

Symbols

| Symbol | Description |
|--------|---|
| | High Voltage Caution: This symbol means high voltage parts included. |
| | EU-Warning or Caution: This symbol indicates hazard. If not avoided, the hazard can result death or serious injury, minor personal injury or product damage. |
| | CE Marking: CE Marking means this device is conformity with provisions of the EU MDD(Medical device directive). It is certified by DNV(NB No. 0434). |
| | Classification of electrical protection symbol: This symbol means the device is CF type(cardiac floating) protection applied. |
| | EU-Consult instructions for Use: This symbol means read manuals or descriptions from manufacture. |
| | IPX Level: This symbol means waterproof level. (IPX0 = No waterproof) |
| | EU-Electronics and Battery Disposal Information: This symbol means that the product and battery should be recycled separately from household waste. |
| | GND symbol: This symbol means equivalent ground terminal |
| | Network symbol: This symbol means TCP/IP terminal |
| | USB device symbol: This symbol means Universal Serial Bus terminal. |
| | SD card symbol: This symbol indicates SD card slot. |
| | Serial port symbol: This symbol means Serial port (RS-232). |

Warnings and Cautions

Warning: Indicates a hazard. If not avoided, the hazard can result death or serious injury.

- Avoid humidity, high temperature, dust in the air, salt or sulfuric material and avoid the unventilated place or the direct sunlight.
- Avoid vibration or mechanical shock.
- Avoid fire and explosion hazard. An explosion hazard may result from the use of flammable anesthetics, skin cleansing agents and disinfectants.
- Dispose of the packaging material, observing the applicable waste control regulations. Keep the packaging material out of children's reach.
- If in doubt the integrity of the AC power source, the device must be operated from its internal battery.
- Check the voltage rating before you connect the device to an electrical outlet to ensure that the required voltage and frequency.
- If use multi-tap inevitably, use the one provided with earth pin by all means.
- Unplug the AC power cord from AC outlet before the device cleaning or disinfecting its surface.
- Do not spray, pour, or spill any liquid directly to the device for cleaning or disinfection.
- When cleaning or disinfecting surface of the device or electrode, fully dry and use it.
- Due to the risk of electrical shock, do not open the cover of the equipment unless absolutely necessary and disassembly of the machine should be done only by a maintenance worker who has the license from MEDIGATE Inc.

Caution: Indicates a potential hazard. If not avoided, this hazard may result in minor personal injury and/or product/property damage.

- For your safety check the device before using.
- If put the electrodes too long time, they may cause skin problems. Therefore, use them for measurement only

Troubleshooting

| Problem | Check or Possible Solutions |
|---|--|
| -Too small or too big ECG wave. | You can adjust the Gain value with the Gain button . Recommended: 10mm/mV |
| -ECG waves looks too tight or too loose. | You can adjust the Speed Value with Speed button. Recommended: 25mm/s |
| -High frequency noises are added. | -Use stronger Low Pass filter. [weak 150 - 100 - 40 (Hz) strong] Note: Stronger filter may make distortion. |
| -Too much ECG baseline wandering. | -Enable the AFS. Refer to Screen ① -Use stronger High Pass filter. [weak 0.05 - 0.16 - 0.3 - 0.5 (Hz) strong] Note: Stronger filter may make distortion. |
| -There is too much noise in ECG wave. -I can't recognize the ECG signal. | -Check the connection lead and electrode. -Make sure all electrodes puts right place and contacts well. -If electrode gel gose dry it may block the contacts. -Check the AC filter setting. -Electrical blanket or heavy energy consume electrical device may occur heavy noise. |
| -Printer crumples up paper. | -Check the printer cover if it is opened. |
| -Printer does not work. -Printer ejects blank paper continuously. -Paper comes out but not printed. | -Check the printer cover may open. -Grid side of paper must contact with the printer header. |
| -Error message shows up after the operation stops. | -Device needs some checks. See the operator's manual Chapter7. |

Checklist before using

- Not physical damage on surface of device.
- A Device was not get wet .
- Rated power is supplied.
- No physical damages on the patient cable.
- No physical damages on the electrodes.

Default setting

Note: After the default setting, all custom setting value will be lost.

- 1) Press the button to enter the Configuration menu.
- 2) Press Enter button on **System>Default Setting**.

| | |
|--|--|
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| | |
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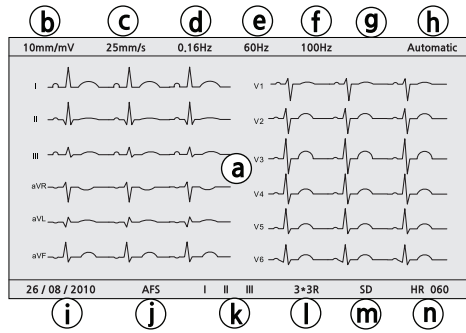
MeCA812i User Guide

Caution

- The electrocardiograph is intended to be used in a hospital and hospital facilities environment by trained medical personnel.
- For operator and patient's safety, before you use the device, read the **Operator's manual** in enclosed CD.
- This User Guide contains only minimum information of product.



Screen

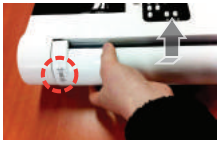


*This screen is default setting.

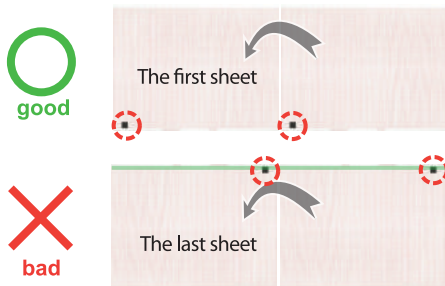
- a** Displaying ECG waveforms.
- b** Displaying gain of waveforms. The adjustment is available with 'Gain' button. *5, 10 or 20mm/mV
- c** Displaying printing speed. The adjustment is available with 'Speed' button. *5, 10, 25 or 50mm/s
- d** Displaying the selected cut off frequency of low cut filter. The adjustment menu is available with 'Filter' button. *lowcut 0.5, 0.3, 0.16 or 0.05Hz
- e** Displaying the selected frequency of AC line noise filter. This parameter setting is available on the System Setup>AC Line Filter.

Paper loading

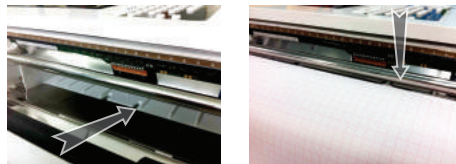
1. Open the printer cover.
Lift up the door to open.



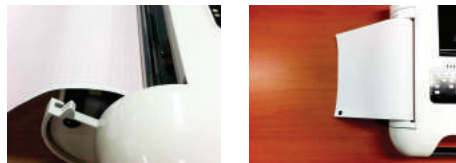
2. Fold out the first sheet.
The marker should be placed at the bottom.



3. Insert the paper into the feeder.
The first page should be positioned at under the guide roller.



4. Fold out the first sheet of the pad to the left and close the cover.

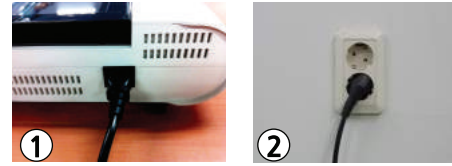


Ordering information

| Items | Code | Unit |
|--------------|-----------|-------|
| Z-fold Paper | A50100-00 | 1 Pad |

Installing and Connecting

- 1-1. Connect AC power cord and device.
- 1-2. Plug the AC power cord to grounded AC outlet.



- Warning:**
- For your safety use grounded AC power or use earth connection.
 - Connect equivalent ground when use with other devices.
 - When connect the patient with several electrical device, it may increase electrical shock hazard by leakage current.

2. AC plugged-in indicator turns on.

| LED | Name | Description / Function |
|-----|------------------|--|
| | AC plugged-in | Off Disconnect AC power line Solid Green Connect AC power line |
| | Power-On | Off The device is off Solid Green The device is on |
| | Battery Charging | Off Battery Operation(at device On) Blinking Orange The battery is charging Solid Orange The battery is fully charged |

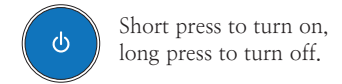
Note: It takes about 6 hours for full-charged.

3. Connect a patient cable to a cable port on MeCA812i



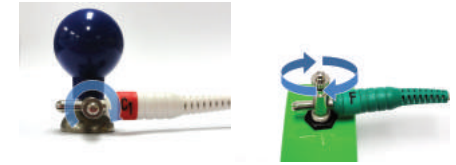
- Warning: Shock Hazard**
Use only provided by MEDIGATE cable and accessories.
Other product may cause safety problems.

4. Press the power button to turn on.



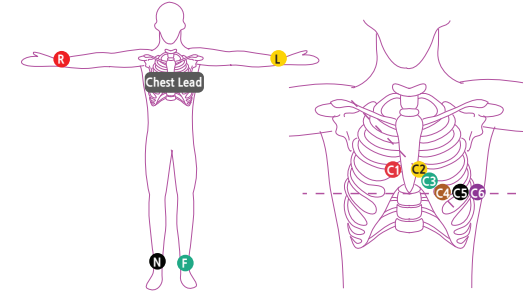
Short press to turn on,
long press to turn off.

5. Connect electrodes with leads.



When electrodes connecting, please screw to clockwise the hold screw of electrode for tight. Loose contact may cause noise on the ECG signal.

6. Attach electrodes to the body of patient.



| | Limb Lead | | | | Chest Lead | | | | | |
|-----|-----------|----|----|----|------------|----|----|----|----|----|
| AHA | RA | LA | RL | LL | V1 | V2 | V3 | V4 | V5 | V6 |
| IEC | R | L | N | F | C1 | C2 | C3 | C4 | C5 | C6 |

- Warning:**
- Operator shall not touch patient and device simultaneously.
 - During use of device, avoid contact between the metal part of device and the patient.
 - Remove all the metal accessories of patient wears before the perform measurement.
 - Do not touch the patient, the patient cable, or the device while defibrillator is operating.

Operating

1. Automatic mode

Automatic mode provides about 10 sec ECG signal and simple diagnosis report print.

- 1-1. Turn the device on and attach electrodes.
- 1-2. **Auto** Press AUTO button to mode select.
- 1-3. Wait until the ECG signals on LCD are stabilized.
- 1-4. **Run** Press RUN button to start record.
The report will be printed by the Acquisition, Analysis, Printing process. Please wait a while.

- Warning:** A qualified physician must overread all interpretation results and computer-generated tracings. Computerized interpretation is only significant when used in conjunction with clinical findings

2. Manual mode

Manual mode provides continuous printing function.

- 2-1. Turn the device on and attach electrodes.
- 2-2. **Manual** Press MANUAL button to mode select.
- 2-3. Wait until the ECG signals on LCD are stabilized.
- 2-4. **Run** Press RUN button to start record.
- 2-5. **Stop** Press STOP button to stop record.

- Notice:** Don't print more than 10 minutes.
If the printer is overheated, it may reduce device's life time.