



€100 User Manual

28 Mar 2011

ASC-MAW-10002-EN

FDA approved

Rx Only

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IT IS IMPORTANT THAT THE USER BE FAMILIAR WITH THIS USER MANUAL. PLEASE READ THE WARNING, PRECAUTIONS, INSTRUCTIONS & SAFETY ISSUES BEFORE USING THIS DEVICE.

The information contained in this document was accurate at time of publication. REKA HEALTH PTE LTD reserves the right to make changes in the product described in this manual without notice and without incorporating those changes in any products already sold.

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Symbols

Manufacturer



Authorised representative in the European community



Indicates this device is in compliance with MDD 93/42/EEC



Date of Manufacture



Separate collection for recovery and recycling



CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Rx Only

Consult Instructions for Use



Attention, See Instructions for Use



Serial Number



Batch Code



REKA E100

The E100 ECG Cardiac Rhythm Monitor is for self-recording of ECG by patients outside the hospital and for long term remote monitoring by medical professionals. The device is intended for patients who may have cardiac arrhythmia.

The E100 records an Electrocardiogram (ECG / EKG) and the ECG data is uploaded to REKA Cloud online health record portal at www.rekahealth.com by connecting the device to a computer or a smart phone.

Visit www.rekahealth.com for registration.

WARNINGS!

CAUTION: Federal law (USA) restricts this device by a physician or on the order of a physician.

- Do not self diagnose.
- Do not use this device during electro magnetic scanning like MRI scan.
- Do not use this device with the electrodes if you have sensitive skin or allergies.



DO NOT SHARE THIS DEVICE WITH OTHERS

This device is designed for personal use by one individual only.

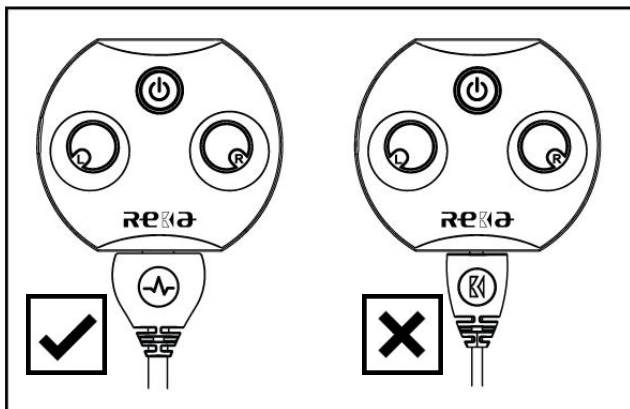
- Do not measure ECG when this device is charging.
- Do not plug ECG cable in this device when it is connected to computer or adaptor.
- Do not disassemble, repair or modify this device
- Only use power adaptor & cables provided by the manufacturer.
- Do not sterilize this device in an autoclave, ultraviolet sterilizer or gas sterilizer.
- Do not wash this device with water.
- Do not use this device for any purpose other than obtaining an ECG.
- Do not induce excessive shock, vibration, external force onto this device.
- Do not take measurements where this device will be exposed to strong

electromagnetic forces.

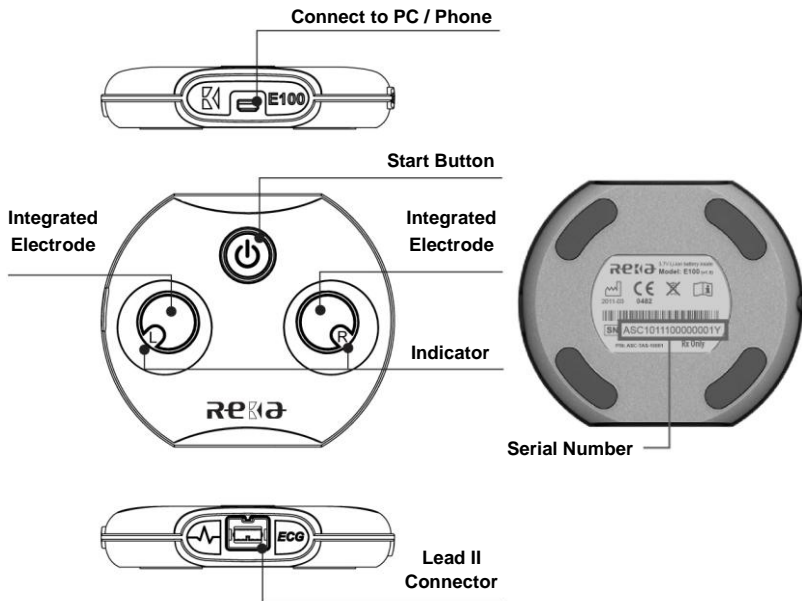
- Do not use in the presence of flammable anesthetics, drugs or pressurized oxygen.
- Keep out of reach of infants, small children, and compromised people.

Important note for correct measurement:

- Do not measure if integrated electrodes are dirty. Wipe any dirt off with a soft cloth or a cotton swab moistened with disinfectant alcohol.
- Read instructions for ECG cable and electrodes carefully before taking a measurement using external electrodes.
- Do not plug USB cable in Lead II connector.

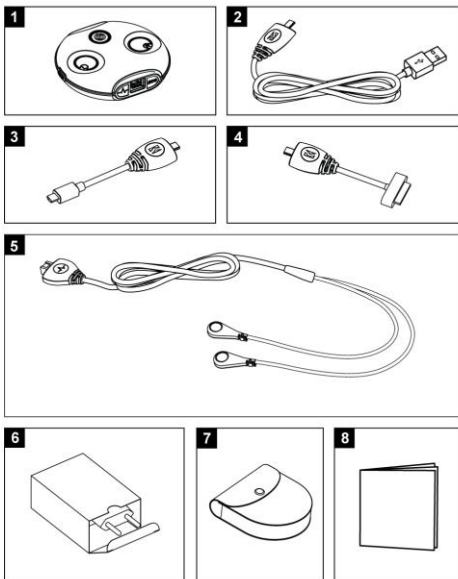


REKA E100 Overview



Packing list:

1. REKA E100
2. REKA USB Cable
3. Micro USB Cable
4. 30 pin Cable
5. ECG Cable
6. Power Adapter
7. Pouch
8. Quick Start Guide and Warnings!

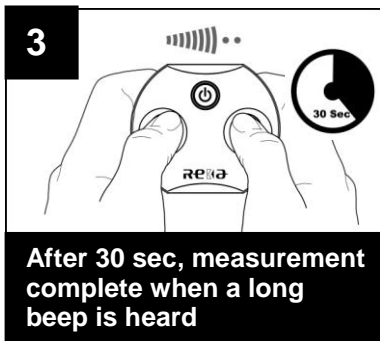
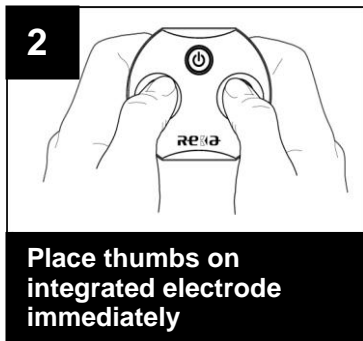
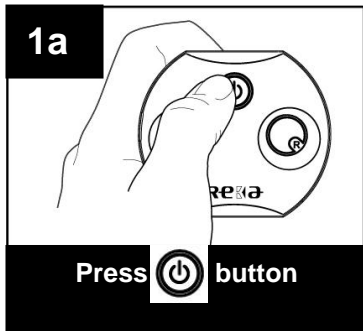


Product Specification

Size (mm)	70H x 81W x 17.4D
Weight	105g (Device Only)
Battery & Power	Built-in 250mAh rechargeable lithium-ion battery
Stand by	Up to 6 weeks, measure up to 200 times
Buzzer Level	70 dB
Input Leads	RA, LA (Integrated Electrodes)
	RA, LL (External Electrodes)
Lead Selection	Lead I (Integrated Electrodes)
	Lead II (External Electrodes)
Input Dynamic Range	$\pm 3\text{mV}$
Input Impedance	$>100\text{M}\Omega$
CMRR (Common Mode Rejection Ratio)	100db
DC Offset	1600mV maximum
Sensitivity	10mm/mV
Sampling Rate	250 Samples/Sec

Band Width		0.5 to 40 Hz (Integrated Electrodes)
Measurement Time		32 seconds
Data Transfer		USB interface
ADC Resolution		10 bit
Measurement Range	Heart Rate	40-240 bpm
	QRS interval	80-120 ms
Accuracy of Heart Rate Measurement		40-100bpm: ± 1
		100-240bpm: ± 2
Memory Storage		Up to 4000 ECG records with the built-in 256MB NAND flash memory
Battery Charge Cycles		Up to 360 times
Operating Environment		+10°C to 40°C, 25 to 80%RH
Storage Environment		-20°C to 50°C, 5 to 80%RH

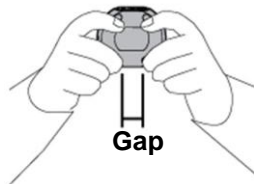
Taking Measurement Using Your Thumbs (Lead I)





ATTENTION! Do not move or talk while taking measurements.

- Please ensure that your hands are clean and dry.
- Gently place thumbs on the integrated electrodes according to “L”(Left) and “R”(Right) indication.

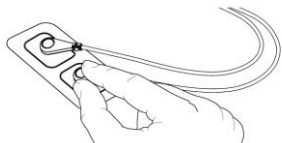


- Take ECG/EKG in sitting position
- Feet resting on the ground, shoulder width apart.
- Breathe gently.

- Leave a gap between hands.

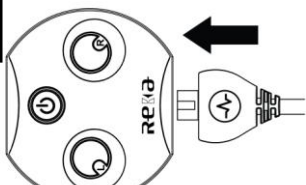
Taking Measurement Using ECG Cable (Lead II)

1

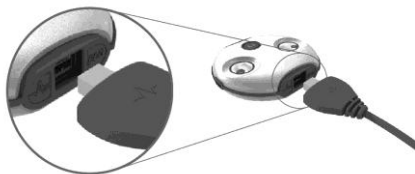


Snap to electrode

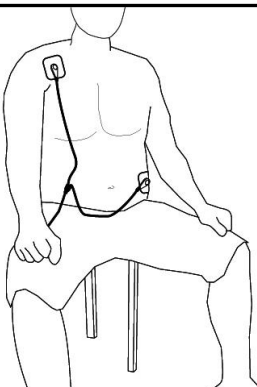
2



Connect to E100

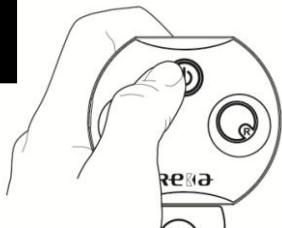


3



Paste electrodes on body

4

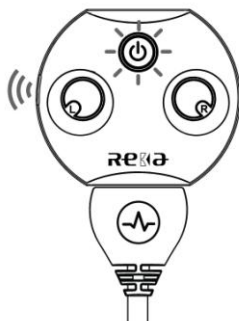


Press



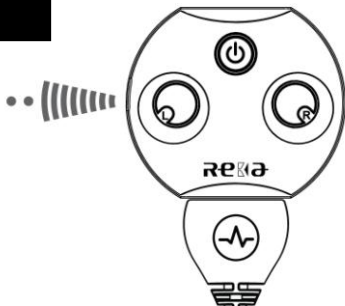
Button

5



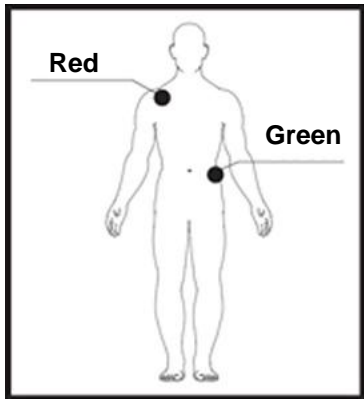
You will observe
beeping tone and
blinking light

6

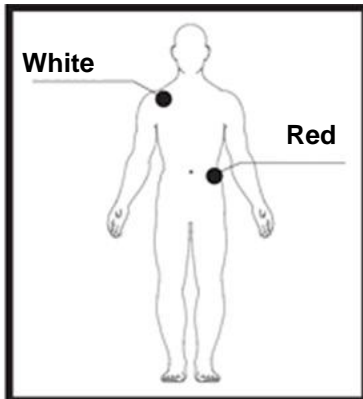


After 30 sec, measurement
complete when a long
beep is heard

Electrode Placement



IEC (European Standard)



AAMI/AHA (American Standard)



ATTENTION!

To improve accuracy, choose an area with little to no hair or shave the skin where the electrodes will be attached.

Do not move or talk while taking measurements.

Upload Through PC, Mac[®], Smartphone

Note: For details of uploading ECG data through PC, Mac and Smartphones, please go to www.rekahealth.com

Battery & Indication Information

About the E100 Battery

E100 has an internal, non user replaceable battery. For best results, the first time you use E100, let it charge for 4 hours.

The E100 battery is fully charged in 4 hours.

Charging the E100 Battery by using USB Cable provided by manufacturer,

Connect E100 to:

- 1 Computer's USB port or
- 2 Power Adapter

To charge the battery using your computer, the computer must be turned on and not be in sleep mode.

Understanding Battery Status

The battery status only will show after measuring. More detail, refer to *indication information*.

You should charge the E100 when the Start button is Orange (Blinking). You can disconnect and use E100 before it's fully charged.

Note: The Rechargeable battery has a limited number of charge cycles and might eventually need to be replaced. Battery life varies based on use.

Maintenance

Cleaning and disinfection

- Wipe the integrated electrodes using a cloth dampened with disinfectant alcohol. If you do not disinfect the electrodes there is a risk of skin disease.
- Do not wipe the device with volatile detergents.

Maintenance and Storage






- Clean the device with a cotton cloth.
- This unit does not require calibration during its expected life cycle.

Do not store the unit in the following ambient conditions:



- Exposed to direct sunlight, vibration or electromagnetic fields.
- Subject to high temperatures or high humidity.
- Wet, damp or dusty environments.
- Near fires or open flames.

Indication Information



During Measuring

	Status	Light Indication	Sound
	Measuring	Light Pink (Blinking)	Short Beep (30 sec)
	Measurement Complete	Steady Light Pink	Long Beep (5 Sec)
	Low Battery	Orange (Blinking) Shown after measuring	Short Beep (5 sec) Continues
	Very Low Battery Unable to upload	Red (Blinking) Shown after measuring	Short Beep (5 sec) Continues
	Unable to measure	Red (Blinking) While pressing button	Short Beep (5 sec) Continues

During Data Transfer (Connected to Phone)

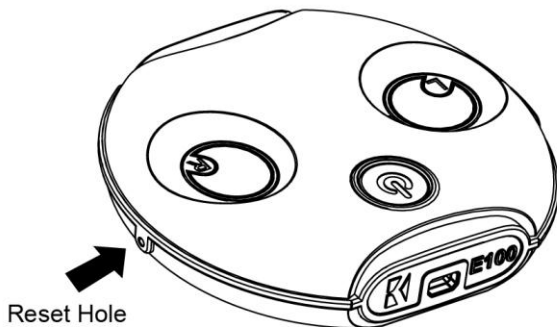
	Status	Light Indication	Sound
	Data Transferring	Steady Orange	-----
	Transfer Completed (Please Unplug)	Steady Blue	Short Beep

Connected to Computer

	Status	Light Indication	Sound
	Charging	Steady Green	-----
	Fully Charged	No Light	-----

Reset REKA E100

- 1 Use a small wire to poke reset hole.
SEE TROUBLESHOOTING BELOW FOR WHEN TO USE.



- 2 Reset is successful when “beep” sound is heard.

Troubleshooting

Problem	Cause	Solution
No response when Start button is pressed	Battery is low	Charge the device.
	System crash	Reset the device
Noisy ECG Signal	Excessive movement during measurement	Check instructions and repeat measurement.
	Thumbs are greasy	Clean hands.
	Thumbs are dry	Moisten hands with a damp towel or ECG gel.
	Integrated electrodes are dirty	Refer to <i>maintenance</i> .
	Thumb press on integrated electrode IS too strong	Place thumbs on the integrated electrodes gently.
	ECG cable is worn out	Replace ECG cable following its Instruction.
	The ECG signal is too weak	Check instructions and repeat measurement. Measure using external electrodes.
	External electrodes do not stick tightly on skin	Refer to <i>electrode placement</i> .

Problem	Cause	Solution
Noisy ECG Signal	Environmental noise	Take measurements in an environment not exposed to strong vibration or electromagnetic force.
Device is not recognized when plugged into computer	The connection is improper or the USB port power supply is too low	Plug in your device properly and ensure plug is securely inserted into the USB port.
Device is not charged when plugged in computer	USB port is low power or computer is in sleep mode	Plug Into main direct USB port & ENSURE the computer IS not in sleep mode. Use the provided power adapter.
Device red blink and beep when plugged in mobile phone	Battery level is low	Charge the device

If the problem persists or other problems occur, contact your dealer or visit REKA HEALTH website www.rekahealth.com