

BioZ® Cardio Profile

Non-invasive haemodynamic monitor

Device Manual

CE0197

Bio Z® Cardio Profile Device Manual, **P15010-01**

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1 Introduction

1.1 Applications

Before using the *Bio Z® Cardio Profile*, read the manual carefully and completely to ensure that you operate the monitor correctly.

When you set up the *Bio Z® Cardio Profile* for the first time, check to see if it has suffered any damage during transportation.

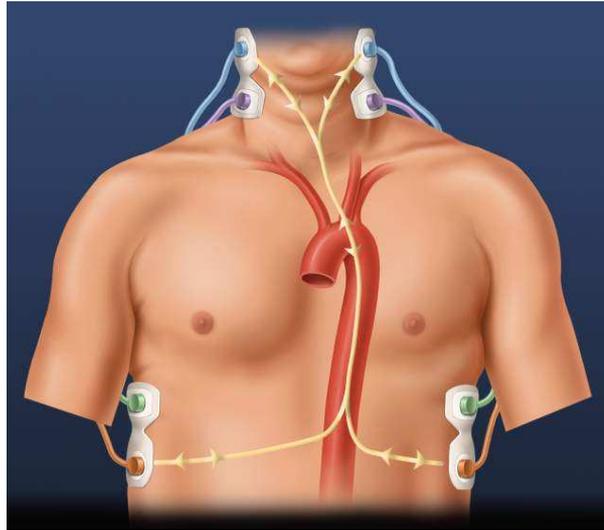
The *Bio Z® Cardio Profile* is a measuring system for non-invasive monitoring of hemodynamic parameters using methods of impedance cardiography (ICG). ICG is based on a theoretical model of blood flow movement in the thorax (aorta). If the physiological and clinical conditions of the patient are not in accordance with the assumptions of the model, inaccuracies in the parameters may occur.

The *Bio Z® Cardio Profile*-monitor allows the examination of adult patients in a resting position. The measured parameters can be used only if the ECG and ICG waveforms have sufficient signal quality and are without artifact.

If the waveforms are of questionable quality, display the Waveform screen and ensure that the key reference markers on the waveforms are accurately placed. Note the hints in the Software Manual.

The cables for ICG and ECG as well as the cuff for NIBP are protected against cardiac defibrillators. No preparation is needed before the application of the defibrillator. The *Bio Z® Cardio Profile* will return to the standard operation within approximately ten (10) seconds after discharge.

If a measurement is to be stored, the measurement must be stopped in the Patient data screen with the button *F1 - Stop* before switching off the monitor. Otherwise storage may not be complete and data could be lost. In impedance cardiography, pulse synchronous variations of the blood flow and volume in the thoracic aorta are determined and used for calculating different hemodynamic parameters. More specifically, with each beat of the heart, the volume and velocity of blood in the aorta changes. This produces a change in the electrical resistance (impedance) of the thorax to electrical alternating current. The change in impedance over time can be used to measure or calculate stroke volume and several other important hemodynamic parameters. The *Bio Z® Cardio Profile* uses four dual sensors, which are placed on the patient's neck and thorax. The most upper and lower gel pads of these sensors (the outer sensors) are used to apply a very low constant and alternating current (1.5 mA, 86 kHz) which is imperceptible to the patient. The other four gel pads are used to receive the applied current and ECG signal:



It is important to note that the ECG obtained and recorded by the *Bio Z® Cardio Profile* is not a standard lead. It is, however, important for the internal signal processing. If an additional ECG lead is necessary (e.g. if the signal quality is bad), an optional ECG cable can be connected to the monitor.

Different terms are used interchangeably when discussing impedance cardiography, electrical bioimpedance or thoracic electrical impedance (TEB). In this manual the term impedance cardiography or ICG is used.

The following conditions may adversely affect the accuracy of ICG systems and should be considered prior to use. Please note that this is not a comprehensive listing of conditions.

- Septic shock
- Aortic valve regurgitation and defect of septum
- Severe aortic sclerosis, aortic prosthesis
- Severe hypertension (MAP > 130 mmHg)
- Cardiac arrhythmia
- Tachycardia with a heart rate higher than 200 bpm
- Patient heights below 120 cm (48inches) or above 230 cm (90inches)
- Patient weights less than 30 kg (67 lbs.) or greater than 155 kg (341 lbs.)
- Patient movement
- Aortic balloon or aortic balloon pump
- Simultaneous use of electrical cautery systems during surgical procedures
- Operations on the opened thorax

Impedance cardiography (ICG)

Impedance cardiography allows the measurement of following parameters:

- Thoracic fluid content / inverse to thoracic basic impedance
- Pre-ejection period
- Left ventricular ejection time
- Indexes of contractility: Velocity Index, Acceleration Index
- Heart rate

Following parameters can be calculated:

- Cardiac Output
- Heather index
- Systolic time ratio
- Systemic vascular resistance (requires blood pressure value)
- Left ventricular work (requires blood pressure value)

With reference to body surface area the following indexed parameters can be calculated:

- Cardiac Index
- Systemic vascular resistance index
- Left ventricular work index

The ICG module of the *Bio Z® Cardio Profile* can be used for following clinical applications:

- Non-invasive monitoring of the above hemodynamic parameters including trend analysis
- Determination and checking of the hemodynamic state of a patient including management of heart failure and hypertension therapy
- Cardiologic diagnosis using hemodynamic parameters and waveform shape analysis

Additional information and a detailed description of the measuring method, the parameters, the application of impedance cardiography, and its limitations are given in the software manual.

1.2 Intended Use

The *Bio Z® Cardio Profile* is intended to monitor and display a patient's hemodynamic parameters including:

Heart Rate (HR)	Velocity Index (VI)
Systolic Blood Pressure (SBP)	Acceleration Index (ACI)
Diastolic Blood Pressure (DBP)	Heather Index (HI)
Mean Arterial Pressure (MAP)	Pre-Ejection Period (PEP)
Stroke Volume (SV)	Left Ventricular Ejection Time (LVET)
Stroke Index (SI)	Thoracic Fluid Content (TFC)
Cardiac Output (CO)	Thoracic Fluid Content Index (TFCI)
Cardiac Index (CI)	Baseline Impedance (Z0)
Systemic Vascular Resistance (SVR)	Total Arterial Compliance (TAC)
Systemic Vascular Resistance Index (SVRI)	Total Arterial Compliance Index (TACI)
Left Cardiac Work (LCW)	Systolic Time Ratio (STR)
Left Cardiac Work Index (LCWI)	Systolic Time Ratio Index (STRI)

The *Bio Z® Cardio Profile* Hemodynamic Monitor is not intended to be used as a vital sign monitor.

1.2.1 Contraindications

No known contraindications.

1.3 Warnings and Cautions

For maximum safety, observe the following warnings and cautions:

WARNING: The *Bio Z® Cardio Profile* is intended for use only within hospitals and other healthcare facilities (e.g. outpatient clinics, physician's office) that provide patient care.

WARNING: The *Bio Z® Cardio Profile* is intended for use on adult patients. It is not intended for use on infants.

WARNING: The *BioZ® Cardio Profile* Hemodynamic Monitor is not intended to be used as a vital sign monitor.

WARNING: ECG measured with the ICG-channel as well as with the additional ECG cable is for triggering purpose only. They are not intended for diagnoses of any kind.

WARNING: The *Bio Z® Cardio Profile* is not intended to be used while exposing the patient to high-frequency current.

WARNING: The *Bio Z® Cardio Profile* is to be used only by or on the order of a physician.

WARNING: All persons using the *Bio Z® Cardio Profile* must be qualified and understand the measuring method and the operation of the monitor.

WARNING: To avoid the risk of an electric shock, this device must be connected to supply mains with protective earth.

WARNING: The sensors can be placed freely on the body surface, but a direct contact with the heart or vessels is not allowed. The *Bio Z® Cardio Profile* belongs to the application class BF (Body Floating).

WARNING: Only connect one patient at a time to the *Bio Z® Cardio Profile*.

WARNING: The sensors must not have a direct contact to other electrically conductive materials.

WARNING: ICG Sensors are single time use devices and should be replaced after a maximum of 24 hours of use. While the patient contact materials have been fully evaluated to the guidelines of ISO-10993-1 (Biological Evaluation of Medical Devices) for biocompatibility, skin irritation may occur at the sites of sensor

placement. If local skin irritation occurs beneath or around any of the sensor sites, discontinue product use and remove the sensors. Persistent use of the device in the presence of skin irritation may be harmful.

WARNING: Before monitoring patients with pacemakers, ensure that the function of the pacemaker cannot be influenced by the measuring current used for impedance cardiography. In the case of minute ventilation pacemakers, the use of the Do not use the *Bio Z® Cardio Profile* if the minute ventilation function of the pacemaker is activated.

WARNING: The *Bio Z® Cardio Profile* must be connected by a three-wire power cable to an electrical outlet that has been properly installed and grounded.

WARNING: The monitor is not protected against explosive substance. Do not use the *Bio Z® Cardio Profile* in the presence of flammable anaesthetics or gases.

WARNING: To ensure that the measurement system functions safely, do not subject it to high levels of humidity or to strong electrical or electromagnetic interference fields.

WARNING: Connecting multiple *Bio Z® Cardio Profile* systems and/or other medical devices to the same patient may pose a safety hazard due to summation of leakage currents. Any potential combination of instruments should be evaluated by local safety personnel prior to being placed into service or applied to a patient.

WARNING: If performing a continuous monitoring session (i.e. in an ICU setting), make sure that all cabling is routed in a way so that it does not present a strangulation hazard to the patient.

WARNING: Do not allow patients to wear ICG Sensors when undergoing Magnetic Resonance Imaging (MRI) due to risk of second and third degree burns.

WARNING: Control during operation, ensure that no long interruption of blood circulation in the current extremity occurs. Detach the cuff if necessary.

WARNING: The *Bio Z® Cardio Profile* applies low-level AC current to the thorax of a patient during a monitoring session. Implanted devices with electrical sensors (such as Minute Ventilation-based pacemakers) may detect the BioZ's current and exhibit erratic sensor operation. It is recommended that electrical sensors of implanted devices be disabled prior to starting a BioZ monitoring session.

WARNING: Before replacing the external fuse on the unit, disconnect the unit from the main power supply by pulling the plug out of the wall socket.

WARNING: Before cleaning or disinfecting the measuring unit, disconnect the unit from the main power supply by pulling the plug out of the wall socket.

WARNING: Do not modify any SonoSite products. Any modifications to the device will void the warranty.

WARNING: Health care providers who maintain or transmit health information are required by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the European Union Data Protective Directive (95/46/EC) to implement appropriate procedures: to ensure the integrity and confidentiality of information; to protect against any reasonably anticipated threats or hazards to the security or integrity of the information or unauthorized uses or disclosure of the information.

CAUTION: Never gas-sterilize the patient cables. They are covered with a PVC shroud that can react with the gas-sterilization procedure to form a highly toxic ethyl nitrite. Sterilization in an autoclave, with ultrasound or gamma rays is also not permitted.

CAUTION: Do not sterilize the *Bio Z® Cardio Profile* parts or accessories. Sterilizing the device or accessories will void the warranty.

CAUTION: Use only cables or components recommended by SonoSite to connect to the inputs and outputs of the monitor.

CAUTION: Do not place the measuring unit on a surface which emits heat or expose it to direct sunlight. Do not cover the ventilation slits.

CAUTION: Do not operate in bathrooms or other areas where water damage is possible. The *Bio Z® Cardio Profile* is not protected against splashing water.

CAUTION: The *Bio Z® Cardio Profile* should be placed near the patient and fixed in such a way that the *Bio Z® Cardio Profile* cannot fall down if someone pulls on the cable.

CAUTION: The *Bio Z® Cardio Profile* is protected against accidental ingress of liquids. If liquids ingress into the case, disconnect the monitor from the wall outlet.

CAUTION: Do not expose the cables to mechanical or thermal impact. Avoid temperatures above 40 °C (100 °F). See page 32 for operating specifications.

1.4 Explanation of used symbols

	Caution, consult accompanying documents!
	Do not dispose with residual waste
	Device type BF, Defibrillator-protected
	Device type BF
	Insulation class I
	Potential equalisation connector
	Caution, electrostatic sensitive devices
	USB-Connector
	Device Powered On
	Stand-By
	Connector for external keyboard
	Network connector
	Connector for external VGA-monitor
	Connector for serial interface

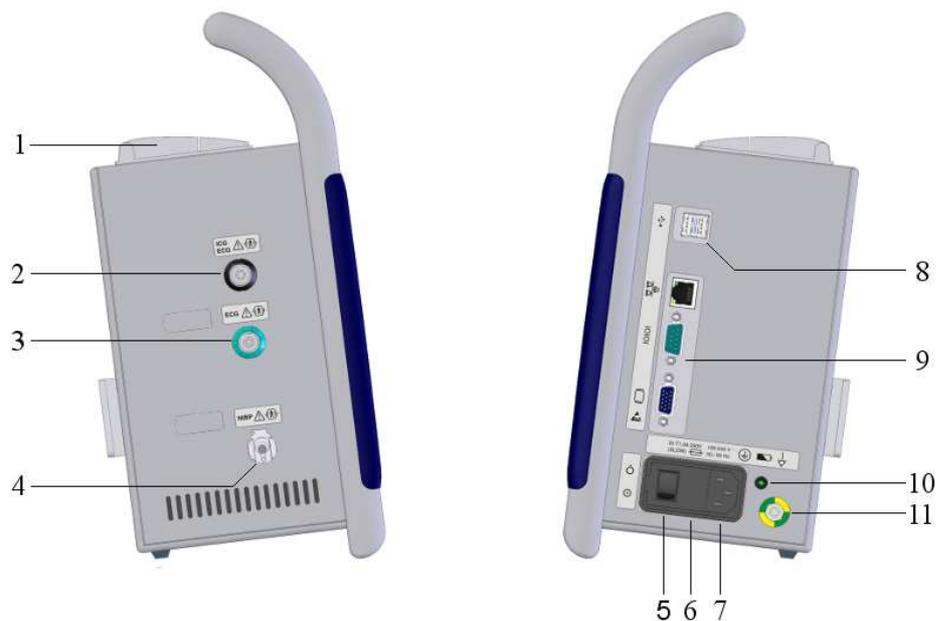
2 Description of the device

2.1 Basic device

The front of the *Bio Z® Cardio Profile* consists of a color TFT display with a touch screen. Except for the operation of the main switch (5) the complete operation of the monitor is done only by the touch screen. In the Software Manual all details are explained.

On the top side of the *Bio Z® Cardio Profile* a printer is built in. The use of the printer is described in detail in section “Printer”.

The following illustration shows the left side and the right side of the device:



1. Integrated printer
2. Socket for impedance cardiography (ICG) patient cable
3. Socket for ECG patient cable
4. Socket for NIBP cuff
5. Power On and Off switch
6. Fuse compartment
7. Socket for power supply connecting cable
8. USB-sockets

9. Connectors for computer peripherals (network, serial interface)
10. Charge and stand-by indicator
11. Potential equalisation connector

The power on and off switch is used to switch the device on and off, whereby the internal power supply remains connected with the main power supply (for example, to charge the battery), even if the *Bio Z® Cardio Profile* is switched off. The charging process is shown by the flashing charge indicator (10) on the right side of the *Bio Z® Cardio Profile*. When the batteries are fully charged the indicator lamp lights permanently and indicates that the device is connected with the main power supply.

The type plate is located on the backside of the device. It lists important information about the *Bio Z® Cardio Profile*, including the value for the external fuse and the serial number of the device. The serial number will be needed to obtain technical service assistance and warranty repairs.

On the right hand side of the *Bio Z® Cardio Profile* connectors for computer inputs/outputs (8, 9) are located and are labelled appropriately.

The following input/outputs are available and can be used if necessary and if the connected components meet all requirements of the Medical Device Directive (MDD) and United States regulation:

USB

Several peripheral devices can be attached to the USB sockets:

- Storage media (e.g. USB sticks or USB hard discs) to export measured data.
- External printer to print out reports at A4 or US-letter paper format. Please note the instructions and safety requirements in section „External printer“.
- A keyboard allows inputting the patient data. If the keyboard is attached the *Bio Z® Cardio Profile* automatically updates the screen display for use with a connected keyboard.

Network

This network connector can be connected to a 10 or 100 MBit ethernet network using TCP/IP protocol. Please note the Safety requirements! A medical network insulation module might be required and is available as accessory.

Serial-I/O

The serial interface of the *Bio Z® Cardio Profile* monitor is a standard RS232 interface and can be used for connecting additional devices, which must be supported by the *Bio Z® Cardio Profile* software.

All sockets necessary for connecting the *Bio Z® Cardio Profile* to the patient are located on the left side of the *Bio Z® Cardio Profile*. These are the sockets for: ICG patient cable (2), ECG patient cable (3) and the cuff for NIBP (6) measurement. All patient cables are colour-coded as well mechanically coded.

Please note, that the mentioned sockets may only be connected to patient cables, which are made for the *Bio Z® Cardio Profile*. The use of other cables is not allowed.

All plugs are self-locking. When the plug is inserted, the connection is secured. The cables can be disconnected by only holding the outer casing of the plug and pulling it out. Do not rotate the plug while it is in the socket. The blood pressure cuff connector can be disconnected by moving the coupling part.

2.2 Device cart

The *Bio Z® Cardio Profile* can be mounted to the optional device cart. See the assembly instructions delivered with the cart, to connect the device.

The cart fulfills the standard IEC 60601-1:1988/A2:1995.

2.3 Patient cable

The patient cable for impedance cardiography (marked with ICG) contains a small box, which includes a cable splitter with integrated electronics:



On the outside of the box, two small LEDs (green and orange) display the current function of the patient cable, as indicated below:

green	orange	Description of function
○	○	The electronic part of the patient cable is not connected with the power supply; cable is disconnected or the device is switched off
☀	○	Patient cable is ready to use, but the measurement has not been started
●	○	Measurement is running; sensor contact is good
●	☀	Bad contact between sensors and patient: at least one lead wire is disconnected or not properly fixed; sensors are too dry (eventually new sensors are necessary)
●	●	Insufficient contact between sensors and patient: at least one lead wire is disconnected or not properly fixed; sensors are too dry (new sensors are necessary)
○	☀	Patient cable has power but the software cannot access the cable; software has not been started or is not ready for measurement

Legend: ○ LED off ☀ LED flashing ● LED on

The application of the sensors and the connection of patient cables are detailed described in the software manual in sections “Impedance Cardiography (ICG)”.

2.4 Printer

Integrated strip chart printer

A thermal line printer is built into the top of the *Bio Z® Cardio Profile*. This printer requires thermal paper with a width of 58 mm.

The button of the printer is for paper feed, but is not necessary for normal operation.

Changing paper



To open the paper box, lift the cover up by placing your fingertip into the hole and moving the cover to the front.



Open the paper box.



Put the paper in the box, with the leading edge of the paper coming from the bottom of the roll. The paper must come up through the printer slot.



Press down the cover of the paper box to close it and to fix the paper in the printer slot.

External printer

An external A4 or letter page printer can be connected to the USB-interface of the *Bio Z® Cardio Profile*.

If the external printer is connected, all printouts are automatically sent to the external printer and the integrated strip chart printer is disabled.

To function properly, the external printer must meet the following requirements:

- Compatibility to the PCL printer language
- Following the requirements for medical devices according to IEC 60601-1

Please note that through combining of the *Bio Z® Cardio Profile* with a printer, a medical electrical system is constituted, which must comply with the requirements of IEC 60601-1 ensured that the leakage current does not exceed safety standards.

2.5 Modules

Internal rechargeable battery

The *Bio Z® Cardio Profile* is equipped with a battery pack including electronics for battery charging and control. It allows the use of the *Bio Z® Cardio Profile* also without an external power supply over a period of at least 30 minutes. The length of time the *Bio Z® Cardio Profile* may be operated on battery power depends on the mode of operation (for example, how often the blood pressure is measured).

When the batteries are being charged the charge indicator on the right side of the *Bio Z® Cardio Profile* (pos. (10) in section “Basic device”) flashes on and off. When the batteries are fully charged, the indicator lamp glows continuously, indicating that the device is connected with the main power supply.

Please note, that generally rechargeable batteries have a limited lifetime and, therefore, must be changed periodically. SonoSite recommends a technical check after a two-year period. When the performance of the battery pack is reduced and affects the operation time, the battery pack must be changed. When this occurs, please contact your local distributor or SonoSite Technical Support directly.

Hard disc / internal data base

The integrated hard disc enables storage of the patient data obtained during a monitoring session and enables an offline analysis. The optional PC software facilitates data transfer to an external PC for further evaluation or data storage

Non-invasive blood pressure (NIBP)

This module uses the oscillometric method and a pressure cuff to obtain systolic, diastolic, and mean arterial pressure. These data may be obtained automatically, at user-entered time intervals, or manually when activated by the user.

3 Turning the device on and taking a measurement

The following steps must be taken to begin a monitoring session with the *Bio Z® Cardio Profile* monitor:

1. The *Bio Z® Cardio Profile* main power supply must be connected (unless the optional internal battery is included with the *Bio Z® Cardio Profile*) and switched on.
2. Depending on the parameters being measured (ICG, NIBP), the necessary patient cable and cuff must be connected to the *Bio Z® Cardio Profile* and properly applied to the patient.
3. Before starting the monitoring session, the patient data must be entered and the mode of measurement selected. Now the measurement and data recording can be started. Please note the hints in the software manual
4. At the end of the measurement, go back to the Patient data screen and stop the measurement before switching off the device and removing the sensors and blood pressure cuff from the patient.

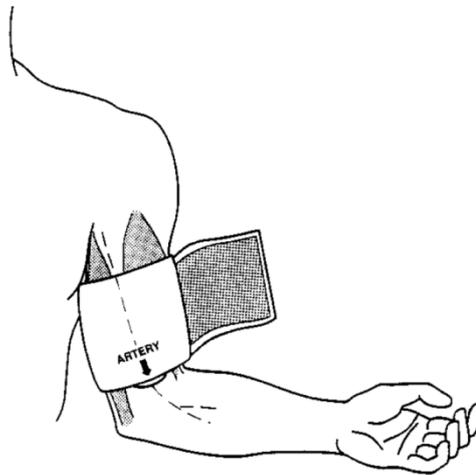
3.1 Application of the electrodes

The application of the sensors and the connection of ICG cable are described in detail in the software manual in sections “Impedance Cardiography (ICG)”.

3.2 Blood Pressure Measurement (NIBP)

It is important to select the cuff size that is appropriate to the diameter of the patient's upper arm. Use the Range Lines on the inside of the cuff to determine the correct size cuff to use.

Wrap the cuff around the arm making sure that the Artery Marker is aligned over the brachial artery as shown in the Figure. If possible, do not wrap the cuff over the patient's clothing. The cuff should fit snug to the patient's arm for maximum oscillometric signal quality. An appropriate sized cuff should be placed on the non-dominant arm where the lower edge of the cuff is located 2 cm above the antecubital fossa (interior bend of the elbow).



Ensure that the air hose from the *Bio Z® Cardio Profile* to the cuff is not compressed, crimped or damaged.

4 Maintenance, cleaning and disinfection

4.1 Basic device and patient cable

Maintenance

The *Bio Z® Cardio Profile* is a self-calibrating system so that external calibration is not necessary. The proper function of the system can be checked using a special signal generator (part no. N1104 for ICG channel).

The measurement system must always be kept in safe and reliable working order and should be checked regularly, at least once a year. The check should cover a function test and the measurement of leakage currents.

If you discover that the measurement system is faulty and/or unsafe (for example, if any of the lines have insulation or breakage defects), repair the system and/or replace faulty cables immediately.

Repairs may only be carried out by persons or workshops authorised to do so by the manufacturer. Otherwise, general liability for improperly operating the measurement system and for injury, damage and consequential damage resulting therefrom will be passed on to the operator or to the persons or workshops that have not been expressly authorised by the manufacturer.

Replacing the external fuse

Use only the prescribed type of fuses as replacements (see type plate). Do not use repaired fuses or short-circuit the fuse holder. Please contact Sonosite Technical Service if the external fuses fail repeatedly.

Cleaning and disinfection

It is recommended to clean and to disinfect the *Bio Z® Cardio Profile* and its cables regularly.

Clean the unit and the cables with a soft cloth. Do not use any abrasive or corrosive substances. We recommend neutral cleaning agents or disinfecting substances, like ethanol (70 - 80 %), propanol (70 - 80 %) or aldehyde (2 - 4 %). Ensure that

no disinfectant gets onto the contact points of the plugs and sockets, and that no liquid seeps into the *Bio Z® Cardio Profile*

Replacing the battery

The *BioZ® Cardio Profile* is equipped with a rechargeable battery (part number N1306-2). The typical lifetime of the used NiMH is 50 - 1000 charging cycles. Depending from usage this equates up to 3 years. Afterwards the capacity reduces and the battery should be replaced.

The following steps must be performed to replace the battery:

1. Turn off the *BioZ® Cardio Profile* and disconnect it from the main power supply by pulling the plug out of the wall socket.
2. Remove 4 screws from the bottom side of the device using a crosstip screwdriver (type PH1) as shown in the following picture:



3. Remove the battery cover.
4. Carefully take the battery and disconnect the plug-in connector while pressing the locking mechanism.
5. Hold the new battery pack and connect the plug-in connector carefully.
6. Insert the new battery into the device. Pay attention that no cable is squeezed.
7. Reinsert the battery cover and the 4 screws.
8. Because the batteries are delivered in empty state, connect the main power supply to load the accumulator.

Calibration of the touch screen

A recalibration of the touch screen may be necessary if you touch an enabled button on the screen and:

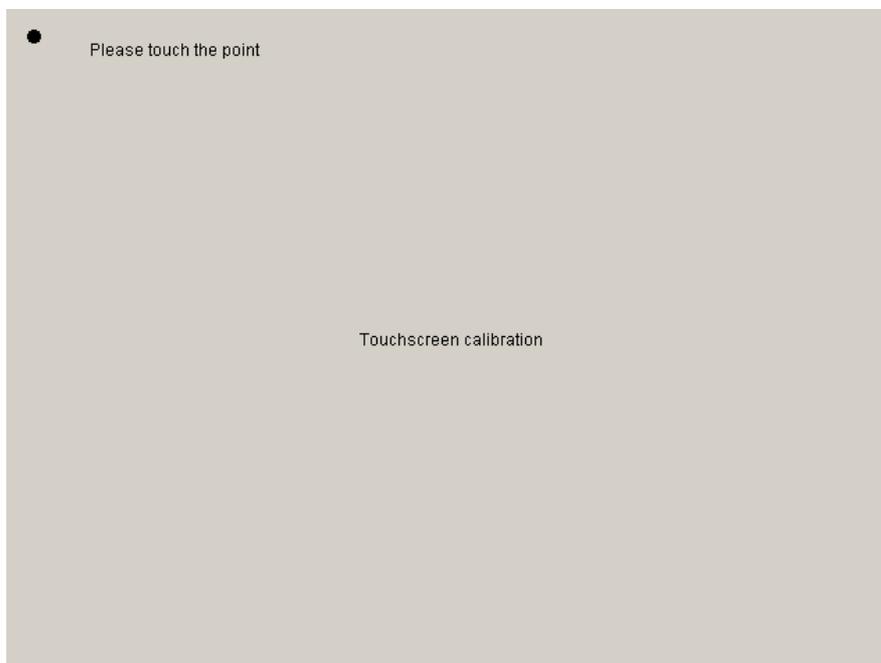
the selected function is not activated or another function (located away from the selected function) is activated.

AND

you hear the normal click sound.

To calibrate the touch screen please carry out the following steps:

1. Turn off and turn on the *Bio Z® Cardio Profile*. (The calibration function can only be activated on a freshly booted device.)
2. When the patient data screen is displayed, touch the screen on a random place and continue pressing the screen (for approximately 5 seconds) until the calibration menu is displayed (see next picture).
3. The calibration menu will prompt you to touch every corner of the screen display. The touched positions will be saved as the references for the following touch screen operations.



4.2 Service Procedures of the optional Blood pressure module

Pressure Transducer Verification

International standards for automated NIBP devices require that the maximum static pressure accuracy shall be ± 3 mmHg. This is a stringent requirement and all test equipment must be in excellent working order to properly perform this test. It is important to verify the calibration before changing it. Although experience has shown that the transducers rarely need to be re-calibrated annually the pressure verification is required.

Equipment

- Calibrated Manometer
- Pneumatic "T" Adapters
- Volume (500 mL bottle or regular-sized cuff wrapped around a solid object is suggested)
- Hand Bulb
- Connection Tubing

NOTE: Volume is added to the pneumatic system so that the user has more control of the pressure increments when using the hand bulb. If no volume is added, it is quite easy to cause unwanted overpressure errors using the hand bulb.

Procedure

1. Connect a manometer, volume and the hand bulb to the Module using "T" adapters.
2. Inflate SLOWLY when adding pressure over 200 mmHg.
3. Apply various pressures (between 0 and 280 mmHg) to the Module with the hand bulb. Verify that the Module pressure is equal to the manometer pressure (± 3 mmHg).

If the Module pressure does not agree with the manometer pressure and need to be calibrated please contact our support.

Leak Test

International standards for automated NIBP devices require that air leakage within the pneumatic system must not exceed 6mmHg/minute. During manufacturing acceptable air leakage is less than 3 mmHg/minute when using a 500 mL rigid volume. Both of these pass criteria will not affect the performance or accuracy of

the NIBP module so we suggest using the 6mmHg/minute pass criteria with a 500 mL rigid volume.

Equipment

- Calibrated Manometer (optional may use pressure values supplied by NIBP module)
- Pneumatic "T" Adapters
- Volume (500 mL rigid bottle a blood pressure cuff is not recommended)
- Hand Bulb
- Connection Tubing
- Timer (i.e. Stop Watch)

NOTE 1: Volume is added to the pneumatic system so that the user has more control of the pressure increments when using the hand bulb. If no volume is added, it is quite easy to cause unwanted overpressure errors using the hand bulb. Also leak rates are exaggerated with extremely small volumes.

NOTE 2: Blood pressure cuffs have large variations in size and materials which can cause large amounts of variation in the leak test results. To limit this effect, we strongly urge to only use a 500 mL rigid volume.

Test Method

1. Connect a manometer, volume and the hand bulb to the Module using "T" adapters.
2. If using a hand bulb, make sure the exhaust valve is closed.
3. Increase the pressure to approximately 250 mmHg using the hand bulb or the pump on the module. It is difficult to slowly increase the pressure in the pneumatic system with the pump so a hand bulb is preferred.

NOTE: When applying high pressures, take special care to increase the pressure at a rate that will not cause unwanted overpressure errors (300 mmHg).

4. Start the timer and wait 60 seconds for the pneumatic system to reach its pressure equilibrium point. All pneumatic systems have some degree of expansion and rebound which are effected by the several factors including volume, material types and material durometers.
5. After the waiting period, record the pneumatic pressure level (P1) and wait another 60 seconds and record the pneumatic pressure level again (P2).

NOTE: Safety circuitry on the module only allows the pressure in the pneumatic system to remain above 10 mmHg for 180 seconds. When this safety time limit is exceeded, the valves will open and the module will be disabled. To reset the NIBP module, it must have the power cycled or it

needs to be set to its sleep mode and awakened. Not all NIBP module customers have the ability to use the sleep mode.

6. Open the hand bulb valve to exhaust the air from the pneumatic system.
7. Subtract P2 from P1 and this is the leak rate per minute.

5 Technical Data

Mains Supply	100 – 240 V AC
Supply frequency	50/60 Hz
Power input	< 60 VA
Battery (optional)	internal NiMH-rechargeable batteries Capacity > 60 min
Fuses external	2 x T 1.0 A
Electrical safety	IEC 60601-1 ANSI/AAMI SP10 21CFR898 FDA class II Insulation class I Classification for patient protection BF
Electromagnetic compatibility	IEC 60601-1-2
Insulation voltage	Patient - Main supply: 4 kVeff ; 1 min Patient - Signal I/O: 4 kVeff ; 1 min
Display	10.4" TFT-Color 640 x 480 Pixel, Touch screen
Dimensions (W x H x D)	11.4 x 12.6 x 5.5 in
Weight	(approx. 11 lbs (with battery pack))
Signal I/O	Serial-I/O serial interface, RS232 USB interface Network 10/100MBit Ethernet, 100Base2
Operating conditions	Temperature: 10 – 40 °C Humidity: 30 – 75 % Altitude: 0 - 3000 m

5.1 Measurement channels

ICG (Impedance Cardiography)

Measuring principle	Bioimpedance-Plethysmography defibrillator safe
Sensors	4 BioZ AdvaSense disposable sensors (solid gel)
Measuring current	1.5 mA _{eff} ; 85 kHz; Sinus
Basic impedance	0 – 60 Ω; 0 – 0.2 Hz
Pulse wave	±1 Ω; 0.2 – 100 Hz

ECG

Max. input voltage	±10 mV AC voltage, defibrillator safe
Frequency range	0.8 – 160 Hz
Common mode rejection ratio	> 90 dB
Noise voltage	< 10 μV

NIBP (non-invasive blood pressure)

Measuring principle	oscillometric with arm cuff
Parameter	systolic and diastolic pressure, arterial mean pressure (MAP)
Range	0 – 280 mmHg
Transducer accuracy	±3 mmHg

Patient safety

Max. cuff inflation time	75 s
Max. BP reading time	130 s (Adult mode) 90 s (Pediatric mode)

Redundant safety

Max. cuff pressure	300 mmHg
Max. time with inflated cuff	180 s

6 Scope of delivery

To the scope of delivery of the *Bio Z® Cardio Profile* the following components belong:

- Measuring device *Bio Z® Cardio Profile*
- Power cord
- ICG Patient cable
- ECG Patient cable
- 3 x NIBP-Cuffs (“Adult”, “Large Adult“ and “Small Adult“)
- 10 rolls thermal paper
- *Bio Z® Cardio Profile* Device Manual
- Software Manual

Accessories and expendable items

- BioZ AdvaSense ICG sensors (part number BZ-1550)
- ICG / ECG Patient cable (P15002-01)
- ECG Patient cable (P15003-01)
- Blood pressure cuffs for the following arm circumferences:
 - 23 ... 33 cm (“Adult”, P15006-01)
 - 31 ... 40 cm (“Large Adult”, P15480-01)
 - 17 ... 25 cm (“Small Adult”, P15481-01)
- Cuff hose (P15007-01)
- Internal battery replacement pack (P15086-01)
- Thermal paper for the integrated strip chart printer (P15009-01)
- Device manual *Bio Z® Cardio Profile* (P15010-01)
- Power Cord – US/CAN Style (P00848-01)

7 Manufacturer guidelines and declarations

Electromagnetic emissions

The *Bio Z® Cardio Profile* monitor is intended for use in the electromagnetic environment specified below.

The customer or the user of the *Bio Z® Cardio Profile* monitor should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Class B	The <i>Bio Z® Cardio Profile</i> monitor is suitable for use in all establishments other than domestic establishments 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	

Electromagnetic immunity

The *Bio Z® Cardio Profile* monitor is intended for use in the electromagnetic environment specified below.

The customer or the user of the *Bio Z® Cardio Profile* monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV 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	±2kV for power supply lines ±1kV for input/output	±2kV for power supply lines ±1kV for input/output	Mains power quality should be that of a typical commercial or hospital environment.

	lines	lines	
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Main 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 ½ cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	<5% UT (>95% dip in UT) for ½ cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	Outlet (AC) power quality should be that of a typical commercial or hospital environment. If the user of the <i>Bio Z® Cardio Profile</i> monitor requires continued operation during power mains interruptions, it is recommended that the <i>Bio Z® Cardio Profile</i> be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz) magnetic field IEC 61000-4-8	3 A/m	3 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 a.c. mains voltage prior to application of the test level.			

Electromagnetic immunity

The *Bio Z® Cardio Profile* monitor is intended for use in the electromagnetic environment specified below.

The customer or the user of the *Bio Z® Cardio Profile* monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	1 V _{rms}	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <i>Bio Z® Cardio Profile</i> monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 3,5 \sqrt{P}$ <p>$d = 3,5 \sqrt{P}$ for 80 MHz to 800MHz</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	1 V/m	<p>$d = 7 \sqrt{P}$ for 800 MHz to 2,5 GHz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,¹ should be less than the compliance level in each frequency range,² Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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.

¹ 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 *Bio Z® Cardio Profile* monitor is used exceeds the applicable RF compliance level above, the *Bio Z® Cardio Profile* monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Bio Z® Cardio Profile* monitor.

²Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Recommended separation distances

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the *Bio Z® Cardio Profile*

The *Bio Z® Cardio Profile* is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Bio Z® Cardio Profile* monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Bio Z® Cardio Profile* monitor as recommended below, according to the maximum output of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter in meters		
	150 kHz to 80 MHz $d = 3,5 \sqrt{P}$	80 MHz to 800 MHz $d = 3,5 \sqrt{P}$	800 MHz to 2,5 GHz $d = 7 \sqrt{P}$
0,01	0,35	0,35	0,7
0,1	1,1	1,1	2,2
1	3,5	3,5	7
10	11	11	22
100	35	35	70

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.

8 Appendix

8.1 Support

If you need additional information or if you have any technical, methodical or clinical questions please contact:



21919 30th Drive SE
Bothell, WA 98021-3904
Tel. 1-800-778-4825 Option 3
www.sonosite.com

If you have questions about your device, please provide the serial number of your device, located on the type plate on the back or bottom side of the device.

For questions about the software, provide the serial number of the software, located in the Hardware-Info screen. Press **F5-Options** in the Patient data screen and then the **F1-Hardware** button.

8.2 Alarm System

In the measuring device an alarm system recommended in the standard IEC 60601-1-8 is used. In the following the specifications and basic settings are described.

Alarm priority

Alarms are classified regarding the type, occurrence and risk. The following visual alarm priorities are used:

Alarm priority	Indicator colour	Flashing frequency	Duty cycle
I - low priority	Cyan	constant (on)	100 % on
II - medium priority	Yellow	0.71 Hz	50 % on

The following acoustic alarm priorities are used:

Alarm priority	Cause	Tone sequence	Alarm repetition
I - low priority	Any	e - c	20 s
II - medium priority	Cardiac	c - e - g	10 s

⚠ Alarms with high priority are not used, because the system belongs to class IIa and, therefore, is not intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient!

If several alarms occur with the same priority, the first alarm is displayed. If this alarm is muted the following alarm is displayed until all alarms have been shown.

If an alarm with higher priority occurs, it will be brought to front automatically.

Alarm deactivation

Following alarm deactivations are used:

Alarm deactivation	Meaning
AP - Audio Paused	The acoustic alarm is deactivated for a period of 1 minute
AO - Audio Off	The acoustic alarm is deactivated
ALP - Alarm Paused	The alarm (acoustic and visual) is deactivated for a period of 1 minute
ALO - Alarm Off	The alarm (acoustic and visual) is deactivated

Physiological alarms can only be paused. A general deactivation is not possible if the alarm control is enabled.

Alarm condition delay

If an alarm occurs, it will be displayed immediately. But note that a high parameter averaging rate can cause delays in the alarm activation. It is also possible that small or temporary exceeding of the parameter limits cause no alarm activation.

If instant alarm activation is required reduce the parameter averaging of the appropriate examination to "1" (averaging deactivated).

Physiological Alarms

The following table states the physiological parameters which can be observed by the system. The manufacturer basic setting can only be configured for a single measurement and can not be saved.

Alarm Condition Physiological Alarm	Alarm Priority / Alarm Deactivation	Manufacturer Limit Value		Unit
		Lower	Upper	
HR - Heart rate	II / AP	58	86	1/min
Z0 - Base impedance	II / AP	♂: 20,0 ♀: 27,0	♂: 33,3 ♀: 47,6	Ohm
TFC - Thoracic fluid content	II / AP	♂: 30 ♀: 21	♂: 50 ♀: 37	1/kOhm
TFCI - Thoracic fluid content Index	II / AP	♂: 30/BSA ♀: 21/BSA	♂: 50/BSA ♀: 37/BSA	1/kOhm/m ²
SV - Stroke volume	II / AP	BSA*35	BSA*65	ml
SI - Stroke index	II / AP	35	65	ml/m ²
CO - Cardiac Output	II / AP	BSA*2.5	BSA*4.7	l/min
CI - Cardiac Index	II / AP	2.5	4.7	l/min/m ²
PEP - Pre ejection period	II / AP	50	100	ms
LVET - Left ventricular ejection time	II / AP	200	300	ms
STR - Systolic time ratio	II / AP	0.3	0.5	-
VI - Velocity Index	II / AP	33	65	1/1000/s
ACI - Acceleration Index	II / AP	♂: 70 ♀: 90	♂: 150 ♀: 170	1/100/s ²
HEATHER - Heather Index	II / AP	7	20	Ohm/s ²
BDsys - Systolic blood pressure	II / AP	100	140	mmHg

BDdia - Diastolic blood pressure	II / AP	60	90	mmHg
MAP - Mean arterial blood pressure	II / AP	70	105	mmHg
LCWI - Left Cardiac Work Index	II / AP	3.0	5.5	kg·m/m ²
LCW - Left Cardiac Work	II / AP	3.0*BSA	5.5*BSA	kg·m/m ²
SVRI - Systemic Vascular Resistance Index	II / AP	1680	2580	dyn · s · cm ⁻⁵ · m ²
SVR - Systemic Vascular Resistance	II / AP	1680/BSA	2580/BSA	dyn · s · cm ⁻⁵
TAC - Total Arterial Compliance	II / AP	0.7*BSA	1.4*BSA	ml/mmHg
TACI - Total Arterial Compliance Index	II / AP	0.7	1.4	ml/mmHg/m ²
PAWP - Pulmonary artery wedge pressure	II / AP	5	15	mmHg
CVP - Central venous pressure	II / AP	3.0	9.0	mmHg
Load	II / AP	75	225	W
Hb - Haemoglobin	II / AP	♂: 14 ♀: 12	♂: 18 ♀: 16	g/dl

Legend: ♂: male, ♀: female

Technical Alarms

The following table states the physiological parameters which can be observed by the system. The manufacturer basic setting can only be configured for a single measurement and can not be saved.

The following table states the technical alarms implemented into the system. Regarding the operation mode two different alarm priorities are used:

- Online: Measurement is running

- Offline: No measurement is running

Alarm Condition Technical Alarm	Alarm Priority / Alarm Deactivation	
	Offline	Online
NIBP: Weak or no oscillometric signal	I / ALO	II / ALO
NIBP: Artefact / erratic oscillometric signal	I / ALO	II / ALO
NIBP: Exceeded retry count	I / ALO	II / ALO
NIBP: Exceeded measurement time limit	I / ALO	II / ALO
NIBP: Pneumatic Blockage	I / ALO	II / ALO
NIBP: Inflate Timeout, Air Leak or Loose Cuff	I / ALO	II / ALO
NIBP: Safety Timeout	I / ALO	II / ALO
NIBP: Cuff Overpressure	I / ALO	II / ALO
NIBP: Power supply out of range or other hardware problem	I / ALO	II / ALO
NIBP: Permission problem such as safety override fitted or autozero out of range	I / ALO	II / ALO
NIBP: Transducer out of range	I / ALO	II / ALO
NIBP: ADC out of range	I / ALO	II / ALO
NIBP: EEPROM calibration data failure	I / ALO	II / ALO
Patient cable disconnected	-	II / ALO
Patient cable connected	-	II / ALO
Low Battery!	I / AO	II / AO
Hardware Failure!	II / ALP	II / ALP