SPHYGMOMANOMETERS

ri-cardio

USER GUIDE

CE 0124

Riester

INTRODUCTION TO AMBULATORY BLOOD PRESSURE MONITORING

Ambulatory blood pressure monitoring is an accepted clinical tool for collecting multiple blood pressure measurements. It better assists clinicians with the diagnosis and management of hypertension by providing: blood pressure variability, an estimation of true blood pressure, overnight changes in blood pressure, and morning surge in blood pressure.[1] In-clinic and home blood pressure measurements cannot provide the same depth of information that a 24-hour study provides. Several studies have shown that ambulatory blood pressure monitoring, when compared to clinic or home blood pressure measurements, is superior in predicting target organ damage, morbid events, or cardiovascular risk.[1, 2, 3]

The data obtained from ambulatory blood pressure monitors is highly accurate and useful for managing a wide variety of hypertensive situations including:

- White-coat hypertension
- Resistant hypertension
- Masked hypertension
- Childhood hypertension
- Efficacy of anti-hypertensive drug therapy on a 24-hour basis
- Nocturnal hypertension
- Episodic hypertension and/or anxiety disorders
- Hypotensive symptoms
- Changes in diet and daily routine designed to reduce hypertension
- Hypertension in pregnancy

1. Pickering, T.G.., Shimbo, D., & Haas, D. (2006). Ambulatory Blood-Pressure Monitoring. **New England Journal of Medicine**, 354(22), 2368-2374.
2. Marchiando, R.J. & Elston, M.P. (2003). Automated Ambulatory Blood-Pressure Monitoring: Clinical Utility in the Family Practice Setting. **American Femily Physician**, 67(11), 2343-2350.
3. White, W.B. (1999). Ambulatory blood pressure as a predictor of target organ disease and outcomes in the hypertensive patient. **Blood Pressure Monitoring**, 4(3), 181-184

INTRODUCTION TO THE ri-cardio ABD-SYSTEM

Indication for Use

The **ri**-cardio is a non-invasive oscillometric blood pressure monitor capable of measuring systolic and diastolic blood pressures of adult patients (13 years or older). It is intended for use as an aid or adjunct to diagnosis and treatment.

Operation

The **ri**-cardio unit is worn by the patient on a waist belt and is connected to a cuff around the non-dominant upper arm. The cuff is inflated automatically at intervals which can be programmed during setup. Blood pressure is measured by the oscillometric method which senses pressure waves in the artery when occluded by pressure in the cuff. Measurement of the frequency of the pressure waves enables heart rate to also be measured.

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard, Electronic or Automated Sphygmomanometers.[1] The Korotkoff sounds heard over the artery below the compression cuff vary in character as the pressure in the cuff is reduced from above systolic toward zero or atmospheric pressure. They are divided into phases. Phase 1 (K1) or systolic begins with the sudden appearance of a faint, clear tapping or thumping sound that gradually increases in intensity. Phase 5 (K5) or diastolic begins when silence develops, and was used to determine overall efficacy of the **ri**-cardio.

Products and Accessories

Your **ri**-cardio package should contain the following items. If you are missing any item please contact **Rudolf Riester GmbH** (refer to Limited Warranty, for contact information)

ri-cardio 24-Hourbloodpressuremonitor
ri-cardio Software
2 Cuffs (Adult and Large Adult)
Pouch with Belt
USB Interfacecable
4 AA Alkaline Batteries
User Guide

SPECIFICATIONS

Method of Measurement:	Oscillometry with step deflation
Blood Pressure Range:	25-260 mmHg (max inflate 280 mmHg)
Heart Rate Range:	40-200 bpm
Accurary:	Clinically validated to ESH International Protocol, BHS (A/A), ANSI/AAMI (SP10)
International Standards:	EN 60601-1, EN 60601-2-30, EN 60601-1-2 (EMC), EN 1060-1, EN 1060-3, "Non-Invasive Sphygmomanometers -General Requirements& Supplementary Requirements For Electro-Mechanical BP Measuring Systems", AAMI SP10 ES1 category C' (battery powered)
Operating Conditions:	10°C (50°F) to 50°C (122°F) 20-95% RH non-condensing
Power:	Two "AA" alkaline batteries or high capacity rechargeable batteries (NiMH)
Data Memory:	Flash memory stores up to 250 readings
Calibration:	Minimally, once every two years
Safety Systems:	Maximum inflation pressure limited to 300 mmHg; Auto safety release valve for power failure; Maximum BP measurement time limited to less than 140 seconds
Sampling Periods:	3 independently programmable periods (5, 10, 15, 20, 30, 45, 60, 90 and 120 minutes)
Size:	120 x 70 x 32 mm
Weight:	Approx 284 g (including batteries)
Storage Conditions:	-20 °C bis +65 °C, 15%-90% RF non-condensing
Data Connection:	USB (RS232-option)

SAFETY AND EFFECTIVENESS CONSIDERATIONS

The following safety and effectiveness issues are to be considered prior to the usage of the **ri**-cardio unit.

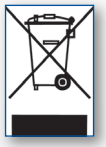
- This device is defibrillator protected.

NOTE:
No precautions specific to the **ri**-cardio are required during defibrillation, and defibrillation discharge has no effect on the **ri**-cardio.

- The monitor is intended for use following consultation and instruction by a physician.
- The reliability of the device is dependent upon conformance with the opera tion and service instructions, as detailed in this manual.
- This device has been designed for use on patients with normal sinus rhythms.
- The interpretation of blood pressure measurements should only be made by a physician. The accuracy of any blood pressure recording may be affected by the position of the subject, his or her physical condition, and use outside the operating instructions detailed in this manual.
- Safety and effectiveness on pregnant women and neonates have not been tested.

Disposal

This symbol indicates that the monitor contains materials (such as electrical components) which are hazardous. Used electrical and electronic devices should not be thrown away with the regular trash but rather should be disposed of separately in accordance with national and/or EU guidelines.



Adverse Reactions

Allergic exanthema (symptomatic eruption) in the area of the cuff may result, including the formation of urticaria (allergic reaction including raised edematous patches of skin or mucous membranes and intense itching) caused by the fabric material of the cuff.
Petechia (a minute reddish or purplish spot containing blood that appears in the skin) formation or Rumple-Leede phenomenon (multiple petechia) on the forearm following the application of the cuff, which may lead to Idiopathic thrombocytopenia (spontaneous persistent decrease in the number of platelets associated with hemorrhagic conditions) or phlebitis (inflammation of a vein) may be observed.

	**Meaning of the symbol on the type plate Caution! Observe accompaying documents!**
	**Start**
	**Stop**
	**Latex-free**
	**PVC-free**

WARNINGS AND CONTRAINDICTIONS

Precautions for Use
This monitor is designed to perform in conformity with the description contained in this manual when operated, maintained and repaired in accordance with the instructions provided. The monitor should not be modified in anyway. Ensure pressure compatibility to all patients. If any abnormality occurs in the monitor, suspend the operation immediately and disconnect it from the patient. If the monitor has been used or stored outside of its acceptable range (see Specifications page), it may not meet performance specifications. If the cuff fails to deflate, the patient should be instructed on its proper and safe removal.

DO NOT use in the presence of flammable anesthetics; this could cause an explosion.

DO NOT immerse the monitor in any fluid, place fluids on top, or attempt to clean the unit with any liquid detergents or cleaning agents. This may cause an electrical hazard. If accidental wetting occurs, please return to **Rudolf Riester GmbH** (see Limited Warranty). Refer to Maintaining and Cleaning the **ri**-cardio System, for care instructions.

DO NOT remove unit covers. The monitor does not contain any user serviceable components.

DO NOT use the monitor if it has failed its diagnostic self test, or if it displays a greater than zero pressure with no cuff attached. The values displayed by such a unit may be inaccurate.

DO NOT use on neonates or children, and patients known to be readily susceptible to bruising.

DO NOT attach the cuff to a limb being used for IV infusions or any other intravascular access, therapy or an arterio-venous (A-V) shunt. The cuff inflation can temporarily block blood flow, potentially causing harm to the patient.

CAUTION: Substitution of a component different from that supplied may result in measurement error. Repairs should be undertaken only by personnel trained or authorized by **Rudolf Riester GmbH**.

CAUTION: If cuff fails to deflate within two and a half minutes, instruct the patient on manual removal of cuff.

CAUTION: Check that operation of the unit does not result in prolonged impairment of the circulation of the patient.

CAUTION: A compressed or kinked connection hose may cause continuous cuff pressure resulting in blood flow interference and potentially harmful injury to the patient.

WARNING: Ensure batteries are inserted with the correct polarity. Improper installation is a hazard.

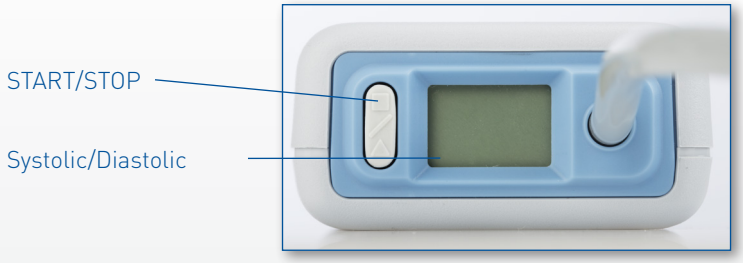
WARNING: Too frequent measurements can cause injury to the patient due to blood flow interference.

WARNING: The cuff should not be applied over a wound as this can cause further injury.

WARNING: The cuff should not be placed on the arm on the side of a mastectomy. In the case of a double mastectomy use the side of the least dominant arm.

WARNING: Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.

ri-cardio AT A GLANCE



Start/Stop Button:	**TO POWER ON:** When the monitor is off, press the Start/Stop button. **TO POWER OFF:** When the monitor is on but not taking a reading, press and hold the Start/Stop button until you hear five quick beeps, then release. **TO ABORT A MEASUREMENT:** When the monitor is taking a reading and the cuff pressure is displayed, press the Start/Stop button. **TO START THE PROGRAMMED ABP STUDY:** When the time is flashing, press the Start/Stop button. **TO START A SINGLE BP READING:** When the time is displayed, press the Start/Stop button.
Time:	Indicates current time; when flashing, the monitor will turn off in the next 20 seconds unless an ABP study is started.
Pressure:	Indicates the pressure of the cuff in mmHg during a BP reading.
BD-Reading:	Immediately after a BP reading, the display shows the results of the reading if enabled. Blood pressure in mmHg followed by heart rate in beats per minute.
Battery:	Indicates low battery voltage; BATTERIES NEED TO BE REPLACED.

SETTING UP THE SYSTEM

Installing the Software

NOTE:
If a previous version of ri-cardio Software is already installed, we recommend backing up any previously collected patient files before upgrading.

Place the installation CD in the CD drive located on your computer. If CD autoplay is enabled on your computer, follow the instructions that appear on your screen.

If autoplay is not enabled, follow these steps:

1. Open Windows® Explorer or Windows® NT Explorer (Press the Windows® "Start" button and find "My Computer" or "Computer").
2. Click on the CD drive.
3. Double-click the AUTORUN.EXE file.
4. Follow the instructions on the screen.

NOTE:
The USB cable should not be connected to the computer before ri-cardio Software is installed.

SETTING UP THE SYSTEM

Powering the ri-cardio for use

Install 2 AA batteries in the bay located at the back of the monitor. The label in the bay shows the orientation in which the batteries should be placed. When batteries are properly loaded, the monitor's display will show the following:

1. Incrementing dashes for two seconds
2. Software and safety version of the monitor
3. Battery voltage for two seconds
4. Three quick beeps
5. The number of BP readings in memory with flashing printer for three seconds
6. One long beep
7. Time flashing for twenty seconds

The monitor is now ready to be used.

Installing the Software

The **ri**-cardio Software components include:

- **ri**-cardio Software User´s Guide
- **ri**-cardio Software CD
- **ri**-cardio USB cable

Place the installation CD in the CD drive located on your computer and follow the instructions appearing on the screen if CD autoplay is enabled on your computer.

If autoplay is not enabled, follow these steps:

1. Open Windows Explorer or Windows NT Explorer (Press the Windows "Start" button and find "My Computer")
2. Click on the CD drive
3. Double click the AUTORUN.EXE file
4. Follow the instructions on the screen

CONDUCTING AN AMBULATORY BLOOD PRESSURE STUDY

Communtication withe the ri-cardio

To successfully complete an ABP study, you need your computer to be able to communicate with your ABP monitor in order to program it and retrieve data from it.

Connecting the monitor to your computer

1. Connect the PC interface USB cable to the connection site at the bottom of the ABP monitor (Fig. 1).
2. Connect the USB end of the PC interface cable to the USB port on the back of your computer (Fig. 2).

Configuring your computer for communication

Installing **ri**-cardio Software will load the driver(s) for the USB cable. Once the cable is connected to the PC, **ri**-cardio Software will recognize the cable and auto-select it as the connection to the monitor (Fig. 3).

Fig. 1

Fig. 2

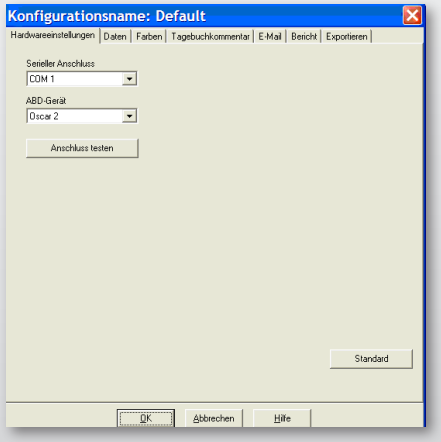


Fig. 3:
Configure Port

PROGRAMMING THE ri-cardio FOR AN ABP STUDY

To prepare the monitor for an ABP study, simply fill out an on-screen form to set the parameters for your patient to be programmed into the monitor.

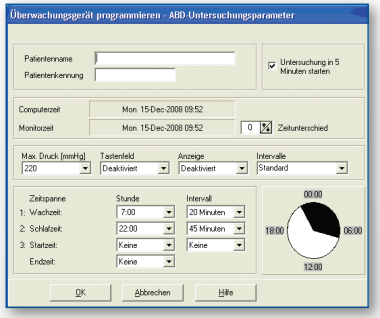


Fig. 4

1. Select the Program button on the toolbar or Program study under Monitor in the menu bar.
2. Enter the settings in the form (Fig. 4). Fields are described below.
3. Programming begins when OK is clicked.
4. An indicator bar shows the progress as the data is transferred to the monitor and disappears when programming is successfully completed.

The test parameters can be adjusted as follows:

Patient name and ID:
For reporting and referencing data.

Start study in 5 minutes:
Check denotes that the study will start automatically after programming; unchecked denotes that the first push of the Start/Stop button with unit powered on will start the study.

Time zone difference:
Adjust the monitor's clock to the time zone that the patient is in relative to your time zone.

Max Pressure:
60 to 280 mmHg; suggested setting is 30 mmHg above the highest expected systolic BP.

NOTE:
The ABP monitor will not inflate to Max Pressure with each reading; it inflates to 30 mmHg above the previous systolic reading.

Keypad:
Enabled will allow the patient to start readings.

Display:
Enabled will allow the patient to view the results immediately after a measurement.

Note:
Keypad and Display are always enabled for the first 30 minutes of a study.

Intervals:
Set intervals between programmed readings to Standard for +/- 5 minutes around selected times or Fixed for exact times. 5 and 10 minute intervals are always exact.

Time Periods:
Up to 3 allowed.

Time Intervals:
None, 5, 10, 15, 20, 30, 45, 60, 90 and 120-minute intervals between readings.

FITTING A PATIENT WITH THE ri-cardio AND BLOOD PRESSURE CUFF

After you have successfully programmed the **ri**-cardio using **ri**-cardio Software, you may begin fitting the patient with the monitor and a blood pressure cuff. Cuffs may be used on either arm.

1. Choose the proper cuff size

To determine the correct cuff size for your patient, wrap the cuff around the patient's upper arm. Use the color-coded RANGE indicator on the inside of the cuff and the bold INDEX marker to check that the arm circumference falls within the cuff range. If the arm is within range, this cuff size is correct for your patient. If the measurement is outside the RANGE indicator, select a new cuff size as indicated by color.

IMPORTANT:
Using an incorrect cuff size could result in erroneous and misleading blood pressure measurements.

2. Apply the cuff

The cuff should be midway between the elbow and shoulder. Be sure the ARTERY indicator is over the patient's brachial artery, between the bicep and tricep muscles. Wrap the cuff snugly around the patient's upper arm. Please make sure that the arm is inserted through the cuff.

3. Connect the hoses

Connect the hoses from the cuff and monitor by twisting the fittings together until you hear a snap. Drape the hose over the patient's shoulder, around the neck and across the opposite side of the body.

4. Attach to patient

Insert the Bravo into its pouch with the display visible. Attach the pouch to the patient using the belt.

5. Begin BP reading

To verify proper monitor operation, ensure that the monitor is on and start a BP reading by pressing the Start/Stop button. If problems occur, review the setup and fitting of the system or consult Troubleshooting for tips.

PREPARING AND EDUCATING THE PATIENT

When conducting blood pressure measurements, including hypertension blood pressure measurements, with an oscillometric NIBP device, it is important to follow suitable procedures to ensure valid, accurate results. Preparing your patient for the ABP study is the most important step to achieving a successful test. Review the following instructions with your patient.

- When the pressure in the cuff increases, the patient should avoid excess movement during measurements. Let the cuffed arm hang loosely, slightly away from the body with the middle of the cuff at heart level. Avoid flexing the muscles or moving the hand and fingers of the cuffed arm.
- The patient can stop a measurement in progress by pressing the Start/Stop button.
- If the keypad is enabled when programmed, the patient can start a measure ment at any time by pressing the Start/Stop button.
- Between BP readings the cuff should not be removed.
- While sleeping, the patient should make sure that the hose is not kinked.
- The batteries can be replaced during a study without the data being lost or interrupting the monitor's program. Alternatively, the monitor can be turned off without losing its data.
- Instruct the patient on how and when to fill out the patient diary.
- Ensure the patient knows how to care for the monitor. Keep the monitor dry and do not drop it.
- If the monitor or cuff causes extreme pain or pain not normally associated with blood pressure measurement, the patient should remove the cuff and turn off the monitor.
- The patient should not talk during the BP measurements.
- The patient should be seated, standing or lying down. If the patient is seated, they should have their legs uncrossed, feet flat on the floor with their back and arms supported.

Starting the study

Before the patient leaves with the monitor and cuff correctly instrumented, verify that the monitor operates correctly.

ri-cardio
PREPARING AND EDUCATING

FINISHING THE STUDY

If you wish to finish the study before the patient returns, instruct the patient to turn off the monitor by holding down the Start/Stop button for 5 seconds. The Bravo will beep 5 times and the display will turn off. When the patient returns, take the cuff, monitor, and belt off.

Notes on blood pressure data

Any blood pressure reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition. Environmental or operational factors which can affect the performance of the device and/or its blood pressure reading are common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, patient motion, trembling, and shivering.

Before retrieving data from the monitor, ensure that the monitor is disconnected from the patient before connecting the ABP monitor to any piece of hardware such as your personal computer.

To retrieve the data

1. Click on the Retrieve toolbar button, or pull down the Monitor menu and select Retrieve Data.

2. Communication starts automatically. The dialog box on the screen shows the progress as the data is transferred.

3. After completion, a dialog box asks if this is a new patient. If you click No, a list of current patient files will appear (Fig. 8). Select the patient file to save the retrieved data.

4. If you click Yes, the Patient information dialog box (Fig. 9) will appear. Enter patient information in the data fields.

5. Click the OK button to save the data.

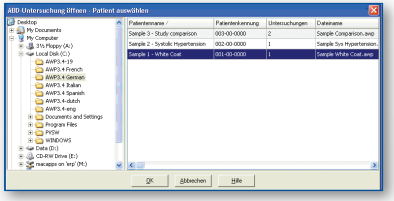


Fig. 8: Retrieving data, choosing patient

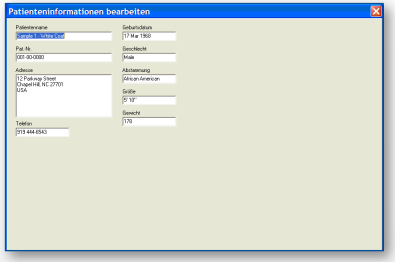


Abb. 9: Retrieving data, patient information

The patient's BP data is now saved as a file on your computer. The ABP Data tab displays the retrieved data. The patient's name, ID#, test date, file name and its location are displayed in the status line located at the bottom of the display area.

NOTE:
If you do not retrieve data from the monitor, this data will be lost when you program it for the next study.

ri-cardio
FINISHING THE STUDY

TROUBLESHOOTING

Event Code	Description in ri-cardio Software:	Solution:
1	Weak or no oscillometric signal	Check position of cuff, tighten cuff.
2	Artifact/Erratic Oscillometric Signal	Remain still during BP reading.
3	Exceeded retry count (4 inflate attempts)	Remain still during BP reading.
4	Exceeded measurement time	Check air hose connections and make certain cuff is tight.
85	Reading Aborted (blocked valves or pneumatics)	Check air hose connections and make certain air tubing is not crimped.
86	Reading Aborted (user abort)	Push START/STOP button to restart readin
87	Reading Aborted (inflate time-out or air leak)	Check air hose and cuff.
88	Reading Aborted (Safety time-out)	Retry reading, push START/STOP button. If problems persist, return unit for servicing.
89	Reading Aborted (cuff over-pressure)	Check for blocked or kinked air hose.
90	Service Required (power supply out-of-range or other hardware problem)	Replace batteries. If problem persists, return unit for servicing.
91	Service Required (safety override fitted or autozero out-of-range)	Retry by pushing START/STOP button. If problems persist, return unit for servicing
97	Service Required (transducer out-of-range)	Return for servicing.
98	Service Required (A/D out-of-range)	Return for servicing.
99	Service Required (EEPROM calibration data CRC failure)	Unit needs to be recalibrated. Return for servicing.

MAINTAINING AND CLEANING THE ri-cardio

After use, it is important to perform preventative maintenance to ensure the safe and efficient operation of the monitor.

Cleaning after use

The **ri**-cardio unit is not sterilizable. DO NOT immerse the monitor in any fluid, or attempt to clean with any liquid detergents, cleaning agents, or solvents. You may use a soft, damp cloth to remove dirt and dust from the monitor. If the unit does become immersed in water, do not use; contact our service department.

You may use a mild disinfectant solution to clean the cuff, belt, and pouch. Alternatively, you may also wash these items in a washing machine. Remove the bladder from the cuff before machine washing. Wash these items using warm water and a mild detergent; if needed, hang to dry.

Maintenance after use

Visually inspect cables, pneumatic hoses, and the monitor case for cracks, fraying, or kinks. DO NOT use the monitor if there are any signs of damage. Please contact our service department.

Maintenance

It is recommended that you check the accuracy of the **ri**-cardio once every two years. If needed, an authorized **Riester** service center may need to recalibrate the pressure transducers in the monitor.

CHECKING THE CALIBRATION

The **ri**-cardio must first be placed into the proper mode. Follow the steps below:

1. Remove and then replace one of the two "AA" batteries.
2. While the LCD is displaying the dashes, press and hold down the START STOP key.
3. The unit will display the software version.
4. The unit will display the battery voltage.
5. You will then hear a click as the valves are closed.
6. You will now see "0 mmHg" displayed.

The calibration of the unit can now be checked against a calibrated mercury column.

1. Place a t-tube (part #98-0030-00) between the hose from the monitor and the cuff.

2. Wrap the cuff around a suitably sized can or bottle. This simulates the upper arm.

3. Attach the third end of the "T" tube into a calibrated mercury column, which gives you access to the bulb and a reference.

4. Using the bulb of the calibrated mercury column, inflate the cuff to 250 mmHg. Once the pressure has stabilized at this level, the LCD should match the mercury column by ±2.0 mmHg.

5. Check the unit against the column every 50 mmHg from 250 to 50 mmHg and the unit should be within ±2.0 mmHg. If not, the unit needs to be returned to the service department for recalibration or repair.

NOTE:
To return the **ri**-cardio to its normal mode, remove and replace one of the batteries.

The **ri**-cardio does not contain any user serviceable internal parts and should only be opened by an authorized service representative. To return for service, please send to **Rudolf Riester GmbH**, care of Support and Service.

LIMITED WARRANTY

ri-cardio **Ambulatory BP Monitor**

Rudolf Riester GmbH provides to the original purchaser the following limited warranty from the date of invoice.

Blood pressure serialized monitor	24 months
Accessories (i.e. patient hoses, interface cables, etc.)	90 days
Cuffs	12 months

Rudolf Riester GmbH warrants each instrument to be free from defects in material and workmanship. Liability under this warranty covers servicing of the instruments when returned from the customer's facility prepaid to the prospective factory depending on location. **Rudolf Riester GmbH** will repair any component(s) or part(s) that it finds to be defective during the period of this limited warranty. Should a defect become apparent, the original purchaser should notify **Rudolf Riester GmbH** of the suspected defect. The instrument should be carefully packaged and shipped prepaid to:

Rudolf Riester GmbH
P.O. Box 35
Bruckstraße 31
DE - 72417 Jungingen
Germany

The instrument will be repaired in the shortest possible time and returned prepaid by the same shipping method as received by the factory.

This limited warranty is void if the instrument has been damaged by accident, misuse, negligence, or serviced by any person not authorized by **Rudolf Riester GmbH**.

This limited warranty contains the entire obligation of **Rudolf Riester GmbH**, and no other warranties expressed, implied, or statutory are given. No representative or employee of **Rudolf Riester GmbH** is authorized to assume any further liability or grant any further warranties except as set herein.

ri-cardio
LIMITED WARRANTY

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Guidance and manufacturer's declaration – electromagnetic emissions		
The Rudolf Riester GmbH 222B is intended for use in the electromagnetic environment specified below. The customer or the user of the The Rudolf Riester GmbH 222B should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Rudolf Riester GmbH 222B 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	N/A	The Rudolf Riester GmbH 222B uses batteries only and is not connected to mains.
Harmonic emissions IEC 6100-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Rudolf Riester GmbH 222B is intended for use in the electromagnetic environment specified below. The customer or the user of the The Rudolf Riester GmbH 222B 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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	N/A	N/A	
Surge IEC 61000-4-5	N/A	N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	
Power frequency (50/60 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 commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

The Rudolf Riester GmbH 222B device is intended for use in the electromagnetic environment specified below. The customer or the user of the Rudolf Riester GmbH 222B device 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 Radiated RF IEC 61000-4-3	N/A 3V/m 80 MHz to 2.5 GHz	N/A 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the SunTech 222B, 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] √P d = [3.5/E1] √P 80MHz to 800MHz d = [7/E1] √P 800MHz to 2.5GHz 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 electromagnetic 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 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.

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 SunTech 222B device is used exceeds the applicable RF compliance level above, the Rudolf Riester GmbH 222B device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Rudolf Riester GmbH 222B device. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the SunTech 222B device

The Rudolf Riester GmbH 222B device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Rudolf Riester GmbH 222B device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Rudolf Riester GmbH 222B device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = [3.5/V1] √P	80 MHz to 800 MHz d = [3.5/E1] √P	800MHz to 2.5GHz d = [7/E1] √P
0.01	N/A	0.12	0.23
0.10	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23

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.

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