Contents

Manufactured by:
Miridia Technology Inc.
1875 N Lakes Place
Meridian, ID 83646
(208) 846-8448

Date of Purchase:

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Please retain this user manual for future reference.

AcuCore M1 User Manual Rev C

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Device Overview

1. Introduction

Congratulations on your purchase of the AcuCore M1 Acupuncture Point Locator. This tool is designed to be employed as part of a system for electronically locating and evaluating acupuncture points. The AcuCore M1 is a class II medical device according US FDA classification.

2. Intended Use

AcuCore M1 is used for detecting acupoints on the human body by means of electrical skin resistance measurement.

3. Recommended Usage

Please carefully read through the operation manual before using this device.

- This device may only be used with original accessories.
- Keep this device away from water or other liquids, except as instructed here.
- Do not drop the device, handle it roughly, or expose it to extreme temperatures.
- Device should only be used at temperatures between 5°C and 40°C (40°F and 100°F) and at relative humidity of less than 85%.
- Never use the device if it is malfunctioning or has been damaged.
- When not in use, store the device in its original packaging to protect it against damage and contamination.

Warning!

To avoid interference, this device should not be used close to other electronic devices, and particularly devices that transmit radio frequencies (RF). If not possible, the device must be observed during operation to ensure that respective functions are operating correctly.

The use of this device close to a source of EMF (electromagnetic frequencies) may interfere with correct resistance readings. Patients with an implanted medical device (e.g. cardiac pacemaker) should consult their physician before use.

4. Included Equipment

AcuCore M1 Probe-QTY 1
-PN XXXXXXX

- 5V Power Supply-QTY 1
  -PN XXXXXXX
- AcuCore Charge Base-QTY 1
  -PN XXXXXXX
- Consumable Supply Package-QTY 1
  -PN XXXXXXX
- User Manual-QTY 1

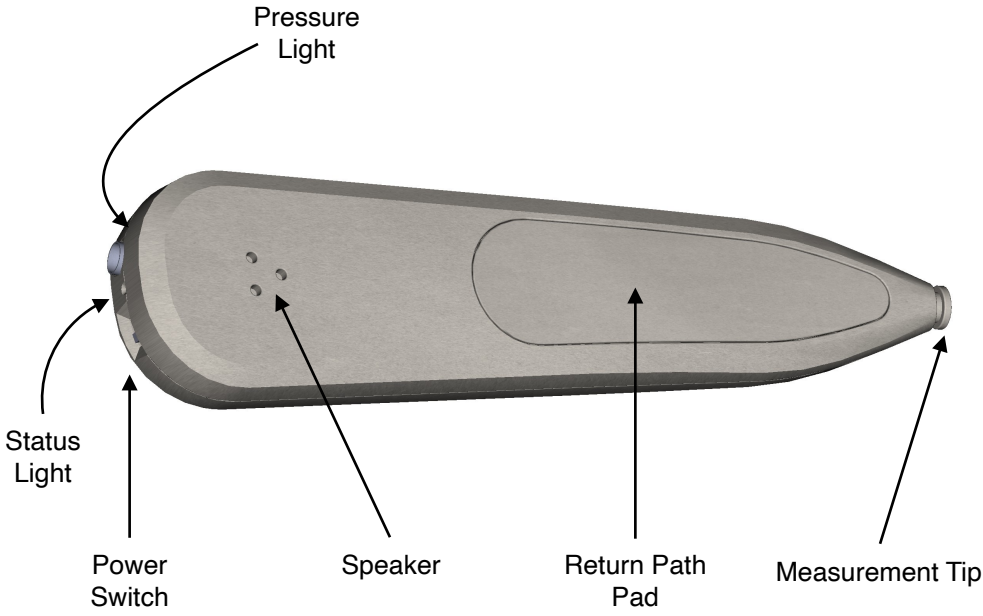
5. Cotton Swab Tips

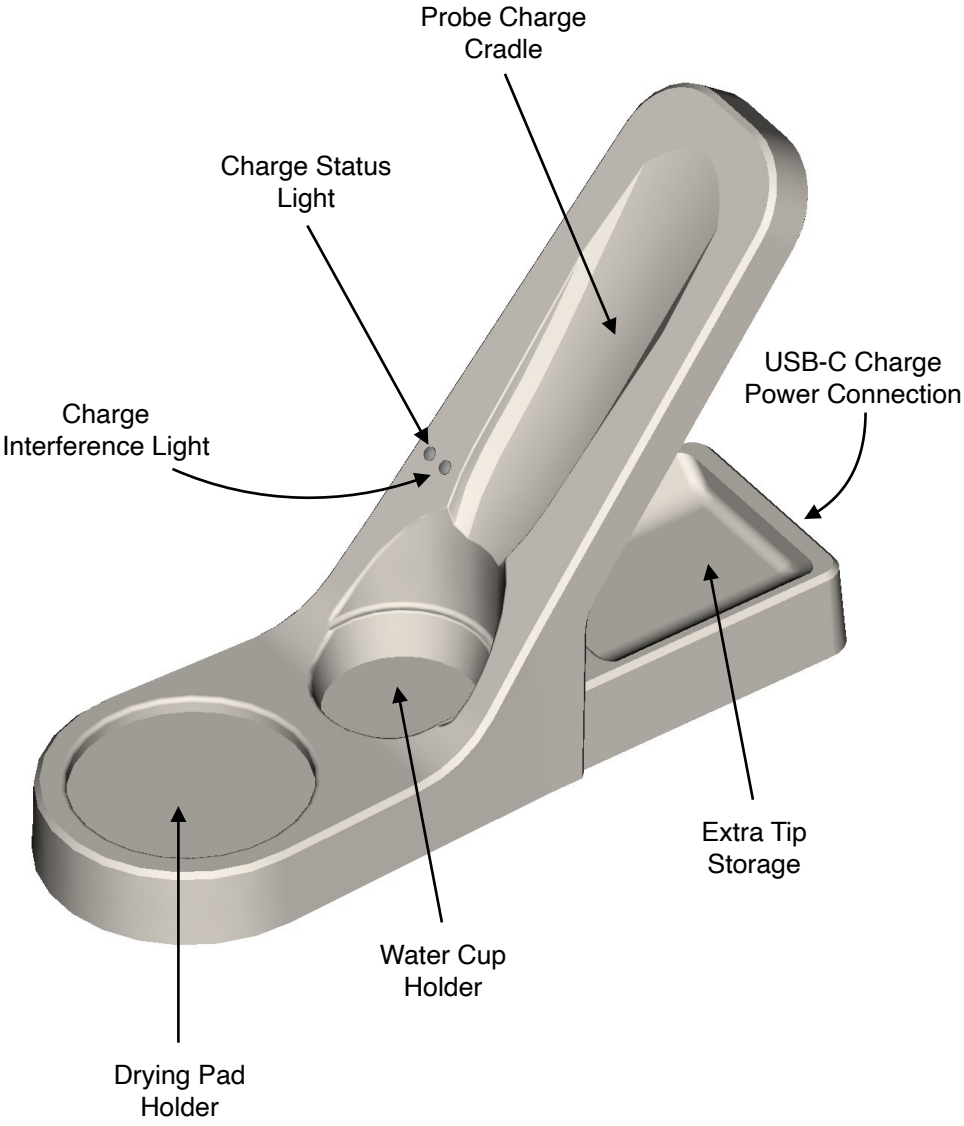
The AcuCore M1 Probe is designed for use with a disposable cotton swab tip. A supply of these tips is provided in the Consumable Supply Package. You may obtain additional tips where you purchased this device, or by simply cutting the tips from standard cotton swabs available at drug or medical supply stores.

6. Absorbent Pads

Your AcuCore M1 comes with a supply of disposable absorbent pads in the Consumable Supply Package. These are designed for drying excess water from the cotton swab tip during use. You may obtain additional absorbent pads where you purchased this device, or you may purchase suitable pads at a drug or cosmetic supply store.

Device Operation




Probe Charge Cradle
Charge Status Light
Charge Interference Light
USB-C Charge Power Connection
Extra Tip Storage
Water Cup Holder
Drying Pad Holder

7. Setting up and Charging

Remove device from packaging and connect Power Supply to USB-C Charge Power Connection, then connect to mains power.

Place the AcuCore M1 Probe in the Probe Charge Cradle to charge, and check to see that the white Charge Status Light is illuminated. If the Charge Status Light fails to illuminate, check that the Power Supply is properly powered and attached to the USB-C Charge Power Connection and that the AcuCore M1 Probe is properly seated in the Probe Charge Cradle.

If the green Charge Interference Light illuminates, check to make sure there is no obstruction between the hand probe and the charge cradle and that the hand probe is properly seated in the cradle in the correct orientation.

Allow the Probe to charge for one hour before initial use.

When the AcuCore M1 Probe reaches 10% charge remaining, it will produce a double beep every 3 minutes while at rest to indicate it needs to be charged. Whenever the Probe requires charging, simply place it on its Charge Cradle as indicated and charging will begin automatically. State of charge can be verified during the charging process in software on the paired computer or mobile device. It is normal for the Probe to become warm to the touch during charging.

The internal battery is not user serviceable. If the probe fails to charge or the battery does not hold a charge, the Probe must be returned to the manufacturer for servicing.

8. Switching the Device Off and On

Switch the Probe on for use with the Power Switch. When the Probe is switched on, it will make its start up tone and the Power Light will flash while Probe is trying to connect to a host. Once connected, the Probe will play the connection tone and the Power Light will switch from flashing to continuous on. When the Probe will not be used for a period of time, switch it off using the Power switch.

9. Initial Pairing

Start the device by turning on the Power Switch. An initial start up tone will sound and the Status Light will begin flashing.

The AcuCore M1 Probe requires a connection with a host device for use. A host device is a computer or mobile device with suitable software to

communicate with the AcuCore M1 Probe. After installing the appropriate software on your host device, follow the instructions in the software to pair the AcuCore M1 Probe with the host device, if required. Some host devices will pair automatically and will not require a specific pairing procedure.

10. Taking Measurements

To take measurements of acupuncture points, follow this procedure:

1. Place a clean cotton swab end in the Measurement Tip.
2. Moisten the cotton swab end in water. Standard tap water or saline solution may be used. Do not use distilled water. **Important: Do not immerse the Probe or the Measurement Tip in water; only the cotton swab end should be immersed.**
3. Tap the cotton swab on an absorbent surface to remove excess moisture from the tip. The swab should be wet, but not dripping.
4. **Return Path Pad:** proper measurements require a return voltage path from the Measurement Tip to the Return Path Pad. Therefore the hand probe should be held by the operator during measurement in such a way as to make good electrical contact between the operator's hand and the Return Path Pad. The operator's other hand must then contact the skin surface of the person being measured to complete the circuit.
5. (Optional) The return path may also be completed with the wrist strap and connection cable to ground strap connection. To do so, connect the wrist strap around the wrist of the person being measured, ensuring good electrical contact between the metal contact on the wrist strap and the skin. Then connect the cable from the wrist strap to the ground strap connection on the hand probe. If this optional return path is used, the operator does not need to make physical contact with the person being measured.
6. Using the connected software app on the host device, place the Probe in measurement mode.
7. Locate the point to be measured and place the cotton swab tip against the skin of the measurement subject. It is permissible to move the tip around on the skin to find the point of best conductance, as reported by the connected software.
8. The amount of pressure applied by the probe against the skin is also measured, and if configured in the software, the probe pressure measurement light will illuminate when the pressure applied is in the correct range.
9. Follow software prompts to capture and take further measurements.

10. **Attention:** When detecting points, orient the Probe vertically on the skin area being measured. Apply light force to the skin during measurement. The attached software may optionally report probe pressure against the skin and confine measurements to a specific pressure range. The pressure indication light on the probe may also be set by software to light within a specific pressure range. See software instructions for more information.
11. During point detection, the AcuCore M1 Probe will provide audio feedback in the form of pitch changes to correlate with measured resistance. Higher pitches mean lower resistance and higher conductance.

11. Software Settings

The following settings may be adjusted in the software on the host device, depending on the software parameters:

- Sound Volume of feedback tone during measurement
- Pressure range for measurement activation
- Pressure indication light

The software may also be configured to report the following parameters:

- Charge state (charging, not charging)
- Percent battery charge
- Probe name

See your host software for instructions on setting or monitoring these parameters.

12. Cautions/Contraindications

There are no known contraindications for the use of the AcuCore M1. There are, however, circumstances in which it has not been tested. Accordingly, it should not be used by those employing implanted medical devices such as cardiac pacemakers, defibrillators or other internal electronic devices, or by those who are pregnant, without ongoing clinical supervision.

There are no known negative side effects from using this device. If you experience any adverse event, discontinue use and consult a physician. Do not use this device in contact with skin lesions, new cuts, skin irritation or sunburn.

13. Care

The outside of your AcuCore M1 Probe and its Charge Base can be cleaned with a damp, soft cloth and mild cleaner or disinfectant. Particular care must be taken when cleaning the Measurement Tip to avoid getting liquid inside the device.

Ensure that no moisture enters the device. If moisture does enter the device, then the device must undergo a technical inspection before being used again.

Store as described in section 16 “Product Operating Environment.”

14. Troubleshooting

Problem	Possible Cause	Solution
No light or start up tone when the power switch is turned on	Battery is low	Charge device for at least 1 hour
Device fails to take measurements in measurement mode	Return path connection is inadequate.	See section 7.4 for instructions
	Cotton swab is too dry	Properly moisten swab as instructed in section 10.2 and 10.3
	Inadequate measurement pressure against skin	Increase pressure slightly
No sound during measurements	Volume setting too low in software	Increase volume setting
Probe fails to charge	Probe not properly seated in Charge Cradle	Adjust Probe to sit properly in Charge Cradle
	Foreign object interfering between Probe and Charge Cradle	Check for and remove interfering object
Probe will not connect with host device	Probe power is off	Turn Power Switch to on position
	Probe is too far from host device	Move Probe closer to host device
Probe loses connection with host device	Probe is too far from host device	Move Probe closer to host device

If your device still does not work, call Miridia Technology Inc. at 208-846-8448 or visit www.miridiatech.com.

Your AcuCore M1 does not require recalibration and there are no user-serviceable parts inside. All repairs must be carried out by the manufacturer or the manufacturer's authorized agent.

15. Limited Warranty

Miridia Technology Inc. warrants equipment of its own manufacture to be free from defects in material and workmanship for one (1) year from the date of shipment to original purchaser, subject to the terms and conditions of this warranty. Miridia Technology Inc. may repair or replace the unit or defective item at its sole option. Buyer must return any part claimed defective to Miridia Technology Inc. shipping prepaid.

1. This warranty is expressly in lieu of any other expressed or implied warranty of merchantability or fitness and any other obligation on the part of the seller.
2. Miridia Technology, Inc. shall have no obligation under this warranty if damage occurs because of improper handling or operation, abuse, misuse, unauthorized repairs made or attempted, or where equipment is operated above rated capacity. Authorization for the return of parts under this warranty shall first be obtained by telephone or letter from the Miridia Technology customer service department. Details of the claimed defect must accompany the returned part.
3. No agent, employee, or representative of Miridia Technology, Inc. has any authority to bind Miridia Technology, Inc. to any affirmation, representation or warranty concerning the goods sold under this contract. Unless an affirmation representation or warranty made by an agent employee, or representative is specifically included within the written agreement, it shall not be enforceable by the buyer.
4. Notice of claims: Immediately upon receipt of the goods, buyer must inspect the same. All claims, including claims for defective goods, must be made within five (5) days after buyer learns of fact(s) upon which such claims are based, but in no event later than one (one) year after buyer's receipt of the goods. All claims not made in writing, and received within the time period specified above shall be deemed waived.
5. Miridia Technology, Inc.'s liability for any and all losses and damage to the buyer, in any way, arising out of, or connected with this transaction, or with the use of the equipment, from any case whatsoever shall be limited to the repair or replacement of defective material or workmanship. In no event shall Miridia Technology, Inc. be liable for consequential or indirect damage.
6. The purchaser of this equipment assumes full liability for the consequence of misuse by him/herself, and all risks in connection with use of the AcuCore M1 Probe by other individuals.

16. Product Operating Environment

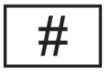
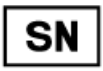
Storage Environment	Specification
Temperature	-10°C - 30°C
Relative Humidity	≤ 80%
Atmospheric Pressure	86-106 kPa
Operating Environment	**Specification**
Temperature	10°C - 45°C
Relative Humidity	≤ 70%
Atmospheric Pressure	86-106 kPa

Store indoors in a non-corrosive atmosphere with good ventilation. Avoid impact, harsh vibration, and moisture during transportation.

17. Technical Specifications

Model	AcuCore M1
Equipment Class	Class II
Power Supply	Input: 100-240V AC, 50-60 Hz. Output: 5V DC 2.0 A
Dimensions	Approx. 160mm X 190mm X 70mm
Weight	330 g
Internal Battery	Li-ion rechargeable, 3.7V 400mAh
Measurement Voltage	0 - 5V DC
Measurement Current	0 - 40μA
Battery Charging Time	1 hour
Battery Operating Time	240 minutes continuous, 72 hours standby
Wireless Charging Standard	WPC - Qi V1.2.4, 5V 1A Max.
Bluetooth Radio	Bluetooth® LE (Low Energy Mode) 2.4 GHz

18. Description of Symbols

	Indicates the medical device manufacturer
	Indicates the date when the medical device was manufactured
	Indicates the date by which the medical device should be used
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the device’s model number so that the medical device can be identified
	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Identifies the product’s country of manufacture
	Indicates a medical device that needs protection from moisture
	To identify a type BF applied part complying with IEC 60601-1

	Do not dispose of electronic products in the general waste stream
	Meets FCC requirements per 21 CFR Part 15
	Indicates a carrier that contains unique device identifier information
	Indicates the need for the user to consult the instructions for use

19. Electromagnetic Interference and Compatibility

Electromagnetic Emissions IEC 60601-1-2		
Emissions Test	**Compliance**	**Electromagnetic environment-guidance**
RF Emissions CISPR 11	Group 1	The AcuCore M1 is classified as group 1 Equipment. Group 1 equipment is all equipment in the in the scope of this standard which is not classified as group 2 equipment.
RF Emissions CISPR 11	Class A	The AcuCore M1 is suitable for use in all locations other than those allocated in residential environments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Pass	
Immunity Test	**Compliance Level**	**Electromagnetic environment-guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	Floor 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	± 0.5, 1, 2 kV	Not Applicable
Surges IEC 61000-4-5	± 0.5, 1 kV	Not Applicable
Proximity Fields from RF Wireless communications equipment IEC 61000-4-3 Conductive Disturbances induced by RF fields IEC 61000-4-6	Per Standard	Portable and mobile RF communications equipment should be used no closer to any part of the AcuCore M1 including cables, then the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommended Separation distance** $d=1.2\sqrt{P}$ 150 kHz to 80 MHz $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output, power rating of the transmitter in Watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (M). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m	Power frequency, magnetic fields should be at levels characteristic of a typical location in a typical commercial or clinical environment.
Voltage Dips and Voltage Interruptions IEC 61000-4-11	Per Standard	Not Applicable

20. FCC Information

FCC Compliance Statement
This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The device has been evaluated to meet general RF exposure requirements. The device can be used in portable exposure conditions without restriction.

21. Safety

When unit is stored at specified minimum temperature of -10°C, allow one hour before use when ambient temperature is 20°C. The unit can be operated at maximum ambient temperature of 45°C.

Use only parts and accessories provided by Miridia Technology, Inc. MTI is not responsible for parts not provided by MTI. Use of accessories, detachable parts, and materials not described in the instructions for use could affect the safety and effectiveness of this device. Other parts are not guaranteed to work properly and will void your warranty. This equipment is not designed or intended to be used on other equipment.

This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers and children. To avoid strangulation, keep small parts and cables away from infants, toddlers, and children. AcuCore M1 does not contain bio-hazardous parts or accessories. However, electronic devices and batteries are generally considered to be bio-hazardous. Please contact local authorities to determine the proper method of disposal.

21. Warning

DO NOT use in an oxygen-rich environment, not intended for use with flammable anesthetics, not intended for use with flammable agents.

Use of this device adjacent to or in close proximity 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.

DO NOT modify this equipment in any way. This equipment is not intended to be field repaired. DO NOT service or maintain this equipment while in use. Please call Miridia Technology, Inc. if your device is not performing properly and discontinue use.

DO NOT use the AcuCore M1 simultaneously with other medical electrical (ME) equipment. This may result in incorrect operation of the AcuCore M1 and/or the other ME equipment.

Portable RF communications equipment (including peripherals, such as antenna cables and external antennas), should be used no closer than 30 cm to any part of the AcuCore M1, including cables included with the device. Otherwise, degradation of the performance of the AcuCore M1 could result in device malfunction. DO NOT use the AcuCore M1 in areas where high energy, magnetic or electrostatic fields are present at levels not typical of a normal clinical environment.

Do not use the AcuCore M1 in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment or computerized tomography (CT) scanners. This may result in unstable operation of the device.

DO NOT use the AcuCore M1 for any purpose other than as described herein.

DO NOT disassemble or attempt to repair the AcuCore M1 or components. If the device requires service, contact Miridia Technology Inc.

DO NOT use the AcuCore M1 in a moving vehicle, such as in a car.

DO NOT drop or subject the AcuCore M1 to strong shocks or vibrations.

DO NOT dispose of this device in the municipal waste stream, in a fire, or in a landfill. This electronic product requires special handling and proper disposal in accordance with environmental regulations for e-waste and lithium batteries.