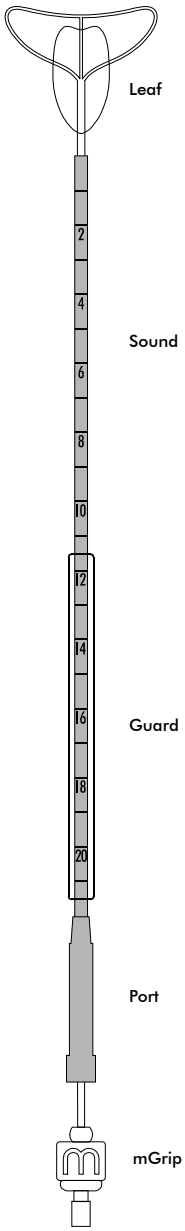
minitouch

SYSTEM

INSTRUCTIONS FOR USE

900064 – rev B, August 2023



Clinical Information

INDICATIONS

The Minitouch System is intended for ablation of the endometrial lining of the uterus for the treatment of menorrhagia (excessive uterine 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. who has active genital or urinary tract infection.
d. who has active pelvic inflammatory disease.
e. who has undergone medical/surgical treatments, or has other conditions, that could lead to anatomic/pathologic weakness or thinning of the myometrium. Classical cesarean section and transmural myomectomy are examples of such treatments.
f. who has abnormal, obstructed or perforated cavity.
g. who has intrauterine implant, such as intrauterine device (IUD).
h. who has known/suspected abnormal uterine/pelvic anatomy, such as frozen pelvis.
i. who has uterine cavity length of less than 4 cm. Treatment in such patients could result in thermal injury to the endocervical canal.

WARNINGS

a. User must be experienced in transcervical intra-uterine procedures and have clinical knowledge of endometrial ablation procedures.
b. Carefully read this “Instructions for Use" before use. Failure to read and follow it diligently could result in serious patient/user injury.
c. Do not begin energy delivery until Leaf is properly deployed, and its position in the uterine cavity is confirmed. Failure to comply could result in serious patient/user injury.
d. Perform checks, such as hysteroscopy, to prevent or mitigate possible injury if an equipment malfunction or other abnormal or unexpected situation is suspected anytime during the procedure. Failure to comply could result in serious patient/user injury.
e. Do not mishandle or damage device. It could result in unsafe or ineffective treatment, or otherwise harm the patient/user.
f. Do not use Device if the sterile pouch appears to be open, or otherwise compromised.
g. Do not reuse or re-sterilize Device. Device is for single-procedure use only. Reuse or re-sterilization could result in unsafe or ineffective treatment, or otherwise harm the patient/user.
h. Keep mGrip area dry. Do not perform treatment if it is wet.
i. Do not perform treatment in presence of flammable materials.
j. Minitouch Procedure is not for female sterilization. Post-procedure contraception and prevention of pregnancy are essential.

PRECAUTIONS

a. Use only Instructions for Use included with Device.
b. Ensure that all connections are proper. Otherwise unsafe or ineffective treatment is possible.
c. ICC is not sterile. Do not place it in the sterile field.
d. ICC is fragile. Do not bend it sharply or otherwise mishandle it. Do not leave it connected to Test Port.
e. Keep the unopened package dry and away from sunlight.
f. Do not use Generator until all checks have been cleared.
g. Do not use Generator in an oxygen rich environment. Spark generation is possible.
h. Do not connect the mains power if Generator is wet.
i. Do not disassemble any component of Generator. Access the fuses at the fuse drawer.
j. Do not use if any component appears to be damaged.
k. Use only a “Hospital Grade” receptacle for grounding reliability.
l. Contact a Minitouch representative to address any questions related to Instructions for Use. Note that they do not have clinical expertise or the authorization to assist in patient care.
m. Device has not been evaluated in patients with cardiac pacemakers or metallic implants.
n. Pause energy delivery if Device feels too warm to hold.
o. Complications and adverse events, such as the following, have been reported with endometrial ablation procedures.

   Uterine Cramping, Pelvic Pain, Nausea, Vomiting, Vasovagal Reaction, Vaginal Discharge/Bleeding, 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.

REFERENCE

Wortman M. Late-onset Endometrial Ablation Failure. *Case Reports in Women's Health;* 2017:(15):11-28.

Woods S, Taylor B. Global Ablation Techniques. *Obstetrics and Gynecology Clinics of North America;* 2013:40(4):687-695.

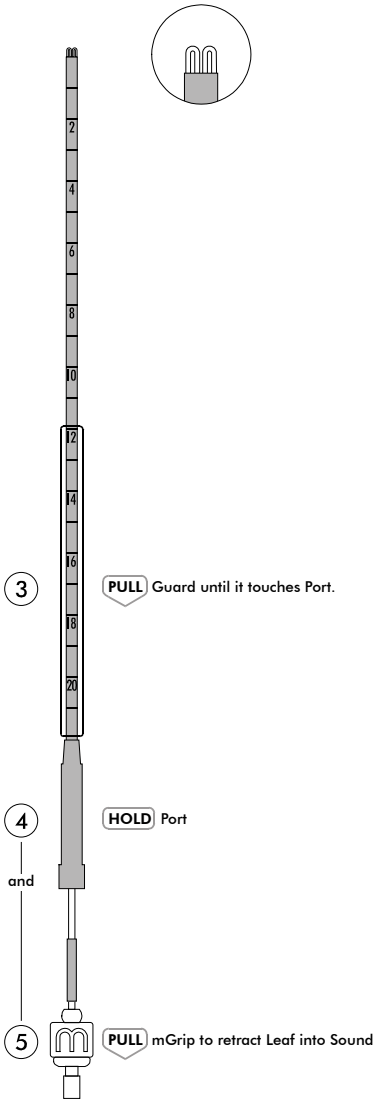
Lethaby A, Penninx J, Hickey M, Garry R, Marjoribanks J. Endometrial Resection and Ablation Techniques for Heavy Menstrual Bleeding. *Cochrane Database of Systematic Reviews;* 2013:(8):CD001501.

MHRA Guidance on the Responsibilities of Manufacturers, the Regulator, and Clinicians with respect to Endometrial Ablation. *Medicines and Healthcare products Regulatory Agency, UK;* 2011.

www.minitouch.eu

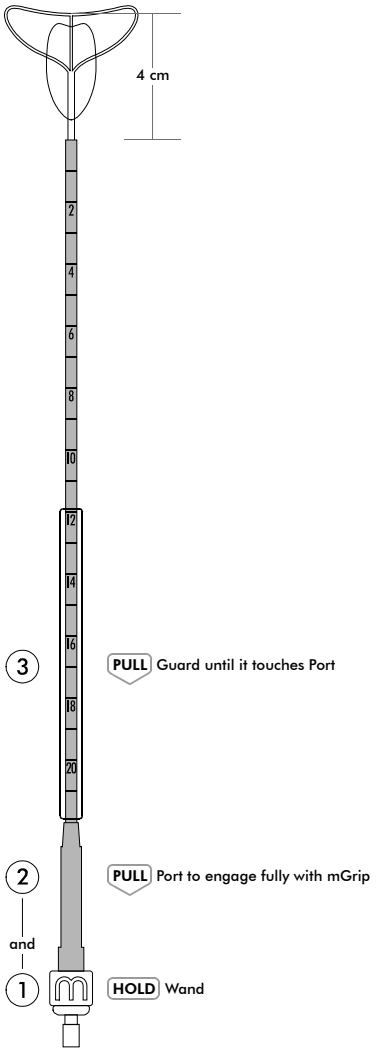
Closed State

1. Align curve of Device with orientation of uterus.
2. Keep ⋒ facing up.



Open State

Wand is flexible. In steps 1 & 2, hold Wand close to Port and pull Port using multiple short, controlled strokes in order to prevent kinking.



Basic Information

Minitouch System

The system consists of a Generator and a sterile single-use Device.

Patient Comfort

Minitouch Device is slim and flexible and will bend to conform to the anatomy. It is not necessary to dilate the cervix or distend the uterus for the Minitouch Procedure. Minimize the dilation, distension and other trauma to the uterus before and after the Minitouch Procedure.

Minitouch Procedure can be tailored for patient comfort. Adjust power and pause/resume as desired for comfortable treatment and recovery.

Energy Field

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

User in Charge

User is in charge of the procedure. Remain mindful throughout of Device state, Leaf position, and associated cmScale readings in order to ensure a normal and efficient procedure.

Desired Treatment Length – DTL

DTL is the length of the cavity that User decides to treat. User may leave a proximal portion of the cavity untreated for clinical reasons. Minimum DTL is 4 cm; there is no upper limit.

Sounding Depth A

This uterine sounding depth measurement, made prior to the Minitouch Procedure, is essential for proper positioning of Device.

cmScale

A cmScale is for ongoing tracking of the distal end of Sound with respect to the external os. Leaf extends 4 cm from the distal end of Sound in OPEN state.

Leaf Position

Proper positioning of Leaf in the uterine cavity by User is the primary determinant of safety related to energy delivery.

Position Bounds

Distal end of Device should not be beyond the sounding depth A in either state of Device under normal conditions.

Distal end of Guard should not be beyond the internal os under normal conditions.

Device/Leaf Alignment

Align the Device curve with orientation of the uterus before insertion.

Keep Leaf aligned with plane of the cavity by keeping ⋒ facing up and Wand in its natural untwisted state.

Energy

It is the amount of energy used up to the moment in a treatment step, or in a procedure where so indicated. It is 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 used.

Target Energy Dose – TED™

TED™ is the target amount of energy to be used in a treatment step. It is expressed in joules.

Available Power – PWR

It is the power available for use. In general, less than 100% of it is used due to impeding factors. It is expressed in watts.

Use Percentage – U

U is the percentage of PWR that is used. Any unused portion is returned to Generator. U is a measure of the ability of Device to deliver and the tissue to receive energy.

Ability of Device to deliver energy can be impeded by factors such as incomplete Leaf deployment and presence of blood, clots or vapor layer adjacent to Leaf. Mitigate the impeding factors and raise U value as high as possible for a more efficient procedure.

Ability of the tissue to receive energy is based on its moisture content. All else equal, U value is highest when the tissue is moist and unablated, and lowest when the tissue is desiccated.

Procedure

A procedure refers to treatment of the desired treatment length DTL 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, and then extended proximally via one or more Extension lesions as necessary. Each Extension lesion partially overlaps the previous lesion and extends it by up to 2 cm.

User concludes the procedure when DTL is fully treated by selecting END in Next Step.

Treatment Step

User may adjust PWR or pause treatment for patient comfort.

The energy delivery will pause if the U value goes below a U limit UL.

A treatment step is concluded when TED™ is reached. User may conclude it if further energy delivery is not practicable due to low U values that cannot be mitigated.

It is terminated automatically if a preset Time Limit is reached.

U-Mapping™

It is a technique that can help User to broadly infer contour of the cavity and the position of Leaf in relation to the cavity. It entails taking U values along the length of the cavity. All else equal, a U value is based on the extent of Leaf deployment, which can depend on the width of the cavity at that particular position.

Settings

Set the values for a desired combination of patient comfort, lesion size and treatment duration. The values in bold should be optimal for most patients. Time limit is preset.

	Unit	Main	Extension
UL range	% of PWR	30 - **40** - 50	30 - **40** - 50
PWR range	watt	20 - **40** - 50	20 - **40** - 50
TED™ range	joule	3200 - **4000** - 4800	800 - **1000** - 1200
Time Limit	second	400	100

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	beeep
value/control not valid	beep
system error	beep-beeep every 5 seconds

Check Hysteroscopy

Perform checks, such as hysteroscopy, to prevent or mitigate possible injury if an equipment malfunction or other abnormal or unexpected situation is suspected anytime during the procedure. Device may be removed from the cavity if necessary, and reinserted after the check.

SoundScopy™

It is a technique that can help User in placing Leaf into the cavity with added certainty. It entails replacing Wand with a scope, performing a hysteroscopy, and then withdrawing the scope while keeping Sound in the cavity. Wand is then inserted back into Sound to end up with Device in the cavity.

Aspiration

Sound by itself may be used for emptying fluids from the cavity.

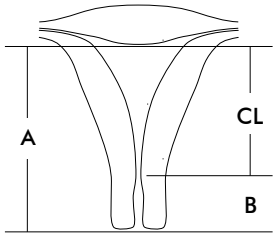
Automonitor

Minitouch System constantly self-monitors the connections and the energy function. The procedure is terminated in case of an error. Go to section H for Device removal.

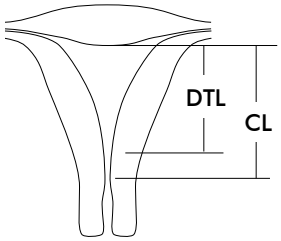
Before the Procedure

A. PATIENT

A1. Measure uterine sounding depth A, cervix length B, and determine cavity length CL in centimeters.



A2. Decide desired treatment length DTL in centimeters.



A3. Empty all fluids from the cavity.

B. GENERATOR

B1. Clear all checks via CHECK.

B2. Store treatment values via SET.

B3. Click H to go HOME.

B4. In HOME, select TREAT, and click OK.

B5. In CONFIRM A, confirm the values for the main treatment step, and click OK.

B6. In CONFIRM B, confirm the values for the extension treatment steps, and click OK.

Minitouch Procedure

C. INSERTION

C1. Ensure ICC connector is free of any debris or damage.

C2. Insert ICC and Keypad in the sterile covers.

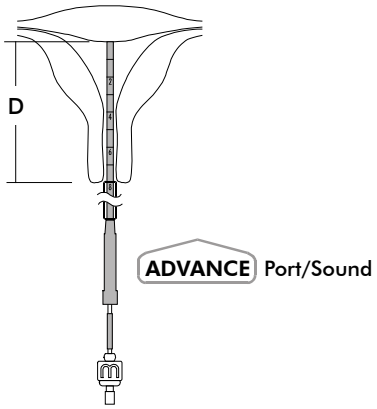
C3. Connect ICC to Device.

C4. Bring Device to CLOSED state.

C5. Gently insert Device into the cavity.

C6. Grasp Port, advance Sound, and measure sounding depth D.

C7. Confirm that sounding depths D and A match.



D. DEPLOYMENT

D1. Bring Device to OPEN state.

D2. In STEP-1, select the setting A, and click OK.

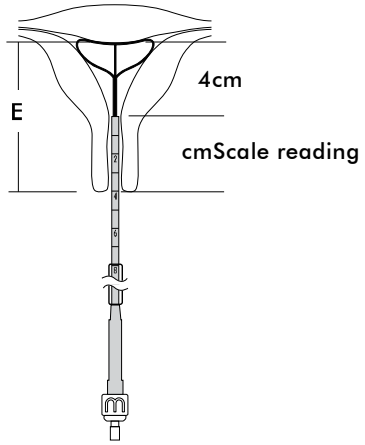
D3. In POSITION, move Device back and forth and get U values at multiple positions until they are as high as possible and stable, and Leaf deployment is satisfactory.

E. POSITION

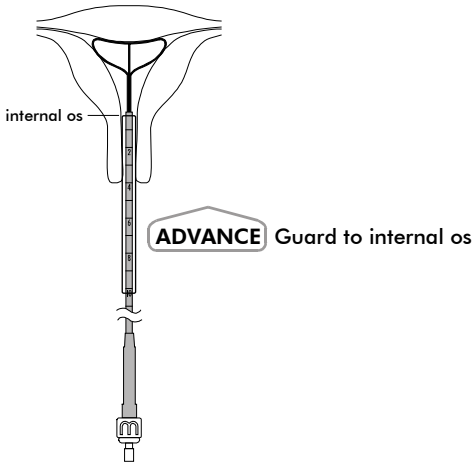
E1. Confirm that Leaf is in the cavity via U-Mapping™ and/or other methods combined with clinical judgement.

E2. Grasp mGrip, advance Leaf to the fundus and determine sounding depth E by adding 4 cm to the cmScale reading.

E3. Confirm that sounding depths E and A match.



F. MAIN TREATMENT STEP



F1. Keep Leaf into firm contact with the fundus.

F2. Advance Guard to the internal os.

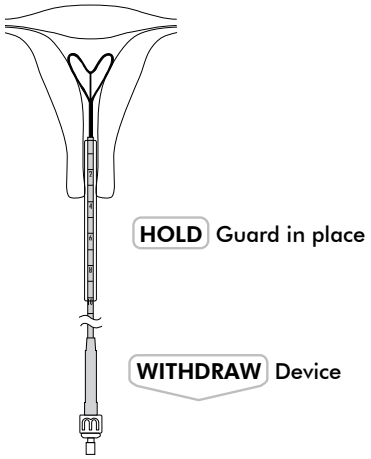
F3. In POSITION, p-click E to begin energy delivery.

F4. In TREAT, adjust PWR, pause/resume, for patient comfort.

F5. NEXT STEP is displayed at conclusion of the current step.

F6. If DTL is longer than 4 cm, continue to section G for extension treatments. Otherwise, go to section H for Device removal.

G. EXTENSION TREATMENT STEPS



G1. Hold Guard in place, grasp Port and withdraw Device by 2 cm or DTL not yet treated, whichever is less.

G2. In NEXT STEP, select the setting B, and click OK.

G3. In POSITION, get U values to confirm the position.

G4. In POSITION, p-click E to begin energy delivery.

G5. In TREAT, adjust PWR, pause/resume, for patient comfort.

G6. NEXT STEP is displayed at conclusion of the current step.

G7. Repeat steps G1 through G6 until the full DTL is treated.

H. REMOVAL

H1. Bring Device to CLOSED state.

H2. Remove Device by pulling on Guard.

H3. Disconnect Device from ICC.

H4. Discard Device and the covers into a biohazard facility.

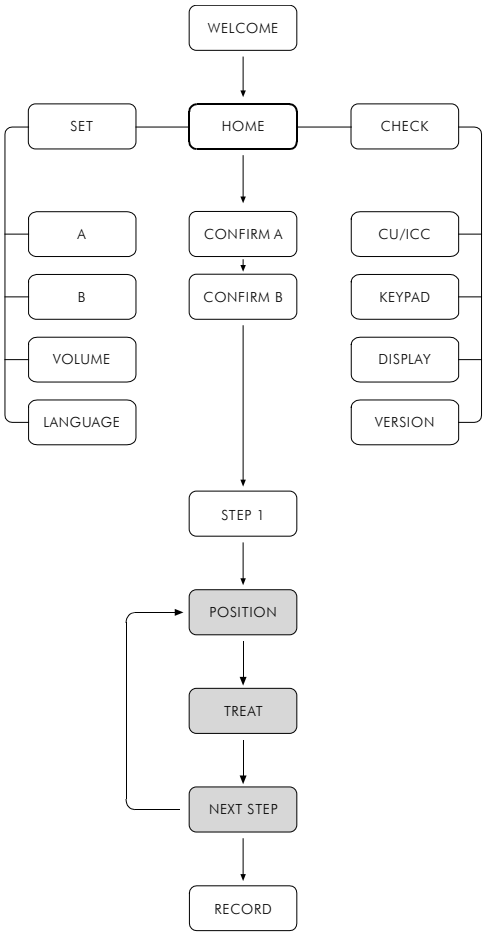
I. RECORD

I1. In NEXT STEP, select END, and click OK.

I2. Record the procedure history.

I3. Click H to go HOME.

Screen Map



WELCOME

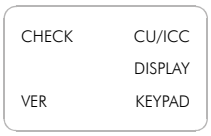
Click H to go HOME.

HOME

Select Set, Check or Treat, and click OK.

Check

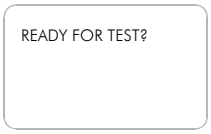
CHECK



Select CU/ICC, Display, Keypad or Version, and click OK.

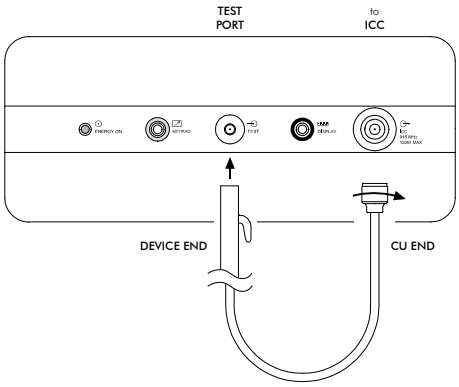
Click H to go HOME.

CHECK CU/ICC



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 Device End to Test Port (also called Park Port).



Click OK when ready to initiate the test.

If "ICC FAILED" is displayed, check connections or replace ICC, and repeat the check.

If "CU FAILED" is displayed, go to Troubleshooting Section.

Disconnect ICC from Test Port.

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

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 or p-Click the highlighted control as indicated.
It will flash confirming that it works.

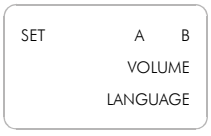
Click OK, except at OK, to go to back to CHECK.
Click H to go HOME.

CHECK VERSION

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

Set

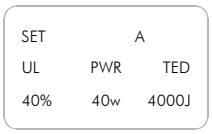
SET



Select A, B, Volume or Language, and click OK.

Click H to go HOME.

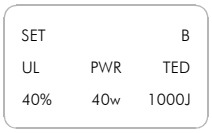
SET A



Select a desired UL value, and click OK.
Select a desired PWR value, and click OK.
Select a desired TED™ value, and click OK.

Click OK to go back to SET.
Click H to go HOME.

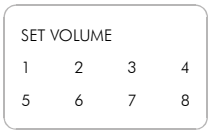
SET B



Select a desired UL value, and click OK.
Select a desired PWR value, and click OK.
Select a desired TED™ 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.

SET LANGUAGE

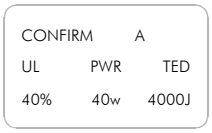
Danish German English Spanish
French Italian Dutch Swedish

Select a desired language, and click OK.

Click OK to go back to SET.
Click H to go HOME.

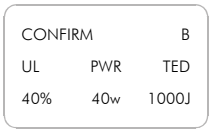
Treat

CONFIRM A



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

CONFIRM B



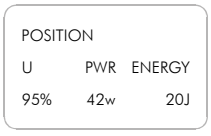
Click OK to confirm the settings for Extension Treatment step.
Click H to go HOME.

STEP-1

Select A or B setting, and click OK.

Click H to go HOME.

POSITION

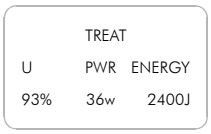


Click E to get a U value.
U value will flash if it is below U Limit.

Click SELECT to adjust the PWR setting by 2 watts.

p-Click E to begin energy delivery.
p-Click OK to terminate the current step.

TREAT



Click E to pause energy delivery.
The delivery will automatically pause if the U value goes below UL.

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

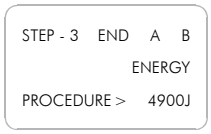
p-Click E to resume energy delivery.

Click SELECT to adjust the PWR setting by 2 watts.

The current step is automatically concluded when TED™ is reached.
p-Click OK to conclude the current step.

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

NEXT STEP

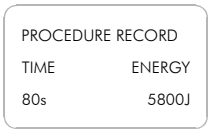


The step number applies to the next treatment step.

ENERGY is the total energy already delivered in this procedure.

Select A or B, and click OK, to go to POSITION.
Select END, and click OK, to conclude the procedure.

RECORD



The procedure history is displayed via screens cycling every 3 seconds.

RECORD displays end states of each step and the whole procedure.
VERSION displays the software version of Generator.
ERROR, if present, displays the cause of termination of the procedure.

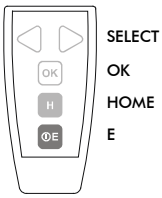
Click OK to cycle the screens manually.
Click H to go HOME.

Generator

Minitouch Generator delivers energy to Minitouch Device.
It is shipped in three boxes with the following items.

Product Number	Description
100001-01	**Minitouch Generator**
100002E	Central Unit
900064	Instructions for Use
100023	Stand Kit – Base, Dock, S Arm
100003E	Display
100024	Keypad
100006	ICC
100012 or 100025	Power Cord CEE 7/7 (EU) Power Cord BS 1363 (UK)

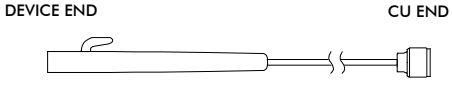
KEYPAD



Keypad is not sterile. Insert in a sterile cover before use.

Action	Description
click	press and release instantly
p-click	press, and release after an audio prompt
select	click a desired backward/forward button for faster action, press until a desired value, and then release

INTER-CONNECTING CABLE (ICC)



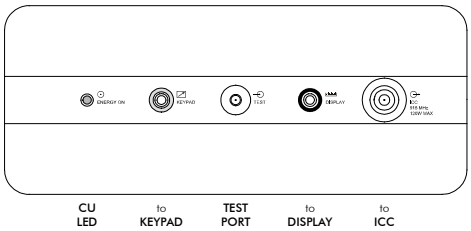
ICC is not sterile. Insert in a sterile cover before use.

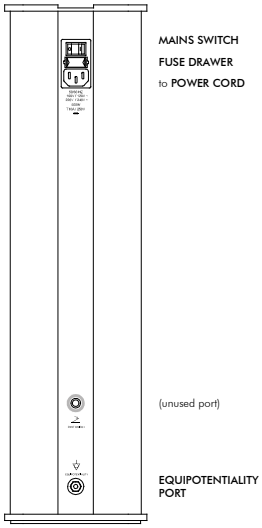
It is fragile and can get damaged if mishandled or bent sharply.
Do not leave it connected to Test Port.

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 from CU.

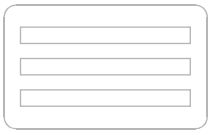




Mains Switch switches Generator on or off.

Equipotentiality Port provides connection to CU frame if desired.

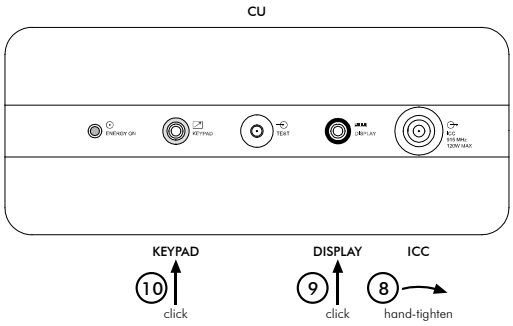
DISPLAY

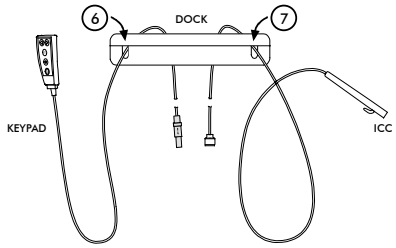


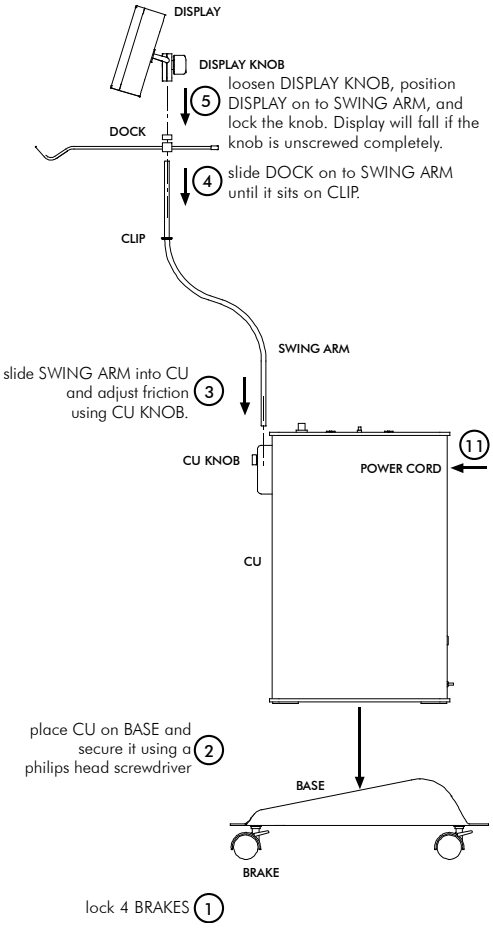
Display provides visual and audio feedback.

ASSEMBLY

a. Unpack the two 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.







MAINTENANCE

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.

TROUBLESHOOTING

Check connections in case of an error message. Contact MicroCube if it does not resolve the problem. There are no user-serviceable parts within.

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.

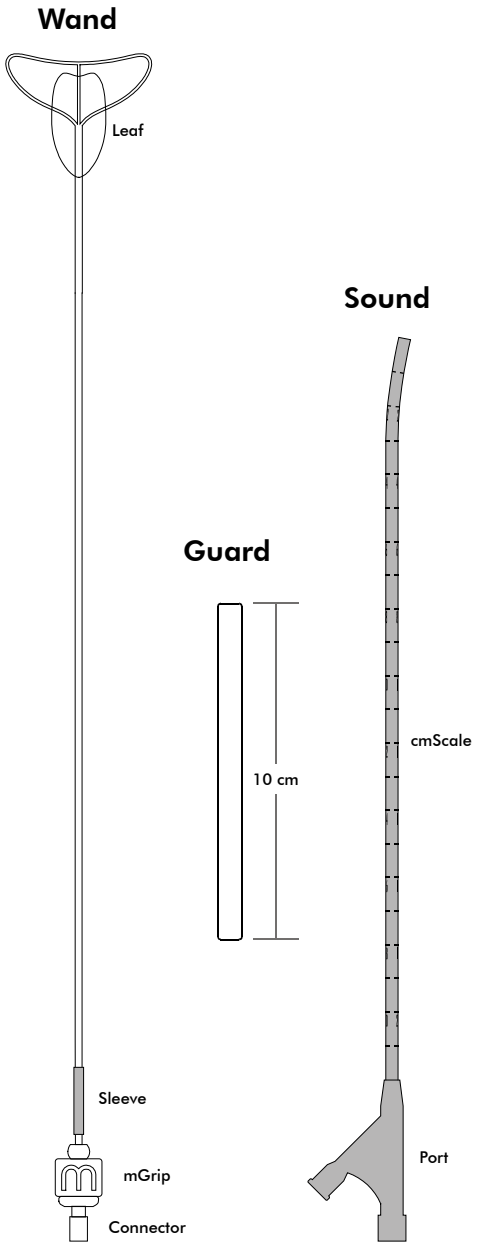
Device

Product Number	Description
102006	Minitouch Device

The box contains Device, Instructions for Use, and 2 sterile covers.

Minitouch Device is for single use only.
It is shipped sterile, and ready for use.

COMPONENTS

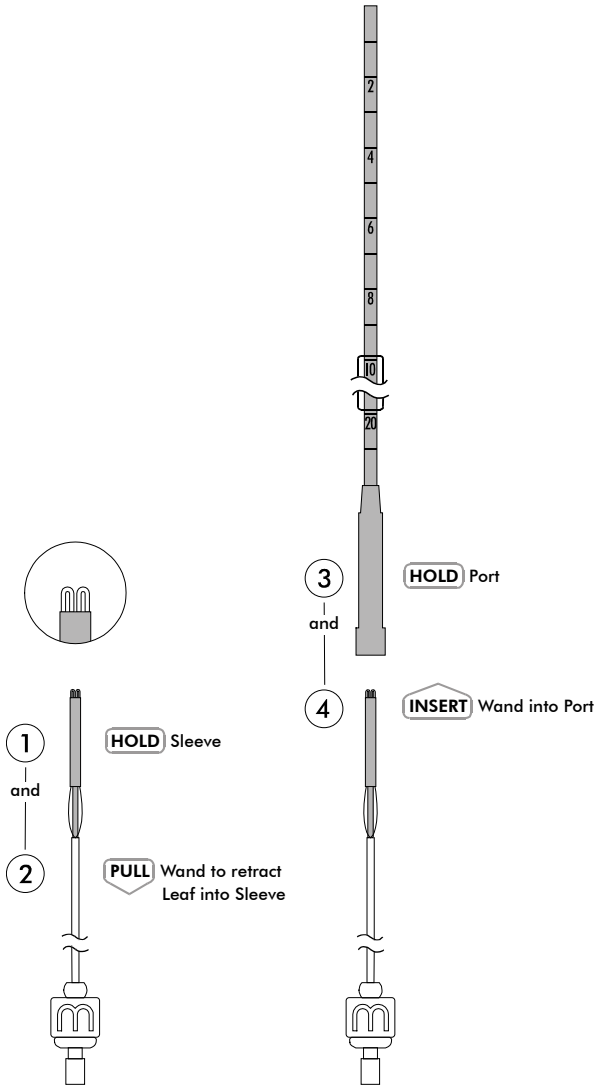


WAND INSERTION

Use the instructions below in case Wand is removed from Sound.

Wand is flexible. While engaging it with Sleeve or Sound, hold it close to the respective opening and use multiple short, controlled strokes in order to prevent kinking.

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



EM Information

The minitouch generator is immune to electromagnetic interference. This equipment has been tested and found to comply with the standards listed in IEC60601-1-2. 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.

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 CISPR 11	Group 2	The minitouch generator must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The minitouch generator is suitable for use in hospitals, clinics and offices other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	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) IEC 61000-4-2	± 8 kV contact ± 15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±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 IEC 61000-4-11	Voltage Dips 30% reduction, 25/30 periods At 0° Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage Dips 30% reduction, 25/30 periods At 0° Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	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 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 IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM radio Bands within 150kHz-80MHz)	3 Vrms	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. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz 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, as determined by an electromagnetic site survey (a) , should be less than the compliance level in each frequency range(b).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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.

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.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 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.

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

EC REP	Authorized Representative in the European Community
REF	Catalog number
	Caution: consult accompanying information
	Do not reuse
	Do not use if package is damaged
FOR EXPORT ONLY	For export only (not for sale in the USA)
	Keep away from sunlight
	Keep dry
LOT	Lot Number
	Manufacturer
SN	Serial Number
STERILE EO	Supplied sterile using ethylene oxide gas
	Use by date
	Alternating current
YYYY	Date of manufacture
	Defibrillation-Proof Type BF Applied part
	Do not autoclave any cable or component
	Do not immerse any cable or component in liquids
	Do not use equipment with flammable anesthetics AP
	Energy On
	Fuse
	ICC receptacle – energy output receptacle
	Display
	Keypad
	Non-ionizing radiation
	Off (power: disconnection from the mains)
	On (power: connection to the mains)
	Test Port
	Protective Earth Ground
	Consult instructions for use
	Mass
	Consult instructions for use

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

MINITOUCH SYSTEM

Device product number: 102006
Generator product number: 100001-01
Instructions for Use number: 900064 – rev 9, September 2019
Class I, Type BF instrument, according to IEC/EN 60601-1
Class IIb device according to the MDD 93/42/EEC
Class A/group 2 device according to IEC 60601-1-2
Meets the requirements of IEC/EN 60601-1 and EN 60601-2-6
Energy accuracy : ±20%

MINITOUCH DEVICE

Shelf Life: 28 months from the date of sterilization
For single-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)

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

The Minitouch System is restricted to sale by or on the order of a duly authorised healthcare professional.

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 further warrants that Device has been validated to remain sterile up to the "use by" date, provided its original packing remains intact.

MicroCube's sole obligation shall be limited to replace Device and replace or repair Generator at no charge, provided a written notification is received and MicroCube determines that Device 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 multiple patents and patent applications including, but not limited to: EP2355738B1, EP2349045B1, US 8,968,287, US 9,615,882, US 9,462,642, US 2017-0273730, ZL200980151261.0, JP 5406933, and JP 6083928.

TED™, U-Mapping™ and SoundScopy™ are trademarks of MicroCube, LLC.

CONTACT

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