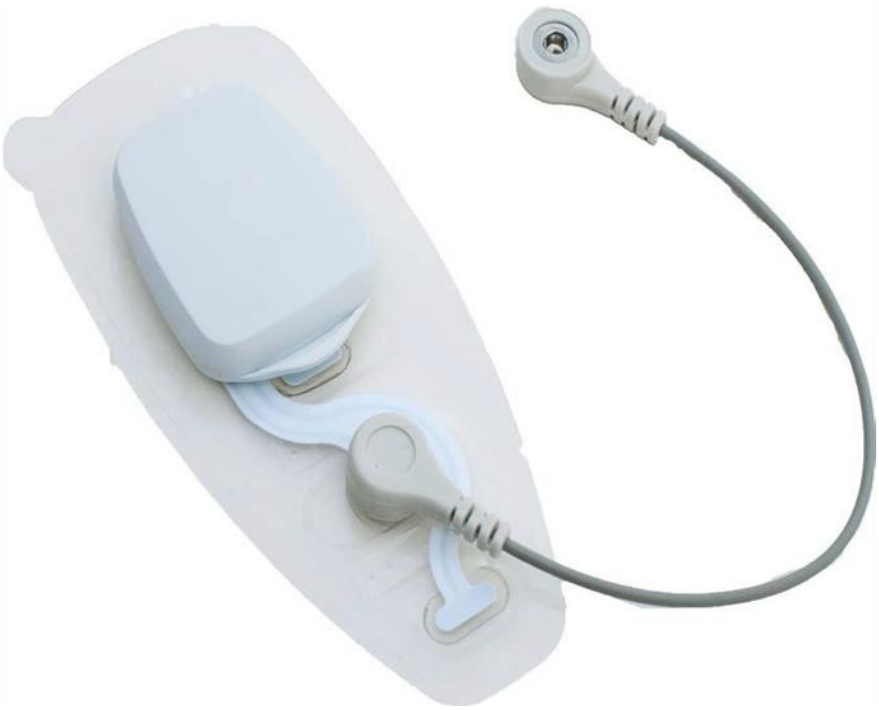
Vasomedical®

BIOX®

Mini™ ECG



USER MANUAL

Model 1201
July 2015

Caution: FEDERAL LAW RESTRICTS THIS DEVICE FOR SALE TO OR ON THE ORDER OF A PHYSICIAN.

Carefully read all instructions prior to use. Observe all warnings and precautions noted in these directions. Failure to do so may result in patient complications.

Read this manual before use. Keep it for future reference.

Thank you for purchasing the Biox Mini™ ECG Holter Recorder (Model: 1201)

The Mini™ ECG Holter Recorder records ECG through a Mini™-compatible ECG electrode (accessory to Mini™ ECG Holter Recorder).

The Mini™ ECG Holter Recorder acquires ECG signals and stores them internally. The device has interfaces to a Mini™-compatible ECG electrode and the Mini™ Micro USB Cable. The Mini™ ECG Holter Recorder is rechargeable and reusable. The Mini™ ECG Holter Recorder contains internal non-volatile storage that stores the ECG data until it is emptied or the start of a new recording.

The Mini™ ECG Holter Recorder contains embedded software appropriate for recording ECG, storing ECG, and for charging. While connected to a PC via the Mini™ Micro USB Cable, the recorded ECG files are accessible from the connected PC as files on an external drive.

During intended use, the Mini™ ECG Holter Recorder is connected to the Mini™-compatible ECG electrode and placed on the patient.

The Mini™ ECG Holter Recorder has a 2 year warranty from date of purchase. All warranty paperwork is included in the Mini™ shipping documents.

Manufactured For: Vasomedical, Inc. 180 Linden Avenue

Westbury, NY 11590 USA

www.vasosolutions.com (516) 997-4600

Copyright

Disclaimer

Vasomedical, Inc. is responsible for the security, reliability, and performance of this equipment only if:

The place where the device is installed or used meets the requirements for electrical installations IEC and other applicable regulations

All repairs, revisions, or modifications, both in and out of the warranty period, are made by technical staff of Vasomedical, Inc. The equipment is used by qualified staff in accordance with the recommendations stated in this Instruction Manual

Information in this manual may change without notice. The manufacturer assumes no responsibilities for errors that may appear in this manual.

Brands

Mini™ is a registered trademark of Vasomedical Inc. Westbury, New York

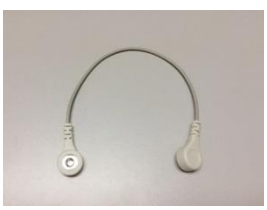
TABLE OF CONTENTS

1 PACKAGING CONTENTS

The package contains:

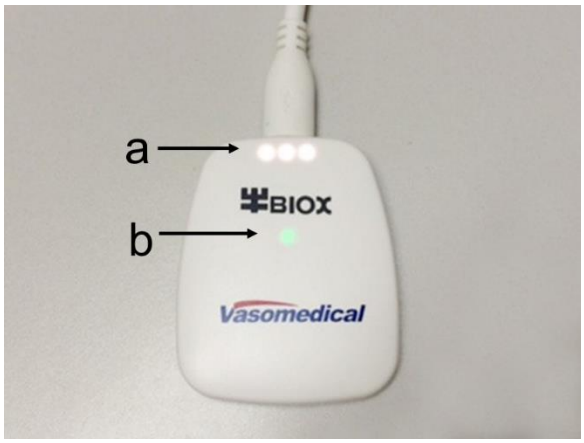
- Mini™ ECG Holter Recorder;
- Quick guide and manual;

Accessories Include: Mini™ Micro USB Cable



2 Nomenclature

2.1 Top Side of Mini™ ECG Holter Recorder

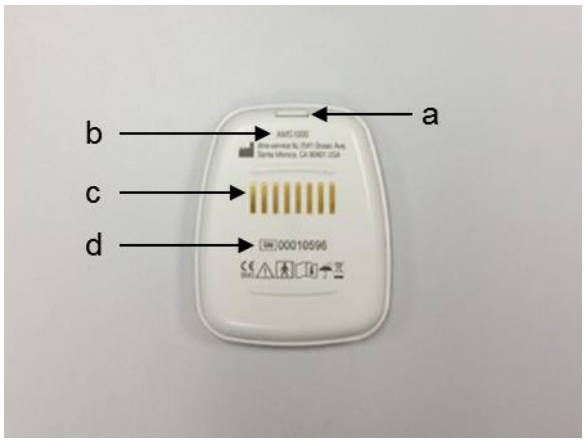


The two lights:

a. The upper placed white Charging Diodes indicate the power state when the Mini™ ECG Recorder is connected to a power source via the Mini™ Micro USB Cable. The Charging Diodes emit a continuous white light to indicate that the Mini™ ECG Holter Recorder has enough battery power to record for 72 hours. If the Charging Diodes are flashing, the Mini™ ECG Recorder is charging and it will not be able to record for 72 hours

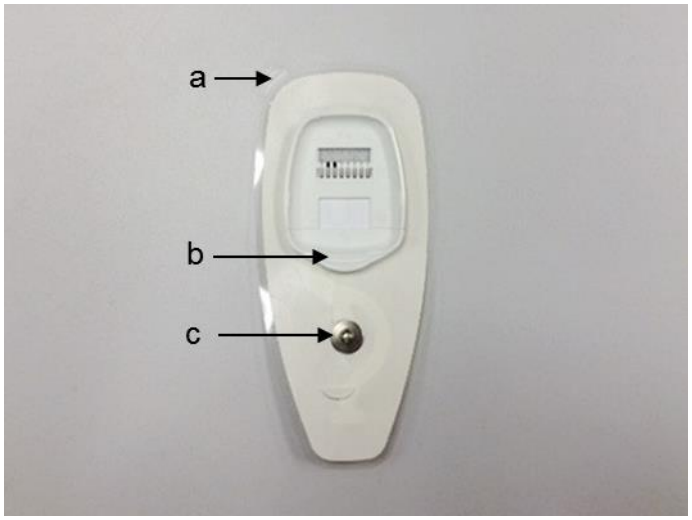
b. The center Status Diode indicates the status of the Mini™ ECG Holter Recorder when powered on and not recording. The Status Diode emits a continuous or blinking green light to indicate that the Mini™ ECG Recorder is functioning, continuous red if it is not

2.2 **Bottom Side of Mini™ ECG Holter Recorder**



a. Micro USB Connector for the Mini™ Micro USB Cable for charging and read out of data
b. The device type
c. Mini™ Specific 8- Terminals Connector for connection to the Mini™-compatible ECG electrode
d. The serial number and marking of the Mini™ ECG Holter Recorder

2.3 **Top Side of Mini™-Compatible Electrode**



(3CH Mini™-Compatible Electrode)

a. Tab for easy separation of back liner from electrode
b. Handle for separating the Mini™ ECG Recorder and its compatible electrode after the end of recording
c. Snap for connecting shield lead wire to electrode

3 IMPORTANT SAFETY INFORMATION

Please read this section carefully before using the Mini™ ECG Holter Recorder.

The Mini™ ECG Holter Recorder has been developed by the Mini™ with Vasomedical, Inc.

The Mini™ ECG Holter Recorder is designed and manufactured in accordance with the Quality Management System of Vasomedical, Inc. which is consistent with the quality standard EN 13485 and European Directive as amended 93/42/EEC concerning medical devices and 2007/47/EC. The Mini™ ECG Holter Recorder also complies with the EN 60601-1 Electrical Safety and Electromagnetic Compatibility EN 60601-1-2 standards, as specified in the Electromagnetic Compatibility Clause.

The Mini™ ECG Holter Recorder conforms to the Packaging and Packaging Waste Directive 94/62/EC and Waste Electrical and Electronic Equipment Directive (WEEE) 2002/96/EC.

3.1 Intended Use

The Mini™ ECG Holter Recorder is a small digital Holter recorder intended for use by professionals to acquire ECG data from a patient in a clinical, point of care or at a patient setting.

The Mini™ ECG Holter Recorder can record ECG up to 72 hours on the sternum of a patient through a Mini™-compatible ECG electrode. The patient's ECG is recorded to the Mini™ ECG Holter Recorder and then transferred via the Mini™ Micro USB cable to a Holter analysis system for review by a physician or other qualified personnel

3.2 Indications for Use

The Mini™ ECG Holter Recorder is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety.

The Mini™ ECG Holter Recorder has been designed for maximum safety. All of the operating instructions should be read before using the Mini™ ECG Holter Recorder. Failure to do so may result in injuries to the user and damage to the device and/or accessories.

The Mini™ ECG Holter Recorder has been designed for use by medical clinical professionals. The medical clinical professionals must instruct the patient in the correct use and it is important the patient can understand the instructions given by medical clinical professionals.

3.3 Limitations in Use – Contraindication

The acceptability of a recording with the Mini™ ECG Holter Recorder is the responsibility of the medical professionals.

The medical professionals should consider the symptoms presented by the patient before starting any recording with the Mini™ ECG Recorder.

3.4 Warnings and Precautions

In case of questions, unexpected events, or complaints, contact your distributor. You can find contact details on page 2 of this instruction manual.

Medical professionals should inform the patient about precautions to be found in this section and to be taken when wearing the Mini™ ECG Holter Recorder.

The Mini™ ECG Holter Recorder is not provided with physiological-type alarms. Therefore, the patient must be instructed by the medical professionals to react on any health symptoms that may arise, as he would do if he was not wearing the Mini™ ECG Holter Recorder.

The Mini™ ECG Holter Recorder does not maintain nor does it help to maintain the life of the patient. Patients must be warned that they must not open the Mini™ ECG Holter Recorder or attempt to adjust it.

Do not use the Mini™ ECG Holter Recorder in an X-ray, computed tomography (CT), or magnetic resonance imaging (MRI) environment, as this may affect the scanning results, can lead to malfunction of the Mini™ ECG Holter Recorder, or may result in injuries to the patient.

Do not use a defibrillator on a patient wearing the Mini™ ECG Recorder, as the Mini™ ECG Recorder is not protected against defibrillation shocks. Use of a defibrillator can lead to the malfunction of the Mini™ ECG Holter Recorder.

Do not use Mini™ ECG Recorder while showering or swimming. The Mini™ ECG Recorder is only resistant to moderate splashing and dripping when connected to Mini™-compatible ECG electrode (Protection level IP22: Protection against access to hazardous parts with a finger; protected against solid objects with a diameter of 12.5

mm and above; protected against vertically falling water drops when tilted up to 15 degrees). The Mini™ ECG Holter Recorder is not resistant to water when not connected to Mini™-compatible ECG electrode (Protection level IP20: Protection against access to hazardous parts with a finger, protected against solid objects with a diameter of 12.5 mm and above; non-protected against water).

Portable and mobile RF communications equipment can affect the Mini™ ECG Holter Recorder. The use of mobile phones, transmitters, and similar equipment generating radio frequency emissions and placed next to the Mini™ ECG Holter Recorder is not allowed during recordings. Follow the recommendations regarding the separation distance specified in the manufacturer's declaration for EMC in this instruction manual, Annex 1 Electromagnetic Compatibility.

Minor discomfort, skin irritation, reddening, itching, or rash can occur by use of the Mini™ ECG Holter Recorder. This risk is unavoidable when using plasters/electrodes in general, but any sign of skin irritation should be followed closely to avoid development of more serious reactions.

The Mini™ ECG Holter Recorder cannot be used for direct cardiac application.

Do not modify the Mini™ ECG Holter Recorder, the Mini™ Micro USB Cable, or the USB Power Adapter. Modification of the Mini™ ECG Recorder, the Mini™ Micro USB Cable, or the USB Power Adapter can lead to electrocution, burns, and malfunction.

Use only the Mini™ ECG Holter Recorder together with Mini™-compatible ECG electrodes and Mini™ Micro USB Cables and USB Power Adapters supplied by the manufacturer. Use of other equipment may result in increased emissions or decreased immunity of the Mini™ ECG Holter Recorder and can cause damage to the device or decrease the quality of the acquired signals. Use of unapproved electrodes might lead to skin irritations, allergy, electrical shock, and malfunction of the Mini™ ECG Holter Recorder. Use of other chargers may damage the device and/or accessories.

Keep the Mini™ ECG Holter Recorder, the Mini™-compatible ECG electrode, the Mini™ Micro USB Cable, and the USB Power Adapter out of reach of children, pests, and pets. Danger of strangulation if the Mini™ Micro USB Cable is misused. Danger of asphyxiation if the Mini™ ECG Holter Recorder and/or accessories is swallowed.

Do not wear the Mini™ ECG Holter Recorder during shower. May cause electric discharge.

Do not submerge the Mini™ ECG Holter Recorder, the Mini™ Micro USB Cable, or the USB Power Adapter in any liquid. May cause electric discharge.

Avoid contact of liquids with the internal parts of the Mini™ ECG Holter Recorder, the Mini™ Micro USB Cable, or the USB Power Adapter. May cause electric discharge.

Store and use the Mini™ ECG Holter Recorder within temperature ranges, pressure, and humidity specified in Section 7.4. Avoid exposing any part of the Mini™ ECG Holter Recorder to heat sources, heat radiators and fireplaces, and direct exposure to sunlight. Temperature changes cause condensation and moisture that can lead to malfunction of the Mini™ ECG Holter Recorder. Before using the Mini™ ECG Holter Recorder, allow the Mini™ ECG Holter Recorder to acclimate to ambient temperature. For reference, if the temperature difference between the Mini™ ECG Holter Recorder and the environment is above 10º C, a 20 minutes wait time in an intermediate temperature is recommended.

Do not connect Mini™ ECG Holter Recorder and Mini™-compatible ECG electrode until after the skin of the patient is prepared, as the Mini™ ECG Recorder powers on and starts the recording five minutes after the connection to the Mini™-compatible ECG electrode. Otherwise, the Mini™ ECG Holter Recorder will shorten its battery lifetime.

Connect the Mini™ ECG Holter Recorder to the Mini™-compatible ECG electrode before placement on the patient, as this will ease the use of the Mini™ ECG Holter Recorder and reduce the risk of touching the terminals at the backside of the Mini™ ECG Holter Recorder.

Do not touch the terminals at the backside of the Mini™ ECG Holter Recorder or let them touch other conductive parts or earth, as this may damage the Mini™ ECG Holter Recorder.

Do not use an obviously broken Mini™ ECG Holter Recorder, as this can cause electric discharge or decrease the quality of the acquired signals. See section 5.2 Preventive Maintenance.

Minimize the number of devices connected to a patient, as there is a risk of accumulation of leakage current.

Do not place the Mini™ ECG Holter Recorder connected to Mini™-compatible ECG electrode on damaged, or in any other way irritated, skin.

Do not reuse single-use accessories as there is a risk of infection to the patient.

As for the Mini™-compatible ECG electrode, a proper contact of the skin with the Mini™-compatible ECG electrode must be achieved to increase the quality of the acquired signals. Follow the placement procedure as described in Section 4.1. Avoid contact with the eyes or mucus membranes of gels, alcohol, acetone, or any substance used in the placement or removal of the Mini™ compatible ECG electrode, as this can damage the eyes or mucus membranes of the patient.

Carefully follow the instruction for the removal of the Mini™-compatible ECG electrode,

see Section 4.2, as careless removal of the Mini™-compatible ECG electrode may cause damage to the skin.

Carefully follow the cleaning instructions of the Mini™ ECG Holter Recorder, see Section 5.1, otherwise there is a risk of infection to the patient.

4 OPERATING INSTRUCTIONS

This instruction describes the use of the Mini™ ECG Holter Recorder and must be followed point by point.

4.1 Start Recording

Take the ready and cleaned Mini™ ECG Holter Recorder from the packaging.
Check battery status before use and recharge if necessary. See Section 4.3.

Connect the download cable to the computer with the Mini enroll program. **Delete any files that are on Mini**. Enter the patient information and disconnect Mini from the computer. See the Mini Utility manual for additional information.

Unpack the Mini™-compatible ECG electrode from the electrode pouch.

Always check the use by date of the Mini™-compatible ECG electrode before use.

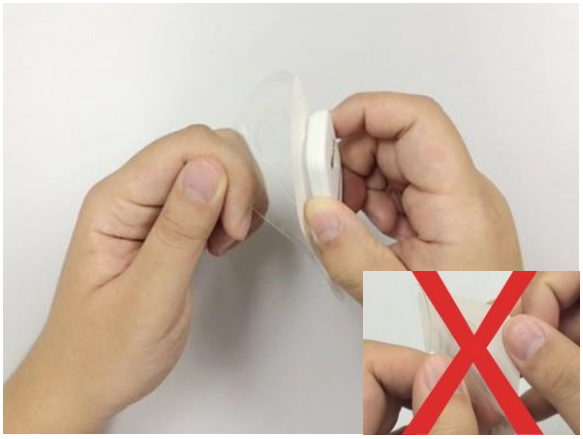
Prepare the skin after normal procedures: Shave any hairy areas. Gently abrade to lower skin impedance. Clean any greasy areas with alcohol swabs, a mild soap and water or similar and dry thoroughly.

Expose the sternum of the patient.

Snap the lead wire on the snap of the electrode.

Place the Mini™ ECG Holter Recorder in the socket of the Mini™- compatible ECG electrode and press the two items firmly together until you hear a couple of click-sounds. Look around the edges of Mini and make sure there is no spacing between Mini and the Mini electrode. Make sure the Mini™ ECG Recorder is correctly attached to the Mini™- compatible ECG electrode

The Status Diode of the Mini™ ECG Holter Recorder will then emit a continuous green light for ten seconds to indicate that the Mini™ ECG Recorder is active. If not, refer to Section 6. Note that after ten seconds the Status Diode will flash a green light for five minutes, after which it will stop flashing and then recording starts.



Hold the Mini™ ECG Holter Recorder with one hand. Hold on the back liner of the Mini™-compatible ECG electrode with the other hand and peel it away from the Mini™-compatible ECG electrode. Please be careful not to touch the adhesive area. If any doubt refer to the instructions on the label of the Mini™-compatible ECG electrode packaging.

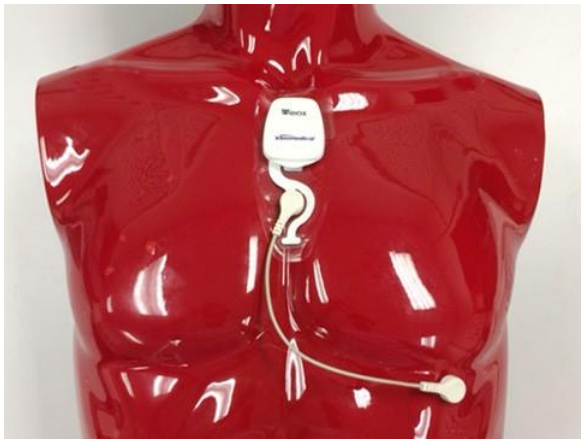
Place the Mini™-compatible ECG electrode on the center of the sternum, a finger width under the clavicles, taking care not to touch the adhesive area

After placement, press around the edges of the Mini™-compatible ECG electrode to improve the adherence.

If the Mini™-compatible ECG electrode is not placed correctly, combine a new Mini™-compatible ECG electrode with the Mini™ ECG Holter Recorder and repeat the placement procedure.

Pull the strip under the Mini™ ECG Recorder clockwise around the Mini™ ECG Holter Recorder to gently peel off the upper liner.

Press again around the edges of the Mini™-compatible ECG electrode to make sure the Mini™-compatible ECG electrode is firmly attached to the skin



The recording will start five minutes after the Mini™ ECG Holter Recorder and the Mini™-compatible ECG electrode were connected and will stop after 72 hours or when the Mini™ ECG Recorder is disconnected from the Mini™-compatible ECG electrode.

The patient does not interact with the Mini™ ECG Holter Recorder during the recording.

No feedback will be given to the patient during use.

4.2 **End Recording**

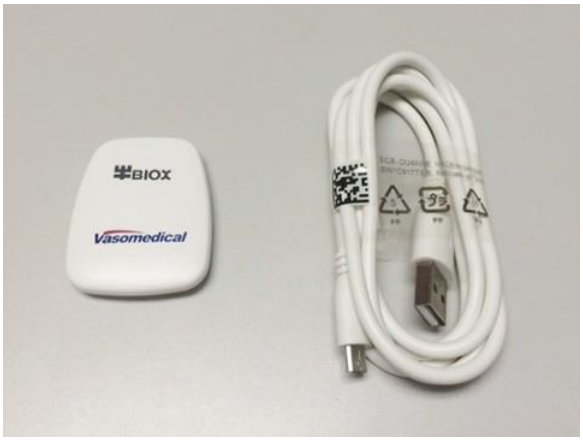
After 72 hours of recording or when the recording is terminated, grab the bottom end of the Mini™-compatible ECG electrode and gently pull it downwards and outwards in the direction away from the Mini™ ECG Holter Recorder. This will reduce the adhesive property of the Mini™-compatible ECG electrode and hereby reduce the stress of the skin, as the Mini™-compatible ECG electrode is removed from the skin. Adhesive residue can be removed using paper towels or water

Hold the Mini™ ECG Recorder with one hand and pull the Mini™-compatible ECG electrode away by breaking the little handle in the Mini™-compatible ECG electrode.

The Mini™ ECG Holter Recorder will now stop the recording, if it has not already stopped due to the automatic shut off after a recording period of 72 hours.

The Mini™-compatible ECG electrode is for single-use and is disposable and should be handled as normal waste and discarded in accordance to hospital or physician guidelines.

4.3 **Charge**



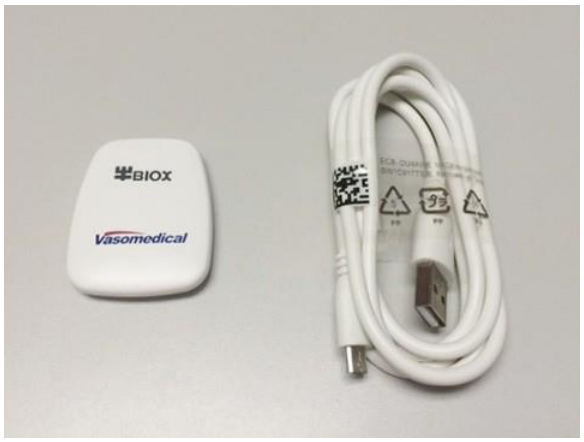
Take the Mini™ ECG Holter Recorder and the Mini™ Micro USB Cable.

Connect the Micro USB-end of the Mini™ Micro USB Cable to the Mini™ ECG Recorder and connect the USB-end of the Mini™ Micro USB Cable to either a powered on computer or the USB Power Adapter plugged into the wall.

The Mini™ ECG Holter Recorder will now indicate its battery power state. The Charging Diodes emit a continuous white light to indicate that the Mini™ ECG Holter Recorder has enough battery power to record for 72 hours. If the Charging Diodes are flashing, the Mini™ ECG Recorder is charging and it will not be able to record for 72 hours. Allow recharge of the Mini™ ECG Holter Recorder before use, approximately 45 minutes.

If the Status Diode of the Mini™ ECG Holter Recorder is turned off please consult Section 6.

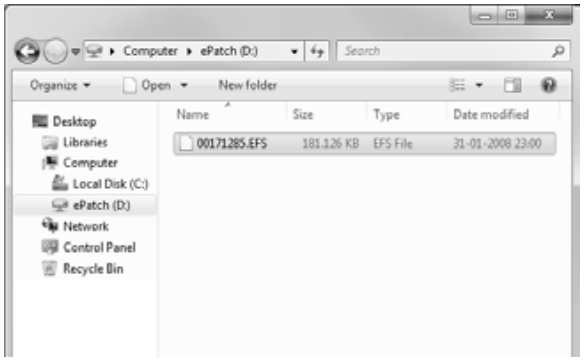
4.4 **Copy Recorded Data to Computer**



Take the Mini™ ECG Holter Recorder and the Mini™ Micro USB Cable

Connect the Micro USB end to the Mini™ ECG Recorder and connect the USB-end of USB Cable to a PC.

The Mini™ ECG Holter Recorder will now indicate its battery power state. The Mini™ ECG Recorder will charge when it is plugged into the computer and you will see the status diodes blinking



The file location of the Mini™ .EFS file will show on your screen.

The Mini utility software will move the folder from the recorder to the Holter analysis software or your Holter analysis software will identify the file and prepare it for loading.

See your Holter Analyzer or Mini™ Utility Software Interface for instructions on how to load Mini to your Holter program.

5 CLEANING, MAINTENANCE AND DISPOSAL

The Mini™ ECG Holter Recorder requires, like any electronic equipment, maintenance in order to:

- Ensure the safety of the patient, the medical professional, and its environment.
- Ensure the reliability and accuracy of the functions for which the Mini™ ECG Holter Recorder was developed.

5.1 Cleaning

The Mini™ ECG Holter Recorder shall be cleaned properly with traditional hospital cleaning material (70% alcohol swabs or similar) after each use. Do not use other chemical products or detergent for cleaning. Please read the Important Safety Information in Section 3.

Properly dispose the disposable Mini™-compatible ECG electrodes immediately after use. Mini™-compatible ECG electrodes are for single use only and must be replaced after each recording.

The device cannot be sterilized.

5.2 Preventive Maintenance

Preventive maintenance consists of all actions needed to keep the equipment in good working order.

Check periodically that the Mini™ ECG Holter Recorder and its accessories are in perfect condition, not broken, with no external damage, and that the performance is okay.

If you detect any problems that you cannot solve, please get in contact with your distributor.

During transportation, storage, and between uses, it is recommended to store the Mini™ ECG Holter Recorder, the Mini™ Micro USB Cable, and the USB Power Adapter in the provided packaging to keep all items protected from shock and vibration. The packaging material provides enough protection against small accidental impacts.

The manufacturer is not responsible for malfunction or damage to the Mini™ ECG Holter Recorder resulting from poor maintenance performed by personnel not employed by the manufacturer or certified in writing by the manufacturer.

Accessories should always be original and requested from the manufacturer or authorized dealer to ensure the proper functioning of the Mini™ ECG Holter Recorder.

5.3 Corrective Maintenance

Corrective maintenance is the process of correcting errors, and hereby leaving the Mini™ ECG Holter Recorder in good conditions for use after an episode of failure due to malfunction or misuse.

If you detect a fault in the Mini™ ECG Holter Recorder that prevents normal operation, please contact your distributor, and specify the type of problem. See page 2 of this Instruction Manual for contact details.

5.4 Service

The Mini™ ECG Holter Recorder, the Mini™ Micro USB Cable, or the USB Power Adapter have no user-serviceable parts. The Mini™ ECG Holter Recorder requires no calibration.

5.5 Disposal of Electrical and Electronic Devices in the EU

 Never dispose the Mini™ ECG Holter Recorder, the Mini™ Micro USB Cable, or the USB Power Adapter in the household trash. It must be disposed of properly and may need to be recycled in accordance with the statutory requirements in your country.

Information on proper disposal is available from your distributor, see details on page 2.

6 TROUBLESHOOTING

1. The Mini™ ECG Holter Recorder Does Not Start

I. Make sure that the Mini™ ECG Holter Recorder is not placed in direct sunlight, as this makes reading the light diodes difficult

II. Make sure that the Mini™ ECG Holter Recorder is correctly connected to the Mini™-compatible ECG Electrode, see Section 4.1

III. Make sure that the Mini™ ECG Holter Recorder is fully charged and ready, see Section 4.3

2. The Mini™ ECG Holter Recorder Is not Visible on the Computer

I. Make sure that the Mini™ ECG Holter Recorder is connected correctly to the Micro USB-end of the Mini™ Micro USB Cable

II. Make sure that the computer is connected correctly to the USB-end of the Mini™ Micro USB Cable

3. The Charging Diodes Are not Turned on at the Mini™ ECG Holter Recorder when Connected to the Computer

I. Make sure that the Mini™ ECG Holter Recorder is not placed in direct sunlight, as this make reading the light diodes difficult

II. Make sure that the Mini™ ECG Holter Recorder is connected correctly to the Micro USB-end of the Mini™ Micro USB Cable

III. Make sure that the USB-end of the Mini™ Micro USB Cable is connected to a powered-on computer or USB Power Adapter connected to the wall

4. The Status Diode of the Mini™ ECG Holter Recorder Lights Red

I. If the Status Diode of the Mini™ ECG Holter Recorder lights red, Mini™ ECG Holter Recorder has a malfunction that prevents normal operation. Please contact your distributor, and specify the type of problem. See page 2 of this Instruction Manual for contact details

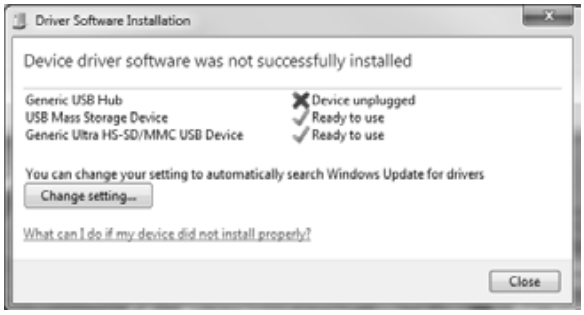
5. The Mini™ ECG Holter Recorder USB Driver was not Successfully Installed

I. Make sure that the Mini™ ECG Holter Recorder is connected correctly to the Micro USB-end of the Mini™ Micro USB Cable

II. Disconnect the USB-end of the Mini™ Micro USB Cable from the computer and reconnect to computer again

III. Make sure that the USB-end of the Mini™ Micro USB Cable is connected to a

powered-on computer



7 SPECIFICATIONS

7.1 Type and Model

Type: Mini™ Model: 1201

Device classification (EN 60601-1): Internally Powered,

Class: Type BF applied parts, not protected against defibrillator, no functional earth terminal

Data acquisition: 3-Channel ECG

Placement: Sternum (vertical)

Recording time: Up to 72 hours

Sampling rate: 256 Hz default; 128, 512 or 1024Hz

Resolution: 12 Bit

Frequency response: 128&256Hz: 0.05 - 55Hz; 512Hz: 0.05 – 110Hz; 1024Hz: 0.05 – 215Hz

Input range: 180 mV_{pv} (Peak-to-Valley)

CMRR (common mode rejection ratio) : >80 dB

Input impedance: 10 MΩ

Connections:

- 1 Mini™ Specific 8-Terminals Connector for connection to Mini™- compatible ECG electrode
- 1 Micro USB-port

Storage medium: 2 GB internal storage

Maximum data file size: 2GB EFS-file (Mini™ File System)

Maximum service life: Minimum 500 life cycles

7.2 Battery

The Mini™ ECG Holter Recorder is powered by an integrated battery with the following specifications:

Manufacturer: EEMB Co., Ltd

Type: Rechargeable lithium-ion polymer battery

Model: LP502030-PCM-LD

Battery capacity: Typical 250 mAh, minimum 230 mAh

Nominal voltage: 3.7 V

Charging voltage: 4.2 V

Weight: 7 g

Battery cycle life: Minimum 72 hours

Battery life: Minimum 500 recharges

Charger: USB 5.0 V_{DC}, 250 mA

Charging of the Mini™ ECG Holter Recorder should be performed by use of the USB Power Adapter or a computer via the Mini™ Micro USB Cable. Use of other charging devices may damage the device and/or accessories. The battery has an internal safety circuit.

7.3 Measure and Weight

Packaging:

Measures (W x H x D): 100 x 100 x 100 mm

Weight (empty): 183 g

Weight (complete): 270 g

Mini™ ECG Holter Recorder:

Measures (W x H x D): 48 x 40 x 8.8 mm

Weight: 16 g

7.4 Environment

Enclosure protection degree: IP22 (when Mini™ ECG Holter Recorder is connected to Mini™- compatible ECG Electrode)

IP20 (when Mini™ ECG Holter Recorder is not connected to Mini™- compatible ECG Electrode)

Operating conditions:

Temperature: +5° C to +40° C

Pressure: 700 - 1060 hPa

Relative humidity: 15 % - 93 % (non-condensation)

Storage conditions (including between uses):

Temperature: - 25° C to +70° C

Relative humidity: 15 % - 93 % (non-condensation)

Transportation conditions (including between uses):

Temperature: - 25° C to +70° C

Relative humidity: 15 % - 93 % (non-condensation)

Exceeding the recommended operating, storage, and transportation directions may result in reduction of the performance of the device and/or accessories

7.5 System Requirements

The Mini™ ECG Holter Recorder requires a computer with the following minimum specifications to read out the recorded data:

- Microsoft® Windows XP or Mac OS X 10.7 by Apple Inc.
- GHz processor 512 MB RAM
- USB 2.0 port for connection of the Mini™ Micro USB Cable
- 1 GB of free hard-drive space

7.6 Validated Accessories

The Mini™ ECG Holter Recorder is used in combination with other medical

accessories manufactured by Vasomedical, Inc. or by other manufacturers. It is only recommend using these accessories for proper operation of the device:

- Mini™-compatible ECG electrodes
- Mini™ Micro USB Cable
- USB Power Adapter (USB 5.0 V_{DC}, 250 mA)

8 REFERENCE TO STANDARDS

The Mini™ ECG Holter Recorder is CE Marked (CE 1008). The CE Mark is a statement that the Mini™ ECG Holter Recorder fulfils the guidelines established by the EU for medical devices.

The Mini™ ECG Holter Recorder is manufactured for Vasomedical, Inc. and the Mini™ ECG Holter Recorder meets the following standards and regulations:

- IEC 60601-1 ed 3.1 Consol. with am1 (2012-08) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2:2007 Collateral standard: Electromagnetic compatibility - Requirements and tests EN 62366:2008 Application of usability engineering to medical devices
- EN 60601-1-11:2010 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance
- Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- EN 14971:2012 Medical devices – Application of risk management to medical devices EN 1041:2009 Information supplied by the manufacturer of medical devices
- EN ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling and information to be sup- plied - Part 1: General requirements (replaces the EN 980:2008 that has DOW August 2012)

9 SYMBOLS

SERIAL NUMBER


DATE OF MANUFACTURE


MANUFACTURER (and DATE OF MANUFACTURE)


CONSULT INSTRUCTIONS FOR USE


CAUTION


KEEP DRY


CE MARKING


BF APPLIED PARTS (the Mini™ ECG Holter Recorder have conductive contact with the patient)


DISPOSAL OF WASTE ELECTRICAL / ELECTRONIC ACCORDING TO THE RAEE DIRECTIVE


USE BY

BATCH CODE


DO NOT REUSE


TEMPERATURE LIMITATION (values stated as part of the symbol provides the minimum and maximum temperatures)

 HUMIDITY LIMITAION (values stated as part of the symbol provide the minimum and maximum relative humidity)

 NO CONTAINS OR PRESENCE OF NATURAL RUBBER LATEX

 CONTAINS OF PVC (Polyvinyl chloride)

 RECYCLABLEMATERIALS STACKING

 LIMITATION THIS WAY UP

 FRAGILE, HANDLE WITH CARE

IP22 PROTECTION LEVEL IP22 (Protection against access to hazardous parts with a finger; protected against solid objects with a diameter of 12.5 mm and above; protected against vertically falling water drops when enclosure tilted up to 15 degrees)

IP20 PROTECTION LEVEL IP20 (Protection against access to hazardous parts with a finger; protected against solid objects with a diameter of 12.5 mm and above; non-protected against water)

ANNEX 1 ELECTROMAGNETIC COMPATIBILITY

Table 1 - Guidance and MANUFACTURER'S declaration - ELECTROMAGNETIC EMISSIONS- for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration - electromagnetic emissions		
The Mini™ ECG Holter Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the Mini™		
Emissions lest	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Mini™ ECG Holter Recorder uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Mini™ ECG Holter Recorder is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supply buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 - Guidance and MANUFACTURER'S declaration - electromagnetic IMMUNITY- for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity			
The Mini™ ECG Holter Recorder is intended for use in the electromagnetic environment specified below, The customer or the user of the Mini™			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment- guidance
Electrostatic discharge (ESD) lEC 61000-4-2	± 6 kV contact ± 8 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	Not applicable	Power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	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	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles	Not applicable	Power quality should be that of a typical commercial or hospital environment. If the user of the Mini™ ECG Holter Recorder requires continued operation during poor interruptions, it is recommended that the Mini™ ECG Holter Recorder be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level			

Table 3- Guidance and MANUFACTURER'S declaration - electromagnetic IMMUNITY- for ME EQUIPMENT and ME SYSTEMS that are not LIFE·SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity			
The Mini™ ECG Holter Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the Mini™ ECG Holter Recorder should assure that it is used in			
			Electromagnetic environment guidance

			Portable and mobile RF communications equipment should be used no closer to any part of the Mini™ ECG Holter Recorder including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance d = [3.5 / V1]$\sqrt{P}$ d = [3.5 / E1]$\sqrt{P}$ 80 MHz to 800 MHz d = [7 / E1]$\sqrt{P}$ 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 strengths from fixed RF transmitters, as determined by an electromagnet- ic site survey a: should be less than the compliance level in each frequency range. B: Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 104Hz 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 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 ME EOUIPMENT or ME SYSTEM is used exceeds the applicable RF compliance level above, the ME EOUIPMENT or ME SYSTEM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary such as re-orienting or relocating the (ME EOUIPMENT or ME SYSTEM).			

Table 4 - Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the (ME EQUIP- MENT or ME SYSTEM]			
The Mini™ ECG Holter Recorder is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Mini™ ECG Recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Mini™ ECG Recorder as recommended below, according to the maximum output power of the communications			
	Separation distance according to frequency of transmitters		
		80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance J 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.			

Immunity Performance Criteria

Medical Equipment Performance Criteria - unacceptable operating conditions / responses are:

- component failures;
- changes in programmable parameters;
- reset to factory defaults (manufacturer's presets);
- change of operating mode;
- initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm;

For ECG Holter in addition the following criteria are applicable:

The ambulatory recorder shall continue to record the signal without loss of any stored data after the test, by inspection, if the stored data of the ambulatory recorder is available