated mid-corpus region, as measured from the cavity surface to 0% ablation region, was 14.5 ± 1 mm, with a maximum depth of 16 mm. Thermal injury depth for the Main Treatment alone was 13.6 ± 0.8 mm, with a maximum depth of 14.8 mm. To mitigate the risk of unintended thermal injury in patients, the Extension and the Main Treatment steps should not be performed at the same Leaf position. Use caution when treating patients with small sized uteri.

End the procedure and perform checks per standard clinical practice if an equipment malfunction or other abnormal situation is suspected at any time.

After the Minitouch Procedure, instruct the patient to immediately contact medical staff in case of unexpected symptoms, such as increasing pain or fever, as it may indicate possible injury to the pelvic anatomy and risk of a serious adverse condition.

### *GI-3 Patient Comfort and Convenience*

Minitouch Handpiece is slim at 3.8mm diameter. It is flexible and will bend to conform to the uterine anatomy. It is not necessary to dilate the cervix, distend the uterus or seal the cavity for the Minitouch Procedure. Minimize dilation, distension, and other trauma to the uterus before and after the Minitouch Procedure for optimum patient comfort.

Minitouch Procedure can be tailored in real time for patient comfort. Adjust Power and pause/resume energy delivery as appropriate for comfortable treatment and recovery. The pauses are instant as there is no residual energy in the system.

### *GI-4 Energy Field*

Leaf has a unique patented design that is matched with dielectric properties of the tissue at 915 MHz microwave energy. Together they create an energy field in shape of the endometrium. The field transfers energy directly to the moisture of any tissue present within and warms it gently without charring or disruption.

### *GI-5 Energy*

It is the amount of energy delivered up to the moment in a treatment step, expressed in joules. One joule of energy equals one watt of power used for one second. All else equal, size of the ablation lesion is proportional to the amount of energy delivered.

### *GI-6 Target Energy Dose – TED*

It is the maximum amount of energy that can be delivered in a treatment step. It is expressed in joules.

### *GI-7 Power – PWR*

It is the speed at which energy is available for deposition into the cavity. It is expressed in watts. In general, less than 100% of PWR is deposited at any given time due to impeding factors. Unused PWR gets returned to Generator.

### *GI-8 Use Percentage – U*

U is the percentage of PWR that gets used at any given time. U indicates efficiency and is a measure of the ability of Handpiece to deliver and the tissue to receive energy. The highest possible U value is 100%.

Ability of Handpiece to deliver energy can be impeded by factors such as incomplete Leaf deployment and presence of blood/clots in the cavity. Mitigate the impeding factors to raise U value as high as possible for a more efficient procedure.

Ability of the tissue to absorb energy is based on its moisture content, temperature, and dielectric properties. All else equal, U value is highest when the tissue is unablated and gets lower as the tissue gets ablated.

### *GI-9 U Limit – UL*

It is the lower limit of the acceptable U value. Energy delivery efficiency below the U Limit threshold would be too low to be meaningful. Energy delivery will not start, or will automatically pause if already started, if at any time a U value is below UL.

All else equal, at the Leaf deployment step, a U value persistently below UL indicates incomplete Leaf deployment, which may be due to technique or a contraindicated cavity.

All else equal, as the tissue gets ablated, the U value gets lower and approaches UL, which indicates diminishing ability of the tissue to absorb additional energy as the ablation progresses.

### *GI-10 cmScale*

A cmScale is for ongoing tracking of the distal end of Sound with respect to the external os. In Open State, Leaf extends 4 cm from the distal end of Sound.

### *GI-11 Minitouch Procedure*

The procedure is organized in two parts.

"Minitouch Procedure – Part 1" is for ensuring that Leaf is properly deployed and positioned in the cavity prior to energy delivery.

"Minitouch Procedure – Part 2" is for treatment of the desired treatment length (DTL) of the cavity via a combination of Main and Extension treatment steps.

Leaf creates an approximately 4 cm long lesion. A Main lesion is created at the fundus, which is then extended proximally via one or more Extension lesions as necessary. Each Extension lesion partially overlaps the previous lesion and extends it proximally by up to 2 cm.

User concludes the procedure when DTL is fully treated. At the end of the procedure, the procedure history is displayed for User to transcribe it for record keeping.

### *GI-12 Handpiece and Leaf – Alignment with the Cavity*

Align the Handpiece curve with anteverted/retroverted orientation of the uterus for ease of insertion into the cavity.

Align plane of the Leaf with plane of the cavity by keeping M symbol of Connector facing up with the Ablator in its natural untwisted state.

### *GI-13 Closed Sounding Depth – S2*

This sounding depth S2 is measured with Handpiece in Closed State.

With Handpiece in Closed State, and firmly against the fundus, User takes the cmScale reading at the external os and enters it into Generator. Generator displays it as the Closed Sounding Depth S2 and compares it with the S1 value.

SOUNDS MISMATCH screen is displayed if the S1 and S2 values are not within 1cm of each other, indicating that the cavity may be contraindicated. Follow the instructions provided in step D7 of the Step-by-Step Instructions section if this screen is displayed.

### *GI-14 Leaf Deployment*

Prior to energy delivery, with Handpiece in Open State and Leaf fully deployed near the fundus, the U values should be high (approximately 70% to 100%) and stable. Gently move Leaf back and forth to facilitate the highest possible U values indicating the fullest possible deployment of Leaf.

If the U values are not stable or remain below 70 %, the Leaf may be physically constrained by obstructions in the cavity, or even be within a possible false passage or a perforation. Follow the instructions provided in step E2 of the Step-by-Step Instructions section if this situation is encountered.

### *GI-15 Leaf Positioning*

All else equal, U values correspond to the extent of Leaf deployment. U values are high (70% to 100%) when Leaf is near the fundus in wider part of the cavity. They become progressively lower as the leaf is withdrawn into the proximal narrower part of the cavity. They are lowest (approximately 50% or lower) when Leaf is positioned near the internal os. They approach 0% when Leaf is withdrawn into the cervix. This technique, called Cavity Mapping, is used to provide additional information to help determine that the cavity anatomy is not abnormal, and Leaf is in the cavity.

If the U value progression as described above is not observed, the Leaf may be physically constrained by obstructions in the cavity, or even be within a possible false passage or a perforation. Follow the instructions provided in step F3 of the Step-by-Step Instructions section if this situation is encountered.

### *GI-16 Open Sounding Depth – S3*

With Handpiece in Open State and Leaf firmly against the fundus, User measures the cmScale reading at the external os and enters it into Generator. Generator displays the Open Sounding Depth S3 by adding 4cm (length of Leaf) to the cmScale reading and compares it with the S1 value.

SOUNDS MISMATCH screen will be displayed if the S1 and S3 values are not within 1.5 cm of each other, indicating that the cavity may be contraindicated. Follow the instructions provided in step G2 of the Step-by-Step Instructions section if this screen is displayed.

*GI-17 Desired Treatment Length (DTL)*

Cavity length is the length from the internal fundus to the internal os. Based on clinical considerations, User may choose to treat the whole cavity length or leave the proximal part untreated. Desired Treatment Length (DTL) is the cavity length that User desires to treat. Minimum DTL is 4cm.

*GI-18 Main Treatment Step*

The Main Treatment Step is performed with Leaf positioned firmly against the fundus. It creates a 4cm long lesion.

User may adjust PWR or pause/resume treatment for patient comfort.

The Main Treatment Step is concluded automatically when the corresponding Target Energy Dose TED is reached.

The energy delivery will automatically pause if the U value goes below the U Limit UL.

User may conclude the treatment step at any time. The energy delivery is terminated automatically if Time Limit is reached.

*GI-19 Extension Treatment Step(s)*

One or more Extension Treatment Step(s) are performed as necessary to extend the Main lesion until the full Desired Treatment Length (DTL) is treated. Each Extension lesion partially overlaps the previous lesion and extends it by up to 2cm.

User may adjust PWR or pause/resume treatment for patient comfort.

The Extension Treatment Step is concluded automatically when the corresponding Target Energy Dose TED is reached.

The energy delivery will automatically pause if the U value goes below the U Limit UL.

User may conclude the treatment step at any time. The energy delivery is terminated automatically if Time Limit is reached.

The following chart lists the Extension Steps corresponding to a given DTL.

Desired Treatment Length (DTL) and Extension Steps

| DTL | **Main** | Remaining DTL | **Extension 1** | Remaining DTL | **Extension 2** | Remaining DTL | **Extension 3** |
|---|---|---|---|---|---|---|---|
| | **AT THE FUNDUS** | | **PULLBACK** | | **PULLBACK** | | **PULLBACK** |
| CM | **CM** | CM | **CM** | CM | **CM** | CM | **CM** |
| < 4 | **NO** | | | | | | |
| 4 | **4** | 0 | **NO** | | | | |
| 4.5 | **4** | 0.5 | **NO** | | | | |
| 5 | **4** | 1 | **1** | 0 | **NO** | | |
| 5.5 | **4** | 1.5 | **1.5** | 0 | **NO** | | |
| 6 | **4** | 2 | **2** | 0 | **NO** | | |
| 6.5 | **4** | 2.5 | **2** | 0.5 | **NO** | | |
| 7 | **4** | 3 | **2** | 1 | **1** | 0 | **NO** |
| 7.5 | **4** | 3.5 | **2** | 1.5 | **1.5** | 0 | **NO** |
| 8 | **4** | 4 | **2** | 2 | **2** | 0 | **NO** |
| 8.5 | **4** | 4.5 | **2** | 2.5 | **2** | 0.5 | **NO** |
| 9 | **4** | 5 | **2** | 3 | **2** | 1 | **1** |
| 9.5 | **4** | 5.5 | **2** | 3.5 | **2** | 1.5 | **1.5** |
| 10 | **4** | 6 | **2** | 4 | **2** | 2 | **2** |

*GI-20 Settings*

| | Unit | Main (A) | Extension (B) |
|---|---|---|---|
| UL | % of PWR | 40% | 40% |
| PWR range | watt | 20 – 50 | 20 – 50 |
| TED | joule | 4800 | 1200 |
| Time Limit | second | 400 | 100 |

*GI-21 Audio*

| | |
|---|---|
| U beep | length inversely proportional to U value |
| during treatment | U beep every 3 seconds |
| during pause | beep-beep every 5 seconds |
| treatment step concluded | 6 beeps |
| end of procedure | 6 beeps, twice |
| timer displayed | beep |
| value/control not valid, User alert | beep |
| system error | beep-beeep every 5 seconds |

*GI-22 Automonitor*

Minitouch System constantly monitors cable connections and the energy function. The procedure is terminated in case of an error. In that event, go to sub-section J for Handpiece removal.

*GI-23 Display Screen Titles*

In the “Step-by-Step Instructions” section, the Display screen titles are listed in all-capital letters – for instance, DEPLOY LEAF. Refer to the “Display Screens – Descriptions” section for a list of all available keypad actions corresponding to a given screen.

*GI-24 General – Handpiece*

Keep the unopened Handpiece package dry and away from sunlight.

*GI-25 General – Generator*

ICC is fragile. Do not bend it sharply or otherwise mishandle it.
ICC is not sterile. Do not sterilize it. Insert in a provided sterile cover before use.

Store Generator in a cool dry place (up to 85% RH, 72 hours, at 38°C (non-condensing)).

Limit access to Generator only for use by authorized personnel. Secure it between use to prevent tampering.
Inspect Generator prior to use for any damage or tampering. Ensure that the cables are not kinked or frayed, and all connections are secure.

There are no user-serviceable parts within Generator. If CU does not power up and the fans cannot be heard, check the fuses. Disconnect the power cord and access the two fuses by prying open the fuse drawer on the side of CU. Check connections in case of an error message. Contact MicroCube if it does not resolve the issue.

Thoroughly clean Generator components using a towel dampened with a mild, non-caustic, nonflammable cleaning and disinfecting agent (such as Cavicide® or Virex™) and wipe dry, as needed.

# STEP-BY-STEP INSTRUCTIONS

## Before the Minitouch Procedure

### *A. GENERATOR*

A1. Clear all checks via CHECK.

A2. Store settings via SET.

A3. Click H to go HOME.

A4. In HOME, select TREAT, and click OK.

A5. In CONFIRM A, confirm the values for the Main treatment step, and click OK.

A6. In CONFIRM B, confirm the values for the Extension treatment steps, and click OK.

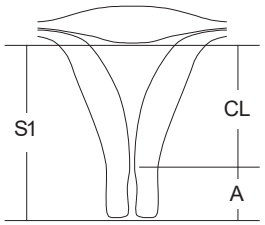
### *B. USER / PATIENT / CAVITY*

B1. Confirm that User is experienced in transcervical intra-uterine procedures, has clinical knowledge of endometrial ablation procedures, has completed the Minitouch Training Program, and is well-versed with the Instructions for Use.

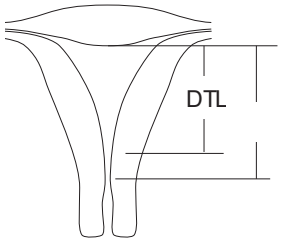
B2. Confirm via standard clinical practice that the patient and the cavity meet the Indications for Use.

B3. Confirm via standard clinical practice that none of the Contraindications apply.

**B4. Determine Reference Sounding Depth S1, cervix length A, and determine cavity length CL in centimeters.**




B5. Decide desired treatment length DTL in centimeters.




B6. Remove all fluids and clots from the cavity.

*C. REFERENCE SOUND – S1*

C1. In SOUND REF – S1, enter the S1 value, and click OK.

## Minitouch Procedure – Part 1

*D. CLOSED SOUND – S2*

D1. Ensure ICC connector is free of any debris or damage.

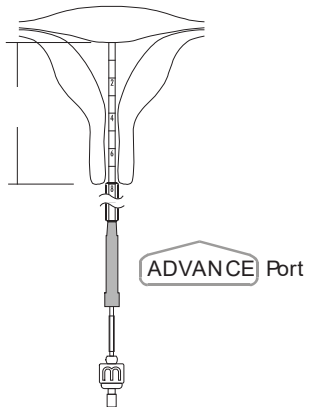
D2. Insert ICC and Keypad in the sterile covers.

D3. Connect ICC to Handpiece.

D4. Bring Handpiece to Closed State.

D5. Grasp Port, and gently insert Handpiece into the cavity.

D6. Grasp Port, advance Handpiece, and measure Closed Sounding Depth S2.




D7. In SOUND CLOSED – S2, enter the S2 value, and click OK.

Note: SOUNDS MISMATCH screen is displayed if the S1 and S2 values are not within 1cm of each other, indicating that the cavity may be contraindicated.

Note: If SOUNDS MISMATCH screen is reached due to an inadvertent click, then select Go Back option to return to the previous screen. **Otherwise, select End Procedure option, remove Handpiece, and check the cavity for contraindications.**

*E. DEPLOY LEAF*

E1. Bring Handpiece to Open State.

E2. In DEPLOY LEAF, gently move Handpiece back and forth and click E to get a U value at a distal position. Repeat until the U values are as high as possible and stable.

Note: If the U values are not stable or remain below 70 %, the Leaf may be physically constrained by obstructions in the cavity, or even be within a possible false passage or a perforation. If a contraindication is suspected, then click H to go to END PROCEDURE?.

Note: If END PROCEDURE? Screen is reached due to an inadvertent click, then select Go Back option to return to the previous screen. **Otherwise, select End Procedure option, remove Handpiece, and check the cavity for contraindications.**

E3. Click OK when the Leaf deployment is satisfactory.

*F. POSITION LEAF*

F1. Click E to get a U value with Leaf still at the distal position. Grasp Guard and pull back Leaf 1-2 cm and get another U value. Repeat until Leaf is in the proximal uterine cavity.

F2. Grasp Connector, gently advance Leaf back to the fundus and get a confirmatory high U value.

F3. Observe that the U values became progressively lower as the Leaf position got more proximal, and then returned to high when the Leaf was positioned again at the fundus.

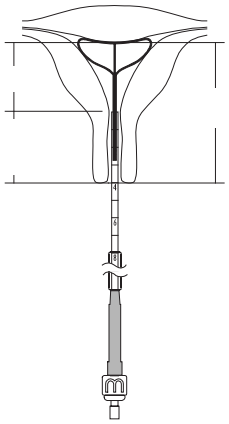
Note: If the U value progression as described above is not observed, the Leaf may be physically constrained by obstructions in the cavity, or even be within a possible false passage or a perforation. If a contraindication is suspected, then click H to go to END PROCEDURE?.

Note: If END PROCEDURE? Screen is reached due to an inadvertent click, then select Go Back option to return to the previous screen. **Otherwise, select End Procedure option, remove Handpiece, and check the cavity for contraindications.**

F4. Click OK when it is satisfactorily confirmed that the Leaf is in the cavity.

*G. SOUND OPEN – S3*

G1. Grasp Connector, hold Leaf firmly against the fundus and measure the cmScale reading at the external os.



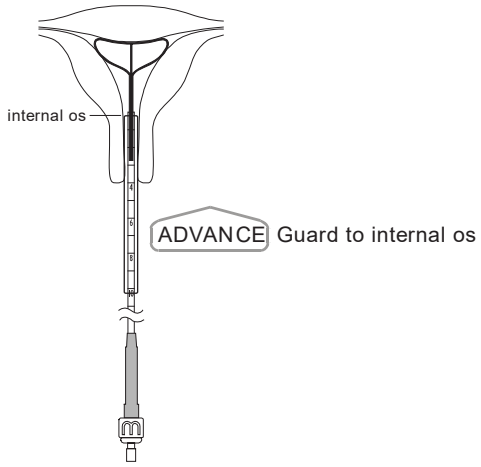
G2. In SOUND OPEN – S3, enter the cmScale value in the space provided, and click OK. Generator will add 4cm to the cmScale value and display it as the S3 value and compare it with the S1 value.

Note: SOUNDS MISMATCH screen will be displayed if the S1 and S3 values are not within 1.5 cm of each other, indicating that the cavity may be contraindicated.

Note: If SOUNDS MISMATCH screen is reached due to an inadvertent click, then select Go Back option to return to the previous screen. **Otherwise, select End Procedure option, remove Handpiece and check the cavity for contraindications.**

## Minitouch Procedure – Part 2

*H. MAIN TREATMENT*




**H1.** Keep Leaf in firm contact with the fundus.

H2. Advance Guard to the internal os, but not beyond.

H3. In TREAT STEP-1, get a U value to confirm position at the fundus.

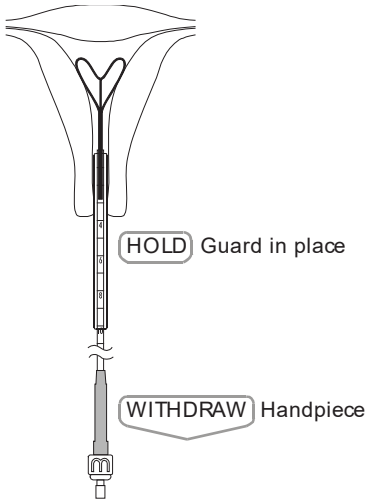
H4. In TREAT STEP-1, p-click E to begin energy delivery.

H5. In TREAT STEP-1, adjust PWR, pause/resume, for patient comfort.

H6. NEXT is displayed at conclusion of the Step-1.

If DTL is longer than 4 cm, continue to section I for Extension Treatment(s). Otherwise, go to section J for Handpiece removal.

*I. EXTENSION TREATMENT(S)*




I1. Hold Guard in place at the internal os, grasp Port and withdraw Handpiece by 2 cm or DTL not yet treated, whichever is less.

I2. In NEXT, select Step-2, and click OK.

I3. In TREAT STEP-2, get U values to confirm the position.

I4. In TREAT STEP-2, p-click E to begin energy delivery.

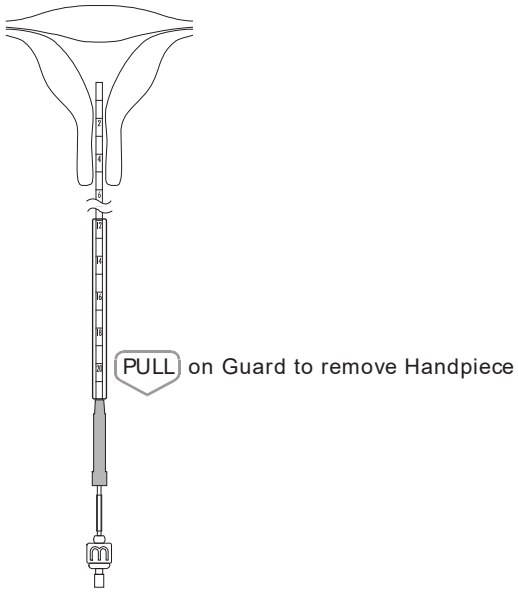
I5. In TREAT STEP-2, adjust PWR, pause/resume, for patient comfort.

I6. NEXT is displayed at conclusion of the Step-2.

I7. Repeat steps I1 through I6, with the step number incremented by one, until the full DTL is treated.

## *J. REMOVAL*

**J1. Remove Handpiece by pulling on Guard.**




J2. Disconnect Handpiece from ICC.

J3. Discard Handpiece and the used covers into a biohazard facility.

## *K. RECORD*

K1. In NEXT, select End Procedure, and click OK.

K2. Record the procedure history.

K3. In ERASE RECORDS, click H to permanently erase records and return HOME.

## After the Minitouch Procedure

*L. IMMEDIATE POST-PROCEDURE CHECK*

**L1. Assess the uterine anatomy per standard clinical practice if any unintended injury is suspected.**

*M. IMMEDIATE RECOVERY PHASE*

M1. Advise the patient regarding normal anticipated recovery progression per standard clinical practice.

**M2. Instruct the patient to contact appropriate medical staff immediately in case of unexpected symptoms, such as increasing pain or fever, as it may indicate injury to the pelvic anatomy and risk of a serious adverse condition.**

# MINITOUCH SYSTEM

The Minitouch 3.8 Era System consists of two main components, used exclusively with each other.

- Minitouch 3.8 Era Handpiece (Handpiece); and
- Minitouch Generator (Generator)

Handpiece is a sterile, single-use energy applicator. It is slim at 3.8mm diameter, flexible and atraumatic, and designed for transcervical access to the cavity without normally requiring dilation of the cervix. It delivers microwave energy into the uterine cavity.

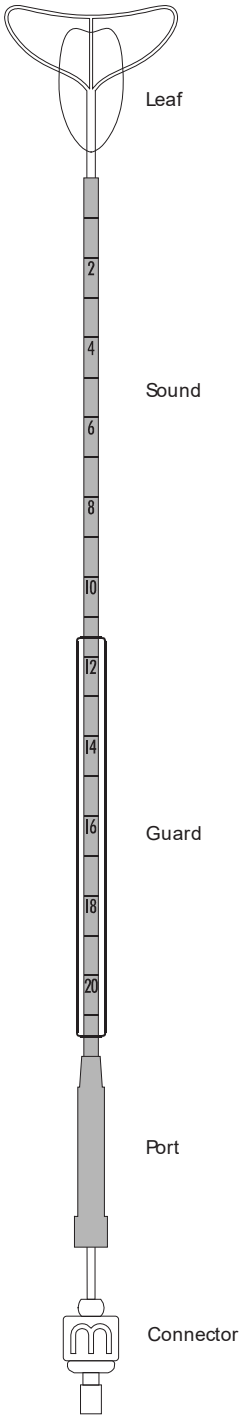
Generator is a line-powered energy source. It consists of 4 main non-sterile modular components – Keypad, Display, Inter-connecting Cable, and Central Unit. User operates Generator by selecting menu items on Display via hand-held Keypad. Generator is all electronic, powers on instantly and does not require any gas, fluid, or other consumables, or preparation prior to the procedure.

Handpiece has a patented Leaf design that is matched with the 915 MHz microwave energy and the dielectric properties of the target tissue to create a 3-dimensional electromagnetic field in the shape of the endometrium. The field transfers energy to the tissue in proportion to its strength at a given location. It does so by oscillating in situ water molecules that are present in the target tissue. The oscillating motion generates frictional heat directly in place. The heat gently warms the tissue without charring or disruption.

# MINITOUCH HANDPIECE

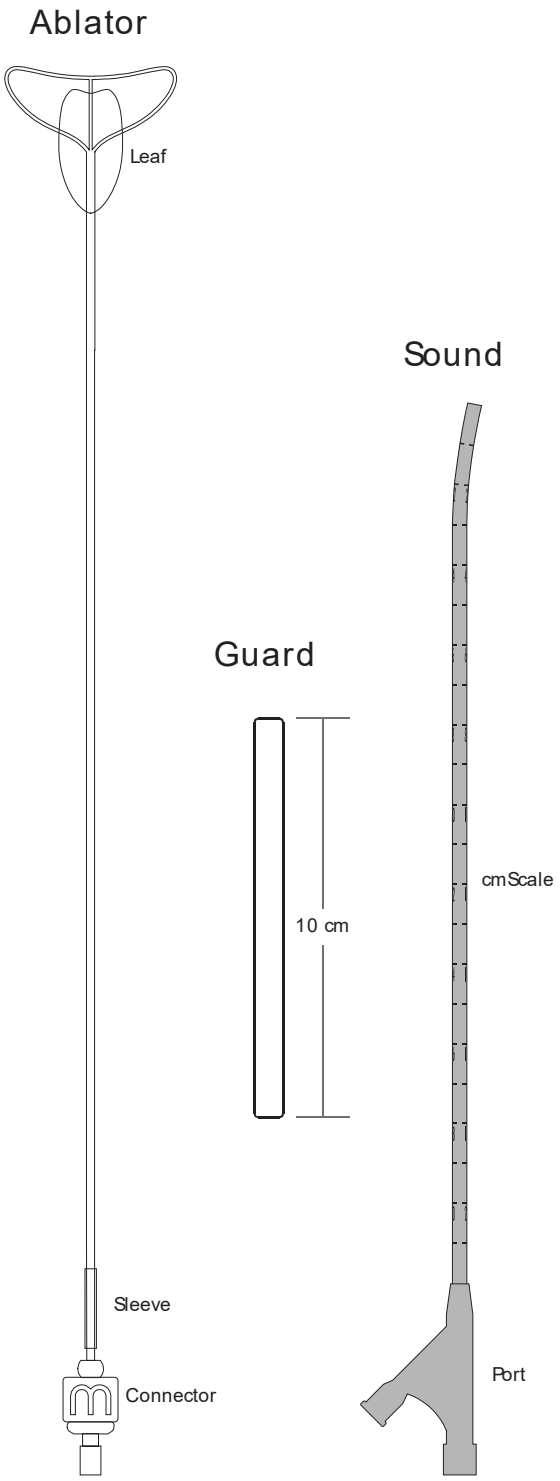
| Product Number | Description |
|---|---|
| **4501** | **Minitouch 3.8 Era Handpiece** |

Handpiece is boxed with Instructions for Use and 2 sterile covers.
It is shipped sterile and is for single procedure use only.



## Handpiece Components

Handpiece is shipped ready for use.
For communication purpose only, its 3 main components are illustrated separately below.

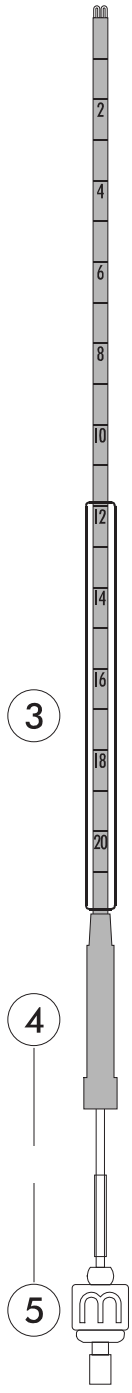


## Closed State

Handpiece is brought into Closed State for its passage through the cervix, and for measuring Sounding Depth S2.

1. **Align curve of Handpiece with orientation of uterus**

2. **Keep M symbol of Connector facing up**




3. **PULL Guard until it touches Port**

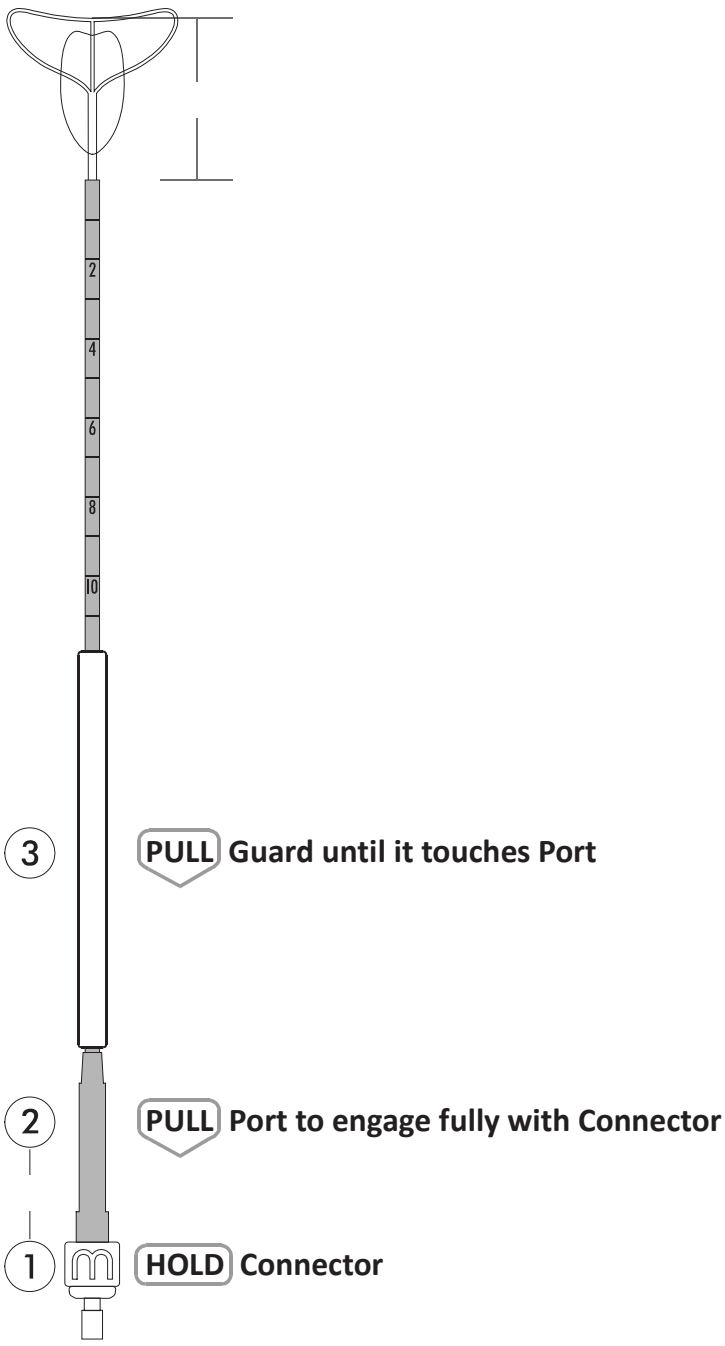
4. **HOLD Port**

5. **PULL Connector to retract Leaf into Sound**

## Open State

Handpiece is brought into Open State for all Minitouch Procedure steps, except for its passage through the cervix and for measuring Sounding Depth S2.

Ablator is flexible. In steps 1 & 2, use multiple short, controlled strokes to prevent it from kinking.

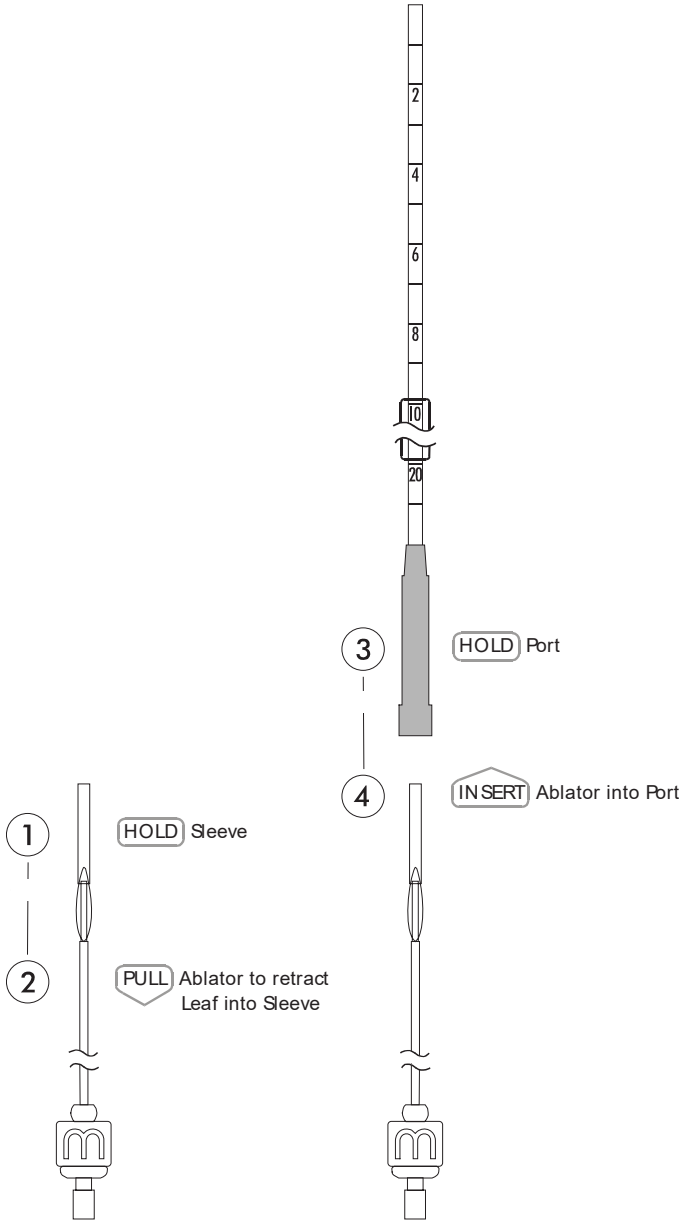


## Ablator Insertion into Sound (If Required)

Use the instructions below in an unlikely case of User accidentally removing Ablator from Sound.

Ablator is flexible. While engaging it with Sleeve or Sound, use multiple short, controlled strokes to prevent it from kinking.

In Steps 1 & 2, ensure that Sleeve does not get detached from Ablator.




Ablator - Insertion

# MINITOUCH GENERATOR

The Minitouch Generator is a modular, line-powered, reusable equipment intended for generating, delivering, and monitoring microwave energy. It is used exclusively with the Minitouch Handpiece. It is all electronic, powers on instantly and does not require any gas or fluid consumables or preparation prior to the procedure.

Generator has a simple, menu-based user interface designed to be conveniently accessible to User via Keypad. Using the provided sterile covers on Keypad and ICC, User can operate Generator from the sterile field without requiring assistance from a staff member.

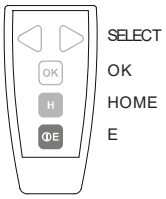
It is shipped in three boxes with the following items.

| Product Number | Description |
|---|---|
| **4001-01** | **Minitouch Generator** |
| | |
| 4002 | Central Unit |
| 5091 | Instructions for Use |
| | |
| | Stand Kit |
| 4007 | Base |
| 4008 | Dock |
| 4009 | Swing Arm |
| | |
| 4003 | Display |
| 4005 | Keypad |
| 4004 | ICC |
| 4006 | Power Cord NEMA 5-15 (US) |

Generator consists of 4 main modular components and accessories.

***Keypad***

Keypad is not sterile. Insert in a sterile cover if it is used in a sterile field.




| Action | Description |
|---|---|
| click | press and release instantly |
| p-click | press, and release after an audio prompt |
| select | click a desired backward/forward button.<br>For faster action, press until a desired value, and then release |

### *Display*

Display provides visual and audio feedback.

### *Inter-Connecting Cable (ICC)*

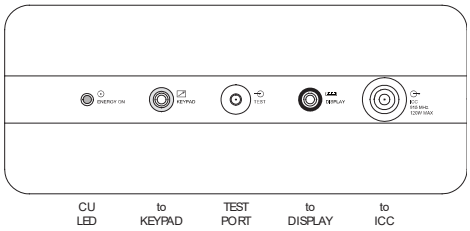
ICC is not sterile. Insert in a provided sterile cover before use.

It is fragile and can get damaged if mishandled. Do not pull or bend it sharply.


### *Central Unit (CU)*

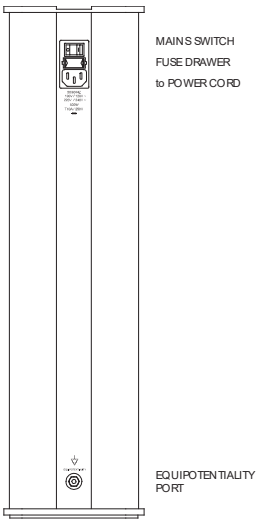
CU generates 915 MHz microwave energy. It is the connection hub for all components and cables.

CU LED is turned on when energy is being delivered.

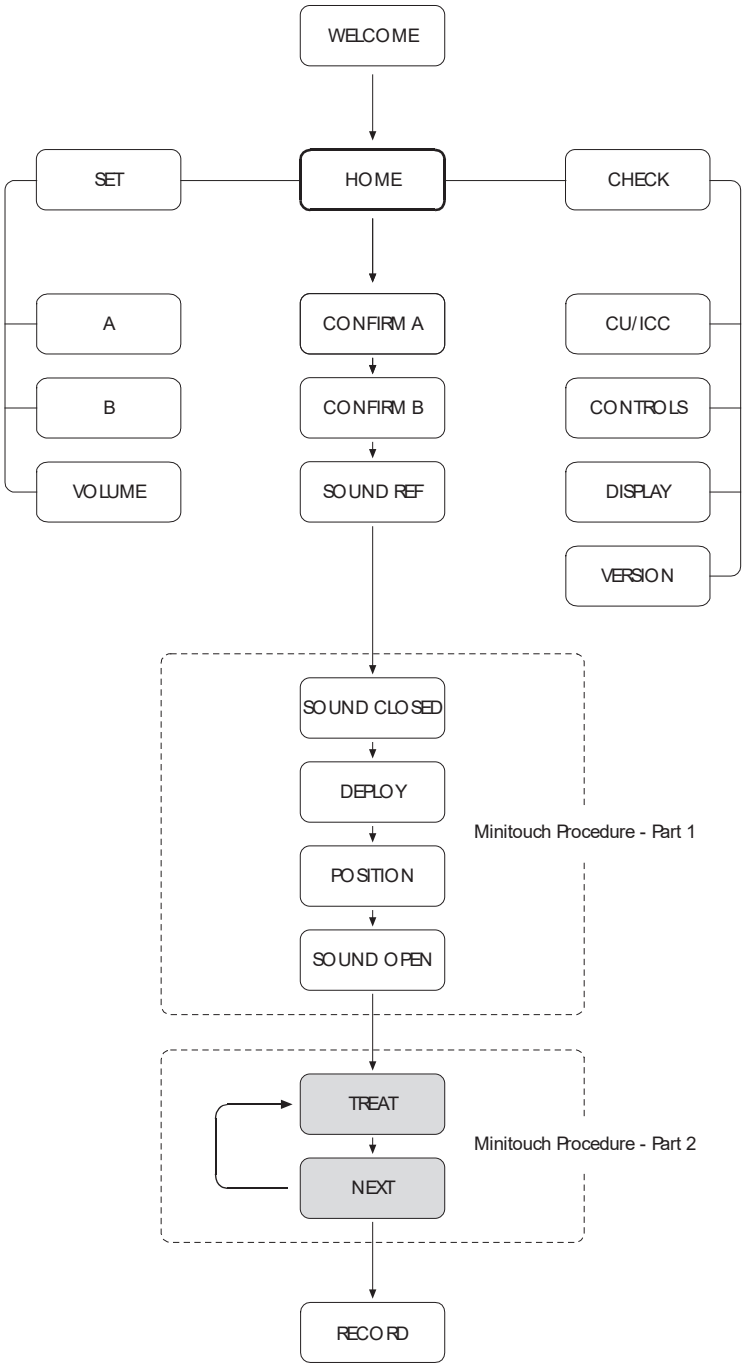



Mains Switch switches Generator on or off.

Equipotentiality Port provides connection to CU frame if desired.



## Display Screens – Map

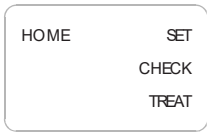


## Display Screens – Descriptions

A complete list of all Keypad and Generator actions available within a given Screen is provided below for reference only. Refer to Step-by-Step instructions section for performing the Minitouch Procedure.

### *WELCOME*

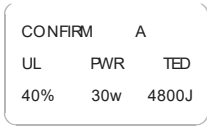

- Click H to go HOME.




- Select Set, Check or Treat, and click OK.

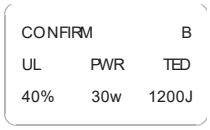
## TREAT ARM

### *CONFIRM A*




- Click OK to confirm the settings for Main Treatment step.
- Click H to go HOME.

### *CONFIRM B*

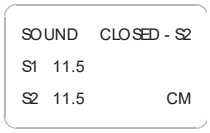



- Click OK to confirm the settings for Extension Treatment step.
- Click H to go HOME.

### *SOUND REF – S1*

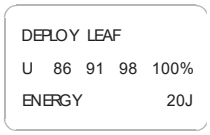

- Select the S1 value and click OK.
- Click H to go to HOME.

*SOUND CLOSED – S2*




- Select the S2 value and click OK.
- Click H to go to END PROCEDURE?.

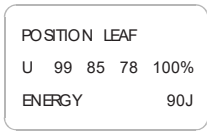
*DEPLOY LEAF*




- Click E to get a U value.
  Most recent U value is displayed on the right, and the previous values are scrolled to the left.
  U value will flash if it is below U Limit.

- Click H to go to END PROCEDURE?.
- Click OK to go to POSITION LEAF.

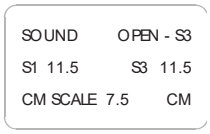
*POSITION LEAF*




- Click E to get a U value.
  Most recent U value is displayed on the right, and the previous values are scrolled to the left.
  U value will flash if it is below U Limit.

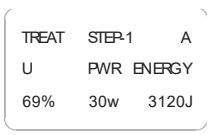
- Click H to go to END PROCEDURE?.
- Click OK to go to SOUND OPEN – S3.

*SOUND OPEN – S3*




- Select the S3 value and click OK.
- Click H to go to END PROCEDURE?.

*TREAT STEP-1*




- Click E to get a U value.
  U value will flash if it is below U Limit.

- Click SELECT to adjust the PWR setting by 2 watts.
- Click H to terminate the current step.

- p-Click E to begin energy delivery.

- Click E to pause energy delivery.

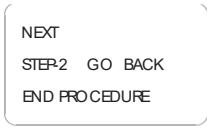
  The delivery will automatically pause if the U value goes below UL.

- Click E during pause to get a U value.
  U value will flash if it is below U Limit.

- p-Click E during pause to resume energy delivery.
- Click H to terminate the current step during pause.

  The current step is automatically concluded when TED is reached.
  The current step is automatically terminated if Time Limit is reached.
  Timer is displayed during the last 30 seconds.

*NEXT*

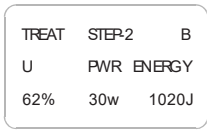



- Select STEP-2, and click OK, for the next treatment step.
  The step number applies to the next treatment step.

- Select Go Back and click OK to return to the current treatment step.
  Go Back option is not available if TED or Time Limit has been reached.

- Select End Procedure, and click OK, to conclude the procedure.

*TREAT STEP-2*




- Click E to get a U value.
  U value will flash if it is below U Limit.

- Click SELECT to adjust the PWR setting by 2 watts.
- Click H to terminate the current step.

- p-Click E to begin energy delivery.

- Click E to pause energy delivery.

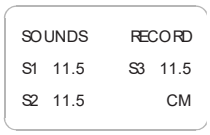
  The delivery will automatically pause if the U value goes below UL.

- Click E during pause to get a U value.
  U value will flash if it is below U Limit.

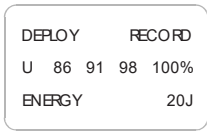
- p-Click E during pause to resume energy delivery.
- Click H to terminate the current step during pause.

The current step is automatically concluded when TED is reached.
The current step is automatically terminated if Time Limit is reached.
Timer is displayed during the last 30 seconds.

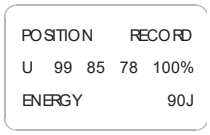
## *RECORD*



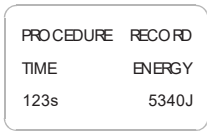
```
SOUNDS       RECORD
S1  11.5     S3  11.5
S2  11.5           CM
```



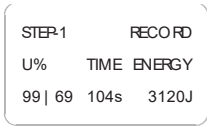
```
DEPLOY       RECORD
U   86  91  98  100%
ENERGY           20J
```



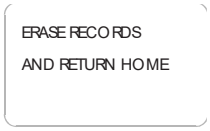
```
POSITION     RECORD
U   99  85  78  100%
ENERGY           90J
```



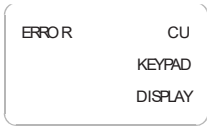
```
PROCEDURE    RECORD
TIME         ENERGY
123s          5340J
```



```
STEP-1       RECORD
U%      TIME ENERGY
99 | 69  104s  3120J
```



```
ERASE RECORDS
AND RETURN HOME
```



```
ERROR            CU
             KEYPAD
            DISPLAY
```

```
VERSION

R10-07-06
```

The procedure history is displayed via screens cycling every 5 seconds.
The RECORD screens display information for the total procedure, and for each individual step.
VERSION displays the software version of Generator.
ERROR, if present, displays the cause of termination of the procedure.

- Click SELECT to cycle the screens manually one at a time.
- Transcribe the history as desired.
- Click H in ERASE RECORDS to permanently erase the history and return HOME.

*SOUNDS MISMATCH*

SOUNDS MISMATCH
GO BACK
END PROCEDURE

- Select Go Back, and click OK, to return to the previous screen.
- Select End Procedure, and click OK, to conclude the procedure and go to RECORD.

- *END PROCEDURE?*

END PROCEDURE?
GO BACK
END PROCEDURE

- Select Go Back, and click OK, to return to the previous screen.
- Select End Procedure, and click OK, to conclude the procedure and go to RECORD.

## CHECK ARM

*CHECK*

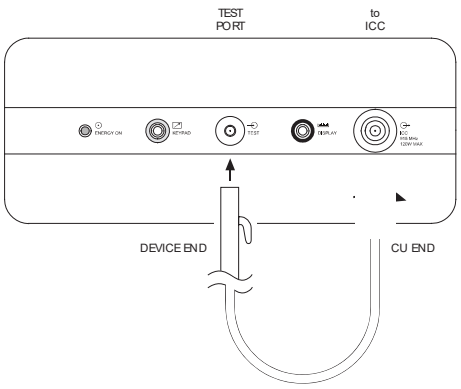
| | |
|---|---|
| CHECK | CU/ICC |
| | DISPLAY |
| VER | KEYPAD |

- Select CU/ICC, Display, Keypad or Version, and click OK.
- Click H to go HOME.

*CHECK CU/ICC*

READY FOR TEST?

- Ensure that both ICC connectors, and their counterparts on CU, are free of any debris or damage.
- Connect ICC's CU End to CU and hand-tighten.
- Connect ICC's Handpiece End to Test Port.



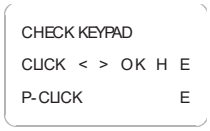
- Click OK when ready to initiate the test.
  Generator will display “CU/ICC PASSED”.
- Disconnect ICC from Test Port.
- Click OK to go back to CHECK.
- Click H to go HOME.
- If “ICC FAILED” or “CU FAILED” is displayed, check connections or replace ICC, and repeat the check.

- Contact MicroCube if the issue is not resolved.

- *CHECK DISPLAY*

- All LEDs are turned on for 3 seconds. Confirm that they are on.
- Click OK to go back to CHECK.
- Click H to go HOME.

*CHECK KEYPAD*




- Click the highlighted control as indicated.
- p-Click E as indicated.

  The highlighted control will flash confirming that it works.

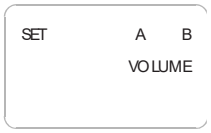
- Click OK, except at OK, to go to back to CHECK.
- Click H to go HOME.

*CHECK VERSION*


- Click OK to go to back to CHECK.
- Click H to go HOME.

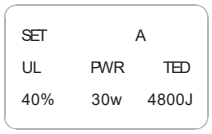
## SET ARM

### *SET*




- Select A, B, or Volume, and click OK.
- Click H to go HOME.

### *SET A*

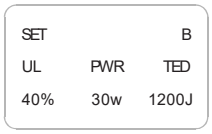



- Select a desired UL value and click OK.
- Select a desired PWR value and click OK.
- Select a desired TEDTM value and click OK.

- Click OK to go back to SET.

- Click H to go HOME.

### *SET B*

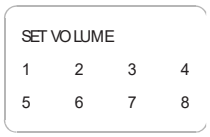



- Select a desired UL value and click OK.
- Select a desired PWR value and click OK.
- Select a desired TEDTM value and click OK.

- Click OK to go back to SET.

- Click H to go HOME.

### *SET VOLUME*



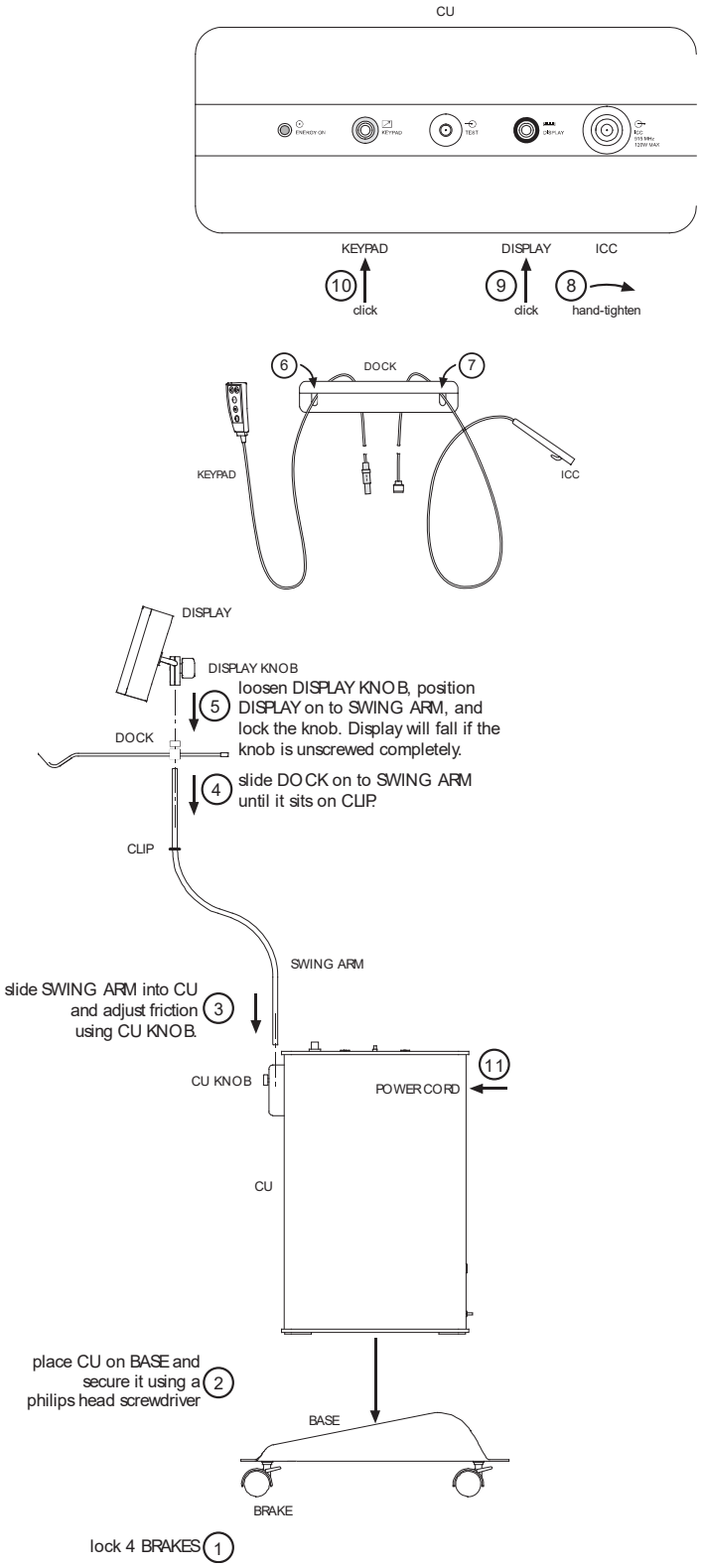

- Select a desired volume and click OK.

- Click OK to go back to SET.

- Click H to go HOME.

## Installation Information

a. Unpack the three boxes and ensure that there is no damage.
b. Assemble via the numbered steps.
c. Clear all checks via CHECK to ensure that Generator is functional.



## MRI Safety Information

a. The Minitouch System is MR Unsafe.

## EM Information

The Minitouch generator is immune to electromagnetic interference at the test levels described below. This equipment has been tested and found to comply with the standards listed in IEC60601-1-2. At the levels tested in IEC 60601-1-2, the Minitouch generator was determined to be immune to electromagnetic interference. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The Minitouch generator is suitable for use in a hospital or physician's office.

EM WARNINGS

a. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
b. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
c. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Minitouch generator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
d. Cell phones, televisions, and other devices using radio frequency identification (RFID) readers, may cause interference.
e. The use of other medical device equipment which generate electromagnetic emissions during their use, such as high frequency (HF) electrosurgical equipment and X-ray equipment, may cause interference. Do not use these types of equipment while in proximity to the Minitouch System.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The Minitouch generator is intended for use in the EM environment specified below.
The customer/user of the Minitouch generator should assure that it is used in such an environment.

| Emissions test | Compliance | EM environment –guidance |
|---|---|---|
| RF emissions | Group 2 | The Minitouch generator must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. |
| CISPR 11 | Class A | The Minitouch generator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| RF emissions | Class A | |
| CISPR 11 | Complies | |

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Minitouch generator is intended for use in the EM environment specified below.
The customer/user of the Minitouch generator should assure that it is used in such an environment

| IMMUNITY test | IEC 60601 test level | Compliance level | EM environment – guidance |
|---|---|---|---|
| Electrostatic discharge (ESD)<br><br>IEC 61000-4-2 | ± 2, 4, 6, 8 kV contact<br><br>± 2, 4, 6, 8, 15 kV air | ±2, 4, 6, 8 kV contact<br><br>±2, 4, 6, 8, 15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst<br><br>IEC 61000-4-4 | ± 0.5, 1, 2 kV for power supply lines<br><br>± 1 kV for input/output lines | ±0.5, 1, 2 kV for power supply lines<br><br>Not Applicable | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br><br>IEC 61000-4-5 | ±0.5, 1 kV differential mode<br>±0.5, 1, 2 kV common mode | ±0.5, 1 kV differential mode<br>±0.5, 1, 2 kV common mode | 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<br><br>IEC 61000-4-11 | Voltage Dips 30% reduction, 25/30 periods<br>At 0°<br><br>Voltage Dips > 95% reduction, 0.5 period<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>Voltage Dips > 95% reduction, 1 period<br>At 0°<br>Voltage Interruptions > 95% reduction, 250/300 periods<br>At 0° | Voltage Dips 30% reduction, 25/30 periods<br>At 0°<br><br>Voltage Dips > 95% reduction, 0.5 period<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>Voltage Dips > 95% reduction, 1 period<br>At 0°<br>Voltage Interruptions > 95% reduction, 250/300 periods<br>At 0° | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Minitouch generator requires continued operation during power mains interruptions, it is recommended that the Minitouch generator be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br><br>IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

NOTE UT is the AC mains voltage prior to application of the test level.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Minitouch generator is intended for use in the EM environment specified below.
The customer/ user of the Minitouch generator should assure that it is used in such an environment.

| IMMUNITY test | IEC 60601 TEST LEVEL | Compliance level | EM environment – guidance |
|---|---|---|---|
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz<br>(6 Vrms in ISM radio Bands within 150kHz-80MHz) | 3 Vrms<br>150 kHz to 80 MHz<br>(6 Vrms in ISM radio Bands within 150kHz-80MHz) | Except as indicated below on page 36, portable and mobile RF communications equipment should be used no closer to any part of the Minitouch generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d = [3.5/V]*\sqrt{P}$<br>$d = [3.5/E]*\sqrt{P}$ 80 MHz to 800 MHz<br>$d = [7/E]*\sqrt{P}$ 800MHz to 2.5 GHz<br>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).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a) , should be less than the compliance level in each frequency range(b). |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m<br>80 MHz to 2.5 GHz | |

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(a)

a 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 Minitouch generator is used exceeds the applicable RF compliance level above, the Minitouch generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Minitouch generator.

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

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

| IMMUNITY test | Services Covered | IEC 60601 test level<br>MHz - Modulation – Field Strength | Compliance level<br>MHz - Modulation – Field Strength | Distance |
|---|---|---|---|---|
| IMMUNITY to proximity fields from RF wireless communications equipment | TETRA 400 | 385 - Pulse 18 Hz - 27 V/m | 385 - Pulse 18 Hz - 27 V/m | 0.3 m |
| | GMRS 460, FRS 460 | 450 – Pulse 18 Hz - 28 V/m | 450 – Pulse 18 Hz - 28 V/m | 0.3 m |
| | LTE Band 13, 17 | 710 - Pulse 217 Hz - 9 V/m | 710 - Pulse 217 Hz - 9 V/m | 0.3 m |
| | | 745 - Pulse 217 Hz - 9 V/m | 745 - Pulse 217 Hz - 9 V/m | |
| | | 780 - Pulse 217 Hz - 9 V/m | 780 - Pulse 217 Hz - 9 V/m | |
| | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | 810 - Pulse 18 Hz - 28 V/m | 810 - Pulse 18 Hz - 28 V/m | 0.3 m |
| | | 870 - Pulse 18 Hz - 28 V/m | 870 - Pulse 18 Hz - 28 V/m | |
| | | 930 - Pulse 18 Hz - 28 V/m | 930 - Pulse 18 Hz - 28 V/m | |
| | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | 1720 - Pulse 217 Hz – 28 V/m | 1720 - Pulse 217 Hz – 28 V/m | 0.3 m |
| | | 1845 - Pulse 217 Hz – 28 V/m | 1845 - Pulse 217 Hz – 28 V/m | |
| | | 1970 - Pulse 217 Hz – 28 V/m | 1970 - Pulse 217 Hz – 28 V/m | |
| | WLAN 802.11 a/n | 5240 - Pulse 217 Hz - 9 V/m | 5240 - Pulse 217 Hz - 9 V/m | 0.3 m |
| | | 5500 - Pulse 217 Hz - 9 V/m | 5500 - Pulse 217 Hz - 9 V/m | |
| | | 5785 - Pulse 217 Hz - 9 V/m | 5785 - Pulse 217 Hz - 9 V/m | |

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE Equipment

The Minitouch generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Minitouch generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Minitouch generator as recommended below, according to the maximum output power of the communications equipment, except as indicated above on page 36.

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter (m) | | |
|---|---|---|---|
| | 150 kHz to 80 MHz<br>d = 1.2√P | 80 MHz to 800 MHz<br>d = 1.2√P | 800 MHz to 2.7 GHz<br>d = 2.3√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.

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

# SPECIFICATIONS

## Symbols

| Symbol | Standard-Reference | Title | Description |
|---|---|---|---|
|  | ISO 60417-5032 | Alternating current | -- |
|  | ISO 15223-5.3.9 | Atmospheric pressure limitation | -- |
|  | ISO 15223-5.1.5 | Batch Code | Lot Number |
|  | ISO 15223-5.1.6 | Catalogue number | Catalog number |
|  | CUSTOM | -- | Do not use equipment with flammable anesthetics AP |
|  | ISO 15223-5.4.4 | Caution | Caution: consult accompanying information |
|  | ISO 15223-5.4.3 | Consult instructions for use | -- |
|  | ISO 15223-5.1.3 | Date of manufacture | -- |
|  | IEC 60417-5334 | Defibrillation-Proof Type BF Applied part | -- |
|  | IEC 60417-5753 | Digital Indicator | Display |
|  | CUSTOM | -- | Do not autoclave the CU, display, keypad, or ICC |
|  | IEC 60417-5995 | Do not immerse in any liquid | Do not immerse any cable or component in liquids |
|  | ISO 60417-5264 | ON for a part of equipment | Energy On |
|  | ISO 60417-5021 | Equipotentiality | -- |
|  | ISO 60417-5016 | Fuse | -- |

| Symbol | Standard-Reference | Title | Description |
|---|---|---|---|
|  | IEC 60417-5035 | Output | ICC receptacle – energy output receptacle |
|  | ISO 7000-2620 | Humidity Limitation | -- |
|  | ISO 7000-0093 | Remote Control | Keypad |
|  | CUSTOM | E | Energy On-Off |
|  | ISO 15223-5.1.1 | Manufacturer | -- |
|  | IEC 60417-5140 | Non-ionizing electromagnetic radiation | Non-ionizing radiation |
|  | CUSTOM | Home | Home – go to Home Screen |
|  | ISO 60417-5008 | OFF | Off (power: disconnection from the mains) |
|  | ISO 60417-5007 | ON | On (power: connection to the mains) |
|  | CUSTOM | OK | OK button; accepts displayed option and/or goes to the next screen |
|  | CUSTOM | Scroll/decrement | Scroll Backward – go to a desired option |
|  | CUSTOM | Scroll/increment | Scroll Forward – go to a desired option |
|  | IEC 60417-5019 | Protective Earth Ground | -- |
|  | ISO 15223-5.1.7 | Serial Number | -- |
|  | ISO 15223-5.2.8 | Do not use if package is damaged | -- |
|  | ISO 15223-5.4.2 | Do not reuse | -- |
|  | ISO 15223-5.3.4 | Keep dry | -- |
|  | ISO 15223-5.3.2 | Keep away from sunlight | -- |
|  | IEC 60417-5034 | Input | Test Port |
|  | ISO 62570-7.3.3 | MR unsafe | -- |
| $R_x$ ONLY | 21CFR 801.109 (b)(1) | RX Only | Caution: United States Federal Law restricts this device to sale by or on the order of a physician |
|  | ISO 15223-5.1.4 | Use by date | -- |
|  | ISO 7000-1321B | Mass; weight | Mass |
|  | ISO 7010-M002 | Refer to instruction manual/booklet | Consult instructions for use |
| STERILE EO | ISO 15223-5.2.3 | Sterilized using ethylene oxide | Supplied sterile using ethylene oxide gas |
|  | ISO 15223-5.2.7 | Temperature Limit | -- |

## Software Disclaimer

The Minitouch generator incorporates software covered by the terms of the GNU General Public License. This software is subject to the terms of the GNU General Public License (Version 2, June 1991): www.gnu.org/licenses/gpl.tx

## Technical Specifications

*MINITOUCH SYSTEM*

| |
|---|
| Handpiece product number: 4501 |
| Generator product number: 4001-01 |
| Instructions for Use number: 5091 |
| Class III device according to FDA classification |
| Class IIb device according to the MDD 93/42/EEC |
| Class I, Type BF instrument, according to IEC/EN 60601-1 |
| Class A/group 2 device according to IEC 60601-1-2 |
| Meets the requirements of IEC/EN 60601-1 and 60601-2-6 |
| Essential Performance:<br>Energy accuracy: ±20%<br>Output Power accuracy into matched load: ±10% (power < 50W) or ±5W (power ≥50W) |

*MINITOUCH HANDPIECE*

| |
|---|
| Shelf Life:12 months from the date of sterilization |
| For single procedure use only |
| cmScale unit: centimeter |
| Length measurement accuracy: +/- 0.5 cm |
| Diameter: 3.8 mm |
| Guard length: 10 cm |
| Sterilization medium: Ethylene Oxide Gas |

*MINITOUCH GENERATOR*

| |
|---|
| Lifetime: 10 years from date of manufacture |
| Energy output frequency: 902-928 MHz |
| Electrical ratings: 50/60 Hz, 100 V/110 V~220 V/240 V~, 500 W |
| Fuses: 10 A, 250 V, Low Break, 5x20 - SCHURTER P/N 0034.1526 or equivalent |
| Water-tightness rating: IPX0 (non-protected) |

| | Weight Unpacked | Height | Width | Depth | Cable Length |
|---|---|---|---|---|---|
| unit | kg | cm | cm | cm | cm |
| CU | 13.6 | 53 | 36 | 15 | - |
| Display | 1.3 | 17 | 28 | 6 | 60 |
| Keypad | - | - | - | - | 180 |
| ICC | - | - | - | - | 180 |
| Power Cord | - | - | - | - | 250 |

*OPERATING ENVIRONMENT*

| | |
|---|---|
| Atmospheric pressure | 700 hPa to 1013 hPa (10,000 to 0 ft altitude) |
| Temperature | +10 °C to +30 °C |
| Humidity | 30% to 75% RH |

*STORAGE (packaged)*

| *Office Environment (Cool dry place)* | |
|---|---|
| Atmospheric pressure | 240 hPa to 1013 hPa (35,000 to 0 ft altitude) |
| Temperature | -18 °C to +60 °C |
| Humidity | Up to 85% RH, 72 hr, at 38 °C (non-condensing) |
| ICC coiling diameter | 15 cm minimum |

# BUSINESS INFORMATION

## Product Returns

Contact MicroCube to obtain a Return Material Authorization (RMA) and instructions before returning product for any reason.

Return Generator to MicroCube at the end of its life.

## Warranty and Limitations

MicroCube warrants that the Minitouch System has been manufactured with reasonable care and will be free from defects in workmanship and materials.

MicroCube's sole obligation shall be limited to replace Handpiece and replace or repair Generator at no charge, provided a written notification is received and MicroCube determines that Handpiece or Generator was defective at the time of shipment.

This warranty is made in lieu of any other warranty, expressed or implied. MicroCube is not responsible for any obligation or liability other than that specifically stated above, or any incidental, special or consequential loss, damage, or expense resulting, directly or indirectly, from use of the Minitouch System.

## Patents and Trademarks

The Minitouch System is covered by the following patents: EP2355738B1, EP2349045B1, EP2831604B1, US 9,993,293, US 10,470,819, US 11,147,619, US 8,968,287, US 9,980,774, US 9,615,882, US 10,299,859, US 10,869,720, US 11,219,484, US 9,462,642, US 10,939,509, ZL200980151261.0, ZL200980149961.6, ZL201710340529.1, ZL201380028062.7, ZL201810360283.9, IN 338486, IN 338493, JP 5406933, JP 6083928, JP 6758797, and JP 6789255.

## Contact

For returns, questions, feedback, or any other reason, write to m@microcube.org

## Manufacturer

MicroCube, LLC.
47853 Warm Springs Blvd.
Fremont, CA 94539 USA

Tel 1 510 651 5000