Zimmer
MedizinSysteme

Instructions for Use

PremoPort*Four*

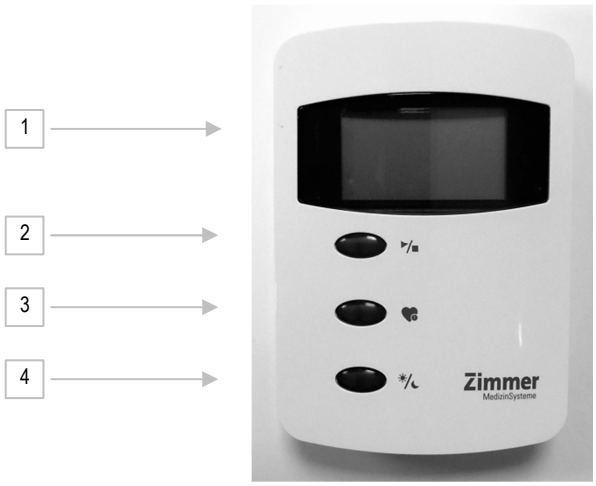
EN

Figure

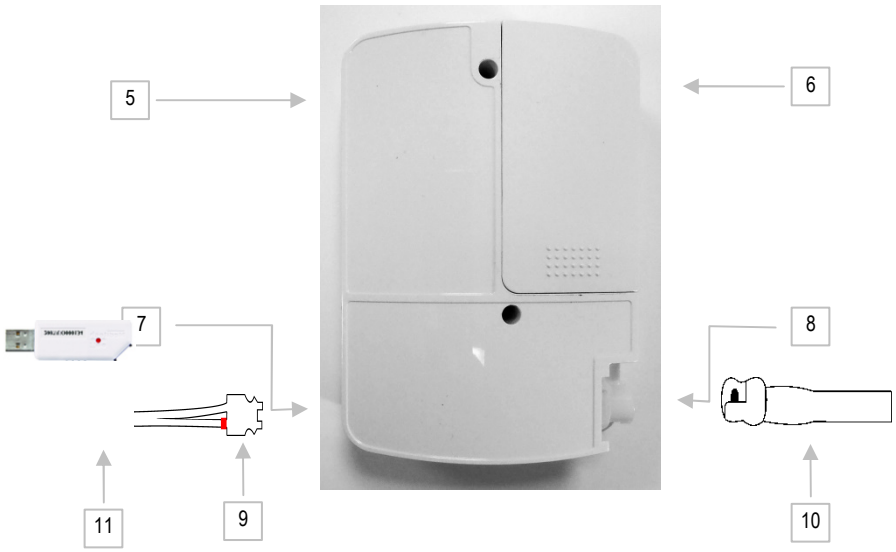
Views / Operating elements

Views

Front



Back with accessories



Operating elements

Front

1	LCD display
2	Start/Stop button
3	Event button
4	Day/Night button

Back

5	Identification plate
6	Battery compartment

Side

7	Fibre optic cable connection
8	Cuff connection

Accessories

9	Fibre optic cable
10	Cuff with bayonet connection
11	USB fibre optic converter

Schematic illustration

Accessories

Accessories*

Image	Art. no. *	Number	Description
	56,200,21	1	Blood pressure cuff, regular
	56,200,31	1	Blood pressure cuff, large
	56,200,270**	1	Fibre optic cable 2-core,
	56,200,260**	1	USB fibre optic converter
	56,200,410	1	Device pouch with shoulder and hip strap
	87,921,001	4	Battery 1.2 V type AA
	56,310,955**	1	Battery charging device

(*Subject to technical changes)
(**Optional accessories depending on version and design)

Brief start-up instructions

Switch on PremoPort *Four*

Hold down the Start/Stop button for at least 5 sec. The device is switched on when the time appears on the LCD display. (e.g. 13:21)

Check voltage

Hold down the Start/Stop button for at least 5 sec. but less than 10 sec. While the button is held down, the voltage is displayed (e.g. 2_23 corresponds to 2.23 V). Prior to starting measurements, this must be more than 2.5 V in the case of rechargeable batteries and more than 3 V in the case of alkaline batteries.

Connect PremoPort *Four* with the PC

- Find a free USB connection on the PC and insert the USB fibre optic converter (11) into it.
- Connect the fibre optic cable (9) to the USB fibre optic converter (11). Ensure that the red mark on the cable matches the red mark on the USB fibre optic converter (11).
- Connect the other end of the fibre optic cable (9) with PremoPort ***Four*** by inserting the small plug into the fibre optic cable connection (7) on the device. Be aware that the red mark on the cable is located on the bottom of PremoPort ***Four***.

Interface configuration

Start the analysis software Diagnostik*Suite* on the PC and check and correct the interface configuration in Diagnostik*Suite*, if necessary.

Select patient

Select the entry “Open” in the navigation area. Double-click to select the desired patient.

Prepare examination

In the navigation area, open the “**New**” tab and, for a new ambulatory blood pressure measurement, select “Prepare measurement”.
Transfer the patient data and the measurement plan to the PremoPort ***Four***.

Record data

Disconnect the recorder from the PC.

Place cuff and device

Place the cuff with PremoPort ***Four*** on the patient. When placing the cuff, ensure that the tube extends upwards and is guided behind the neck. Connect the cuff to PremoPort ***Four***. Start a manual measurement to test the function of the blood pressure monitor.

Instruct patient

Instruct the patient on correct behaviour during the measurement and how to operate the device properly.

Take back device, read in measurement data

After recording the examination, disconnect the cuff from the patient and recorder and connect the recorder to the computer.

- Start Diagnostik*Suite* and open the patient.
- In the “**New**” tab of the navigation area, select “Read measurement” in order to read the new examination into Diagnostik*Suite*.
  After the data are transferred, they are displayed on the screen. To save, press the “**Save**” button.

Switch off the examination device(s) and remove all accessories, such as the blood pressure cuff, from the patient.

Explanation of symbols

	In the instructions for use this symbol indicates “Danger”. Observe the warnings.
Caution!	In the instructions for use this symbol indicates **“Caution” with regard to possible damage of the device**.
CE 0123	CE mark according to MDD (93/42/EEC)
	Applied part type CF according to EN 60601-1
	Note instructions for use
SN	Serial number
REF	Item number
	Manufacturer
	Date of manufacture
	Start/Stop button
	Event button
	Day/Night button
◄Fibre optics	Fibre optic cable connection
Cuff►	Cuff connection

Table of contents

Table of contents

Valid for PremoPort ***Four***.

These instructions for use are an integral part of the device. They must be stored with the device and kept accessible at all times for anyone authorised to operate this device.

Last updated: May 2017

1. Background medical information

Clinical preconditions

Ambulatory blood pressure measurement (ABPM) over a 24-hour period is an important instrument nowadays for the diagnosis and treatment of hypertension. As a result of the relatively high measurement density of about 70 measurements over 24 hours, the reliability of the evaluation of the true blood pressure level increases significantly in comparison to individual measurements. The following, among others, can be recorded by means of ABPM:

- The average blood pressure level,
- Blood pressure fluctuations and blood pressure variability,
- Increases in blood pressure which occur only in a clinical setting (office hypertension),
- The lack of or a decrease in the normal blood pressure decrease at night,
- Unusual blood pressure increases (e.g. in the morning) or decreases.

Measurement algorithm

Blood pressure measurement in adults using the PremoPort ***Four*** is equivalent to that performed by a trained and experienced person with a cuff and stethoscope using the auscultatory method according to Korotkoff, phase V, within the limit defined in the national American standard for electronic and automated sphygmomanometers.

The algorithm also meets the requirements of the protocol for automated blood pressure monitors of the British Hypertension Society. (The algorithm in PremoPort ***Four*** corresponds to that of the Meditech ABPM-04 device which achieved a quality class of B for systolic and diastolic accuracy. The validation study was published in Blood Pressure Monitoring 1998; 3(6):363-8 by I Barna & al).

1.1 Indications / Contraindications

Indications

The following indications are listed in the guidelines of the European Society of Hypertension for ambulatory blood pressure measurements (2003):

- Suspected white coat hypertension
- Suspected nocturnal hypertension
- Determination of nocturnal decrease in blood pressure
- Treatment-resistant hypertension
- Elderly patients
- As a guideline for drug treatment with antihypertensives
- Type 1 diabetes
- Hypertension during pregnancy, including patients with preeclampsia
- Assessment of hypotension
- Autonomic disorders

Contraindications

- Uncooperative patients, unconscious patients or patients with other limitations.
- Patients who require urgent or emergency cardiac treatment.
- Patients with coagulation disorders (for ambulatory blood pressure monitoring).
- Patients with severe impairment of mobility or other functions without monitoring.
- Unsupervised children or children under 8 years of age.
- Although the algorithm for blood pressure measurement in PremoPort ***Four*** has proven reliable in patients with atrial fibrillation or other common rhythm disturbances, the oscillometric blood pressure measurement is generally recommended only with particular caution in patients with rhythm disorders, Parkinson's disease or other diseases which are accompanied by tremors.

1.2 Side effects

Side effects

- Just as in the case of office blood pressure measurements, there can be petechial haemorrhages despite correct positioning of the cuff. These petechial haemorrhages are independent of the type of measurement device used.
- The safety and efficacy in children and pregnant women has not yet been quantified!

Take note of the indications, contraindications and side effects listed in the medical literature as well.

2. Application information

Prior to using the device on a patient, the user should become familiar with the instructions for use and individual treatment methods to be used as well as the indications / contraindications, warnings and application information. Additional sources of information about the diagnosis and treatment should be followed.

Caution !

Inspect the device before use. If there is any damage, it must not be used.

Caution !

Only accessories provided by Zimmer MedizinSysteme GmbH may be used.

Caution !

Operation of this device in the vicinity of strong electromagnetic fields (e.g. tomographs, x-ray or diathermy equipment) may interfere with the operation of the device. Please keep a safe distance of several meters.

Caution !

PremoPort ***Four*** is not suitable for use in areas with an explosive, flammable or combustive environment.

Caution !

The device may cause malfunctions or may interfere with the operation of equipment in the vicinity by electromagnetic effects. It may be necessary to take appropriate remedial action, such as realignment, re-arrangement of the device or install electromagnetic shielding.

Occurrence of discomfort during the recording

Inform your patient that any measurement can be immediately interrupted by pressing any button. The interruption causes an immediate decrease in pressure in the cuff. Events of this type should be reported to the physician no later than after the monitoring.

Cuff incorrectly placed

Ensure correct positioning of the shoulder strap and the cuff tube. Incorrect positioning can result in strangulation.
The physician should inform the patient that the cuff should only be worn on the upper arm. It should be ensured in any case that neither the shoulder strap nor the pressure tube can ever become wound around the neck. For this reason, the air tube should always be placed under outer clothing (including at night).

Placing the cuff

It is recommended to always place the cuff over a thin item of clothing. This helps to avoid any possible problems caused by longer periods of wear (such as sweating or itching).

3. Warnings

Users of the device must be trained in how to use the system properly and have the appropriate skills.

Use in wet areas is not permitted and may in case of non-compliance lead to considerable damage and endanger both the patient and the user.

Dispose of the packaging material properly. Make sure that it is not accessible to children.

Remove batteries from device if it is not used for a long period of time.

The use of the device outside of the settings or applications specified in the instructions for use may lead to hazards to the patient.

Patients may not be connected to a high-frequency surgical device at the same time. This can lead to burns.

General safety information

- PremoPort ***Four*** may only be operated in accordance with these instructions for use. All other applications are the responsibility of the operator.
- For maintenance measures, expansions, readjustments or modifications, the provisions of the German Medical Devices Act and the Medical Device Operator Ordinance apply.
- According to the Medical Device Operator Ordinance, medical devices may be set up, operated and used only by persons who have the necessary training or knowledge and experience to do so.

Safety information for setup and installation

- Prior to putting the device into operation, the connection cables should be checked for damage. Damaged cables must be immediately replaced.
- The environmental conditions indicated in the “Technical information” chapter must be observed.
- Conventional computer and PC screens which do not correspond to EN 60601-1 may not be set up in the vicinity of the patient. The minimum distance to the patient must be 1.5 m.
- PremoPort ***Four*** must not be operated in rooms where there is a risk of - explosion.
- For reasons of functional safety, diagnostic devices should not be operated in the vicinity of devices which generate large electromagnetic fields, such as X-ray or diathermy equipment or MRI machines. A minimum distance of 5 m must be ensured. Protective measures such as shielding wallpaper, shielding plaster or shielding curtains can reduce this distance.

Connection with other devices

- Additional equipment connected to the analogue and digital interfaces of the PC must demonstrably meet its corresponding EN specifications (e.g. EN 60950 for data-processing devices and EN 60601 for electromedical devices). In addition, all configurations must satisfy the system standard VDE 0750 part 1-1. Devices may only be connected to each other or with parts of systems if it is ensured that the safety for the patient, the user and the environment is not impacted by this coupling.
- Provided that safe coupling is not readily apparent from the device data, the user must determine, by contacting the respective manufacturers or inquiring with a qualified person, that the necessary safety for the patient, the user and the environment is not impaired by the intended coupling. Standard IEC 601-1-1 / EN 60601-1-1 must be complied with in any case.
- Only the original blood pressure cuff and the fibre optic connection cable from Zimmer MedizinSysteme may be used.

- The use of components which are not included in the scope of delivery or not approved by Zimmer MedizinSysteme for PremoPort ***Four*** may lead to measurement errors and malfunctions.

Hazards to persons

- The device should never be connected to a PC or other devices while it is still placed on the patient.
- PremoPort ***Four*** should not be used if any of the contraindications applies (see chapter “Background medical information / Contraindications”).
- The device should also not be used for patients without a corresponding indication for ambulatory blood pressure monitoring.

Information about blood pressure measurement

- Prior to each use of the PremoPort ***Four***, the user must ascertain its functional safety and proper operating condition.
- Ensure that air circulation in the cuff and in the tube are not obstructed since this can lead to circulation problems with serious injury to the patient. The pressure tube should never be knotted, compressed or pulled apart between PremoPort ***Four*** and the cuff.
- Ensure that neither the cuff nor the connection tube nor the connection cable leads to strangulation or circulation problems.
- If blood pressure measurements cause bruises, dizziness or pain in the arm, the cuff should be removed from the arm and disconnected from the recorder. Events of this type should be reported to the physician no later than after the monitoring.
- If the patient should experience dizziness or pain in the arm after ending a blood pressure measurement, the cuff should be removed to avoid permanent vascular or neural injuries.
- A physician should always be consulted for the interpretation of blood pressure measurements. Be aware that any blood pressure measurement can be affected by the patient’s body position, physiological constitution or other factors.
- Overly frequent measurements can cause injury to the patient due to circulation problems.
- Never place the cuff over a wound since it can cause further injury.
- Be aware that the placement and inflation of the cuff on any body part with intravascular access or intravascular therapy or arteriovenous (AV) shunt can lead to injury to the patient due to occasional interruption of blood flow.
- The cuff should not be placed and inflated on the arm on the side of a mastectomy.
- Check (for example, by observing the affected extremity) that operation of

the device does not lead to longer periods of impaired blood circulation of the patient.

Protection against electrical shock

The ambulatory blood pressure recorder meets the relevant standards for protection against the risk of electrical shock. PremoPort ***Four*** works with two 1.5 V AA disposable batteries or two 1.2 V AA rechargeable batteries. This excludes any hazard due to electrical shock, even in the unlikely case in which several device errors occur simultaneously. Use exclusively standard long-life alkaline batteries or standard NiCd or NiMH batteries of the appropriate size. Do not use lithium batteries. Do not mix battery types under any circumstances, do not mix new and old batteries and do not use any defective batteries.

Safety distance to computer

Many personal computers (PC) do not comply with certain standards to protect against the risks of electrical shock or the strict safety regulations for medical devices. Zimmer MedizinSysteme recommends a safety distance of at least 2 meters between the patient and PC while PremoPort ***Four*** is connected to the PC. PremoPort ***Four*** communicates with an optical plastic cable whose 4 m standard length allows the required safety distance. The optical plastic cable ensures optimal galvanic separation and reduces the effects of external electronic interferences. It does not conduct any electricity.

Hazardous substances

Used batteries are classified as hazardous waste and should be accordingly - disposed of.
PremoPort ***Four*** does not contain any materials from pharmaceutical substances or tissues of animal origin. PremoPort ***Four*** does not emit any material or energy hazards for humans.

Risk of incorrect diagnosis

The fundamental intended use of the recorder is to record blood pressure and heart rate. Patients should be informed about the rules regarding cooperation, appropriate handling of the recorder and the expected monitoring results. PremoPort ***Four*** provides only data to support diagnostic decisions by a qualified physician. PremoPort ***Four*** itself does not make a diagnosis. When reviewing recorded blood pressure values, attention should be paid to possible artefacts and electronic interferences and they should be handled with care.

4. General description

4.1 Range of services

What is PremoPort *Four* used for?

PremoPort ***Four***, in combination with the Diagnostik*Suite* analysis software, is an ambulatory blood pressure measuring system (ambulatory blood pressure) for long-term monitoring of patients.

The PremoPort ***Four*** blood pressure monitor oscillometrically measures blood pressure in adjustable time intervals, saves the values determined and, after the measurement is completed, transfers them for further evaluation to the PC. The Diagnostik*Suite* software which runs on Windows ™ analyses and archives the measured values. Diagnostik*Suite* provides a blood pressure profile in graph and table form of all measurements as well as statistical evaluations.

Where is PremoPort *Four* primarily used?

- During the measurement of ambulatory blood pressure profiles.
- For clarifying and treating hypertension and hypotension as well as borderline hypertension and nephrological dysfunction.
- For monitoring antihypertensive therapy.

Please also take note of the corresponding medical literature.

What does PremoPort *Four* do?

PremoPort ***Four*** achieves excellent measurement quality and is favoured because of its fast and safe handling as well as high reliability.

What are the other benefits of PremoPort *Four*?

- Compact dimensions and lightweight for more than 24 hours of wear comfort
- Operates with just two disposable or rechargeable batteries
- Internal read-only memory
- Large LCD display and clear push-button operation
- Galvanically separated, optical data transfer to the PC via a USB port
- Possibility to start separate blood pressure measurements at any time
- Differentiation between active day and passive night phase as well as a special phase – such as to record the increase in blood pressure in the early morning.
- Can be set up for a new patient in just a few minutes
- The benefit can be significantly expanded through integration in practice management.

Note: *Also take note of the DiagnostikSuite instructions for use.*

Note: *The application of the device is reserved for medical professionals (such as physicians, therapists and health paraprofessionals).*

4.2 Intended use

PremoPort ***Four***, in combination with the Diagnostik*Suite* analysis software, is an ambulatory blood pressure measuring system for long-term monitoring of patients.

PremoPort ***Four*** should not be used for monitoring vital signs.

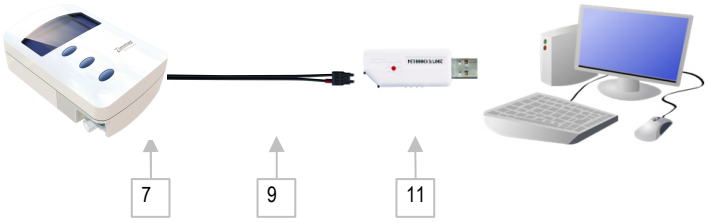
Not suitable for infants and small children.

5. Start-up

5.1 Interfaces

Fibre optic cable with fibre optic converter

PremoPort ***Four*** is connected to the PC via a fibre optic cable (9) with directly connected USB fibre optic converter (11). The PC must have a free USB connection.



Caution!

To guarantee the reliable function of the ambulatory blood pressure system, only additional devices and connection cables approved by Zimmer MedizinSysteme may be used.

5.2 Power supply

General

PremoPort ***Four*** blood pressure monitor works with two 1.5 V AA disposable batteries or two 1.2 V AA rechargeable batteries. Use only commercially available, long-life (alkaline) batteries or standard NiCd or NiMH rechargeable batteries in the correct size. Do not use lithium batteries. Do not mix different types of batteries and do not mix old and new batteries under any circumstances. Never use batteries of low or unknown quality since they may not meet the energy requirements of the recorder and they may destroy the recorder under certain circumstances because they may contain acidic electrolytes which could leak and allow the electronic components to corrode. Do not use defective batteries under any circumstances. Nonetheless, if the battery capacity should run down during an ambulatory recording, the batteries can be replaced. The monitoring will continue and the data will be preserved. If the recorder is not used, it is advised to remove the batteries, due to the minor but steady power consumption of the integrated components. The data in the recorder will not be lost even if the batteries are dead or removed. Used batteries are hazardous waste and must be accordingly disposed of.

Important

It is strongly recommended to use newly charged rechargeable batteries or new disposable batteries for each patient so that there is enough battery capacity for the complete monitoring – especially in the case of very high blood pressure values and/or longer periods of ambulatory measurements. After inserting the batteries in PremoPort ***Four***, it is advised to check their voltage prior to programming. Do not start any monitoring with batteries which have a low capacity. The typical voltage of two fully charged rechargeable batteries should be more than 2.5 V and that of new alkaline batteries should be more than 3 V. PremoPort shows you the voltage on the display.

Important

If a recorder is not used for a longer period of time, the internal battery cell, which powers the internal clock module, may be fully discharged. In this case, insert fresh main batteries in the device for at least one overnight period. The internal battery cell will be recharged as a result. During this time, the recorder can be used normally. If the internal battery cell contains too little energy, the internal clock may work incorrectly and during this time, the recorder would not be able to begin any measurement.

With one set of fully charged rechargeable batteries, PremoPort ***Four*** can record 250 to 300 blood pressure measurements during a 24- to 48-hour ambulatory blood pressure measurement.
Please observe the relevant product description when charging the rechargeable batteries.

Insert batteries

Take the PremoPort ***Four*** out of the pouch and remove the battery compartment lid on the back of the device. Insert two charged high-capacity rechargeable batteries or two new long-life disposable batteries in the battery compartment in accordance with the indicated polarity and close the battery compartment. If you decide to use alkaline batteries, select batteries with a high capacity and long life to enable reliable operation.

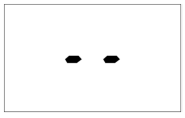
A narrow, struck-through battery symbol on the LCD display indicates a low battery voltage.

6. Operation instructions

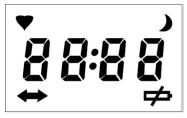
6.1 Displays

LCD display

The device has an integrated LCD display (1) on which the measurement results and various information is displayed. The most important information is listed below.



Two lines indicate that the recorder is switched off

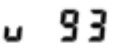


LCD test: All segments are shown

In normal status, the time is shown

During night-time operation, the time is shown together with the moon

Communication with the computer



Release of pressure during measurement; current pressure is displayed [mmHg]

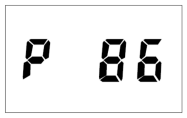
Starting cuff pressure during blood pressure measurements

Inflation during current blood pressure measurement

Heart symbol blinking at heart rate: Active measurement

Systolic value of the measurement which has just ended [mmHg]

Diastolic value of the measurement which has just ended [mmHg]

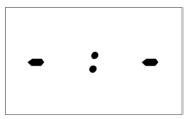


Pulse rate of the measurement which has just ended [beats per minute]

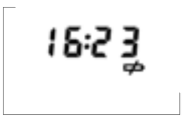
Blood pressure measurement discontinued by pressing a button

Battery voltage display (2.37 V)

Error display



Event marking with button



The struck-through battery symbol warns against a weak battery

In addition to the most important messages, there are situations, malfunctions or errors which are displayed with a certain code. These error codes are saved, transmitted with the measurement results to the computer and displayed in the Diagnostik*Suite* software. This helps service staff to better identify and correct the causes of errors or incorrect measurement results.

6.2 Buttons

Start/Stop button

The Start/Stop button is located nearest the LCD display and combines these functions:

Manual blood pressure measurement

If it appears necessary, the patient can start an additional manual blood - pressure measurement by briefly pressing the Start/Stop button. The result is marked as a manual measurement and is saved in the device. Reasons for an additional measurement: feeling of dizziness, pain (angina pectoris or headaches), palpitations.

Switch device off

Hold down the Start/Stop button for more than ten seconds. Release the button when two horizontal segments appear on the LCD display. PremoPort ***Four*** is now switched off. If you do not release the button within two seconds after the two horizontal segments are displayed, the recorder returns to normal operation. This function helps reduce the chance of inadvertently switching the device off. While the recorder is switched off, no other functions are available. The recorder can only be manually switched on.

Switch device on

PremoPort ***Four*** is switched on by pressing the Start/Stop button and holding it down for at least 3 seconds. If the device is switched off, no other functions are possible.

Checking the LCD display

Press and hold the Start/Stop button to illuminate and check all segments of the LCD display.

Checking the battery voltage

Press and hold the Start/Stop button for more than 5 seconds to display the battery voltage on the LCD display (e.g. 2_64 corresponds to 2.64 V). The volt display lasts as long as the button is held down, however, no more than 5 seconds. Then the device returns to the time display. The voltage of fully charged rechargeable batteries must be more than 2.5 V and more than 3 V in the case of alkaline batteries.

Event button

Mark an event

By briefly pushing the Event button, the patient can mark any event without a blood pressure measurement being necessary. Typical reasons for this are: Waking up, going to bed, taking medications, feelings of dizziness, palpitations, pain, athletic activities. The patient should be informed that he/she should note the reasons in an event block.

Day/Night button

Record going to bed and getting up

With the Day/Night button, the patient records when he/she goes to bed and when he/she gets up in the morning.

Discontinuing a blood pressure measurement

The patient may discontinue a blood pressure measurement at any time by pressing any button while the cuff is under pressure. Immediately after doing so, the cuff will be quickly deflated. This interruption affects only an individual measurement currently being performed and does not have any influence on further operation. This function is available via any of three keys.

6.3 Blood pressure cuffs

Cuff sizes

PremoPort ***Four*** detects and supports three different cuff sizes:

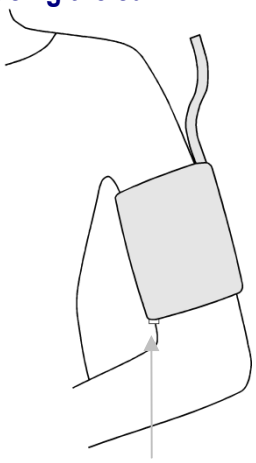
Type	Bladder size	Cuff size	Arm circumference*
Regular adult	12.5 x 22.5 cm	15 x 52 cm	24 – 32 cm
Small adult (child)	6 x 28.5 cm	9 x 41 cm	< 24 cm
Large adult	14.5 x 32 cm	16 x 70 cm	32 – 42 cm

* When positioned correctly, the end of the cuff (the end closer to the tube) should be in the area indicated.

If no special cuff size is pre-set in the device measurement plan, PremoPort ***Four*** determines the actual cuff size during the initial measurements. As needed, the actual cuff size can be transferred to the device in the measurement plan.

Placing the cuff

Place the device pouch with PremoPort ***Four*** on the patient. The pouch can be secured to the body with the shoulder strap and hip strap.



White mark over the brachial artery

When placing the cuff, it is recommended to wear a thin shirt or blouse under the cuff. This does not affect the accuracy of the measurement but it prevents possible problems which can occur after the cuff is worn for a long time, such as itching, sweating. Place the cuff on the upper arm such that the plastic tube points upwards. The small white mark should be over the brachial artery. Guide the tube behind and around the patient's neck to the PremoPort ***Four***. Connect the tube of the cuff with the air connection on the device which is located in the upper right. In doing so, insert the tube into the port and rotate it clockwise using gentle pressure on the tube connection until it audibly clicks into place. It is recommended to wear the cuff on the left upper arm and the device pouch on the right side of the body so that the tube can be run more easily.

Important

- The cuff must be positioned such that the pressure tube is not kinked anywhere. The tube connection to the cuff should therefore be aimed upward. The pressure tube should be positioned so as to ensure free movement of the upper arm.
- The lower edge of the cuff should be about 2 cm above the patient's elbow.
- The cuff should be secured relatively tightly around the upper arm. The correct position can be checked by a simple examination. It should be possible to insert a finger diagonally underneath the cuff. The right cuff size is also important for a correct blood pressure measurement. In order for reproducible values to be able to be measured, there should be standardised measurement conditions, that is, the cuff size should be fitted to the patient.
- For children, use the small cuff, for adults with a normal arm circumference use the standard cuff (regular), and for adults with adipose arms, use the large cuff.

Important

Please ensure that the cuff is secured tightly but is still comfortable for the patient to wear. A cuff which is applied too loosely causes a longer measurement time because the pump first inflates the cuff and only then can the pressure needed for the measurement develop. The measurement may be discontinued because the time limit was exceeded. The patient perceives longer measurement times as unpleasant and this leads to fewer measurement results being available for evaluation. If the patient takes off the cuff during an ambulatory measurement, it should be ensured that it is tight enough when it is put back on.

If blood pressure measurements cause bruises, dizziness or pain in the arm, the cuff should be removed from the arm and disconnected from the recorder. Events of this type should be reported to the physician no later than after the monitoring.

6.4 Monitoring rules

The recorder is programmed by the Diagnostik*Suite* installed on the PC. After the pre-programmed start time has been reached, the recorder will automatically begin the measurement program and perform the blood pressure measurements based on the measurement plan. To obtain reliable blood pressure values, certain rules must be observed.

Guidelines

- Inform your patient of the objective and expected results of the monitoring. Provide him/her with an event block and the rules to be observed.
- It is recommended to wear a thin shirt or blouse under the cuff. This does not affect the accuracy of the blood pressure measurement but prevents problems as a result if the cuff is worn for a long period of time (sweat, itching, pain, etc.).
- The cuff must be correctly placed and connected.
- Patients should avoid excessive movements during the blood pressure measurement. Opening and closing the hand should be avoided during the measurement, as should moving the fingers.
  Patients should keep their arm loose and somewhat away from their upper body:
  When standing Allow arm to hang loosely, place hand in pants pocket or hang fingers from waistband of pants.
  When sitting Place lower arm loosely on a table or support surface.
- If the blood pressure measurements cause bruises, numbness or pain in the hand, the cuff should be immediately removed from the arm and disconnected from the recorder. Events of this type should be discussed with the physician no later than after the monitoring.
- Patients should also not remove the recorder during the night. By loosening the straps, problems due to movements during sleep can be avoided.

- Patients can start manual additional blood pressure measurements with the Start/Stop button on the PremoPort ***Four***. They should use the Event button to mark special events such as the administration of medication. Waking up or going to sleep are saved using the “DAY/NIGHT” button. They can interrupt any individual measurement, as needed, by pressing any button.
- The “DAY/NIGHT” button can only be operated effectively during an interval of four hours before and after the start of night and day (active and passive phase).
- The device can be put down for short periods, for example, when showering. To do so, the ambulatory blood pressure recorder must be switched off, the cuff is slid off the upper arm without opening it. After showering, the cuff is slid back on. It is very important to explain to the patient about the proper positioning of the cuff. He/she should not forget to switch the ambulatory blood pressure recorder back on!
- If the battery capacity should run down during the measurement, the batteries can simply be replaced. The monitoring is continued and the data recorded up until that time are saved.
- During their ambulatory blood pressure measurement, patients should never record another person's blood pressure using the ambulatory blood pressure recorder.

7. Technical information

7.1 Technical data

Energy supply	Power supply	2 x 1.5 V AA alkaline batteries or 2 x 1.2 V AA NiCd or NiMH rechargeable batteries.
	Measurement cycles with fully charged high-capacity rechargeable batteries	250 – 300 individual measurements in 24 to 48 hours
	Current consumption device off Current consumption device on Current consumption pump process Current consumption measurement (without pumping)	1.2 mA 2.8 mA < 1 A 120 mA
	Power consumption	3 W max.
Display	Display	LCD
Signal transmission	Measurement data memory	Internal read-only memory
	Data transmission	Optical
	PC interface	Fibre optic adapter with a USB connector
Blood pressure measurement	Blood pressure measurement method	Oscillometric
	Storage capacity	> 600 individual measurements
	Pressure system	0-300 mmHg
	Blood pressure measurement range	30-260 mmHg
	Heart rate range	40-200 bpm
	Pressure sensor	Piezo-resistive
	Pressurisation	Automatically controlled pressurisation
	Safety	Maximum pressure: 300 mmHg, independent overpressure valve
	Pressurisation and quick-release valve	Automatic pressure release valve
	Design	Corresponds to EN 1060-1:1995
Electrical safety	Applied part	Type CF according to EN 60601-1
	Protection against the penetration of liquids	None
	Operating mode	Continuous

Mechanical data

Dimensions Width x height x depth	105 x 73 x 37 mm
Weight	248 g including batteries 200 g without batteries

Accuracy

Static accuracy	± 3 mmHg or ± 2% of the measured value (Stability: 2 years)
Accuracy of the blood pressure measurement	The blood pressure measurement algorithm was validated by the British Hypertension Society and AAMI.

Environmental conditions

Transport and storage	-20°C to +50°C 10% to 95% relative humidity without condensation
Operating conditions	10°C to 45°C (device) 10°C to 40°C (cuff) 10% to 95% relative humidity without condensation 700 hPa to 1060 hPa air pressure

Subject to technical changes.

7.2 Storage and transport

Storage and transport

Please keep the packaging. The device should be shipped and stored only in the original packaging.

8. Cleaning / Disinfection

PremoPort ***Four*** and also any accessory parts should be regularly cleaned; they should be cleaned daily if used correspondingly.

Information on cleaning

- Before cleaning, the device must be switched off and disconnected from the fibre optic cable.
- No high-temperature sterilisation (such as autoclaving) should be performed, nor should sterilisation with electromagnetic radiation or gamma rays be performed.
- Do not use any cleaning agents or disinfectants which contain alcohol or solvents.
- Under no circumstances should the device be immersed in a fluid or subjected to heat sterilisation with water, steam or air. Protect the device from spray or spilled fluid. The ambulatory blood pressure recorder PremoPort ***Four*** has no separate protection against leaking liquids or the penetration of water or other liquids.
- If PremoPort ***Four*** was immersed in a liquid or a liquid was spilled on it, it should in no case be put back into operation. If liquid penetrated the device, remove the rechargeable/disposable batteries from the device and contact Zimmer customer service.
- Do not expose the device to heavy rain or water vapour and do not bring it into a wet environment, such as under a shower, in the bath or in swimming pools.
- Do not expose the recorder to extreme heat or radiation nor to any long periods of direct sunlight.

Cleaning / Housing care

- Water and soap or commercially available, solvent-free plastic cleaning - agents can be used for cleaning.
- Wipe the surface of the PremoPort ***Four*** until the dirt is removed, using a soft cloth soaked according to the specifications of the manufacturer of the cleaning agent but not dripping wet. Then dry using an antistatic cloth.
- Ensure that no liquid penetrates the device.
- Aggressive cleaning agents or solvents (acetone, paint thinners, diluted acids, bases, etc.) should not be used either for cleaning or for disinfection!

Disinfection of the housing

We recommend that disinfection is to be carried out at least once a week, as well as if there is any indication of contamination. Consult with your hygiene specialist when doing so. Always perform cleaning prior to disinfection. The housing can be disinfected with wipe disinfection. Use a commercially available alcohol-free disinfectant for plastic, with bactericidal, virucidal and fungicidal properties. Observe the instructions for use of the respective manufacturer.
Wipe all surfaces using a soft cloth soaked according to the specifications of the manufacturer of the disinfectant, but not dripping, or with cloths pre-impregnated with disinfectant (wipes).
Also observe requirements for drying or post-cleaning, where applicable.

Cuff

Clean the cuff with a damp cloth, having been previously moistened with a mild soap solution or a suitable disinfectant fliud (e.g. ethanol 70%, isopropyl alcohol 70%, mikrozid sensitiv).

For disinfection Zimmer MedizinSysteme recommends applying mikrozid sensitiv.

Note: *Please note that the bladder cannot be removed from the cuff. Bladder and cuff are one part.*

Note: *Ensure that no water gets into the tube opening of the cuff during cleaning and disinfection. Close the sleeve with a cap or a clip.*

Note: *The cuff is not suitable for sterilisation in a steriliser.*

Note: *Do not use bleach.*

9. CE mark

The device has the CE mark

 0123

in accordance with the EC directive on medical devices 93/42/EEC.

10. Scope of delivery, accessories

10.1 Scope of delivery

Scope of delivery	Art. no. *	Number	Description
		1	Blood pressure monitor PremoPort ***Four***
	56,200,021	1	Blood pressure cuff, regular
	56,200,270**	1	Fibre optic cable 2-core, Opto fibre optic cable (depends on delivery)
	56,200,260**	1	Converter, Opto / USB, for fibre optic cable (depends on delivery)
	56,200,410	1	Device pouch with shoulder and hip strap
	87,921,001	4	Battery 1.2 V type AA
	56,310,955**	1	Battery charging device
		1	Instructions for use

(*Subject to technical changes)
(**Optional accessories: dependent on version and design)

10.2 Accessories

To ensure reliable function of the ambulatory blood pressure system, only original accessories from Zimmer MedizinSysteme may be used.

List of accessories

Art. no. *	Description
56,200,021	Blood pressure cuff, regular
56,200,031	Blood pressure cuff, large
56,200,270	Fibre optic cable, 2-core, Opto fibre optic cable
56,200,260	Converter, Opto / USB, for fibre optic cable
56,200,410	Device pouch with shoulder and hip strap
87,921,001	Battery 1.2 V type AA
56,310,955	Battery charging device

(*Subject to technical changes)

Additional accessories for the ambulatory blood pressure measurement are available from
Zimmer MedizinSysteme GmbH.

11. Device combinations

PremoPort ***Four*** can be combined with the Diagnostik*Suite* evaluation software.
Anyone who combines devices and thus creates a medical system does so under his/her own responsibility.
When combining devices, observe the specifications of standard DIN EN 60601-1.
In doing so, please note the information in chapter 3 “Warnings”.

Note: *The installation, start-up and operation of the connected devices are described in the respective instructions for use.*

12. Safety and maintenance

12.1 Safety

As the manufacturer, Zimmer MedizinSysteme can only consider itself to be responsible for safety and reliability if

- PremoPort ***Four*** is only operated in accordance with the instructions for use.
- Repairs, expansions, readjustments, installations or modifications to the device are only performed by Zimmer MedizinSysteme or by persons authorised by Zimmer MedizinSysteme.
- Only accessories provided by Zimmer MedizinSysteme GmbH are used.
- The user has ascertained the functional safety, the proper operating condition and the mechanical integrity of the device before use.
- The device is operated only by properly trained personnel.
- The device is not operated in hazardous areas and / or a combustive atmosphere.
- The device is immediately taken out of service when penetrated by liquid.

Note: *The user must ascertain the safe function of the device prior to each use.*

12.2 Maintenance

PremoPort ***Four*** does not contain any parts to be maintained by the user.

13. Functional test

Prior to initial start-up, perform a functional test to check the functionality of the ambulatory blood pressure system.

Functional test PremoPort *Four*

Proceed as follows:

- Connect the individual components as described in the previous chapters.
- Place the disposable or rechargeable batteries in the battery compartment and close the lid. The voltage of the disposable or rechargeable batteries will be shown on the display for approx. 5 seconds. (e.g. 2_23 corresponds to 2.23 V). Then the display changes to show the time.
- To check the display and blood pressure measurement unit, place the blood pressure cuff on the upper arm and connect the cuff to PremoPort ***Four***. Briefly push the Start/Stop button. All segments of the LCD display can be seen for approx. 3 seconds.
- Then the pump process begins. The increasing numerical values on the display and an increase in pressure in the cuff can be seen.
- After a successful measurement, the systolic blood pressure, the diastolic blood pressure and the pulse are displayed sequentially six times consecutively.
- ***Disconnect the examination device(s) and remove the disposable or rechargeable batteries.***

Note:

In the event of malfunction or visible damage, do not use the ambulatory blood pressure measurement system. Contact the service department of Zimmer MedizinSysteme.

14. Legal notice

The device is not listed in attachment 1 but it is listed in attachment 2 of the Medical Device Operator Ordinance (MPBetreibV). According to section 14 MPBetreibV, the device must undergo a metrological control (MTK) every two years. The result must be documented in the medical device book and identified by a test seal on the device indicating the year during which the next control is due. The metrological control may only be performed by an approved testing facility. Contact Zimmer MedizinSysteme in this regard.

In Germany, the regulation regarding electrical systems and equipment (German Social Accident Insurance (DGUV) Regulation 3), as amended, must additionally be observed.

Note: This information applies to the operation of the unit in Germany. Please consider divergent national regulations in your country, if applicable.

15. Error messages / Troubleshooting

15.1 Error messages, troubleshooting

Malfunctions and corrections

In the event of technical problems or interference, observe the explanations, descriptions and solutions in these instructions for use.

If you require support or if there is interference which cannot be corrected, please contact your sales consultant or, for matters of urgency, please contact the factory directly.

Zimmer MedizinSysteme GmbH
Junkersstraße 9
89231 Neu-Ulm
Germany
Telephone +49 731 / 9761 - 0

Diagnostic hotline:
Telephone +49 731 / 9761 - 115
Fax +49 731 / 9761 - 4443

You can also receive support via email: support@zimmer.de
Visit us online at: http://www.zimmer.de

You will help us solve the problem if you have the following information at hand:

- Accurate description of the problem
- Version number of the Diagnostik*Suite*
- Serial number of PremoPort ***Four***
- Computer configuration

Typical sources of error

The following causes may be responsible for inaccurate measurements or non-evaluable results:

- Use of the device outside of the areas of application described in the instructions for use
- Use of the device despite functional problems
- Improper handling
- User errors, mistakes on the part of the user
- Arm movement during the measurement
- Switching the device off (e.g. at night)
- Wrong cuff size placed
- Cuff shifts during wear
- No successful manual measurement in the doctor's office
- Prescribed medications not taken
- Protocol set incorrectly by the medical staff
- Rechargeable batteries which have not been fully charged, incorrectly charged or are outdated are used
- Defect in charging device

Error codes

The PremoPort ***Four*** has various error codes which quickly provide information about the cause of the error. The error is displayed on the device, saved, and transferred with the measurement data to Diagnostik*Suite*.

Error - code	Description	Possible cause
01	Measurement discontinued	Due to an arm movement or a vibration, the device needed more than the maximum possible measurement time. For the safety of the patient, the device discontinues a measurement in progress after 120 sec. if the measurement is not being performed successfully.
02	Manually discontinued	The patient pressed a button on the device to discontinue the measurement.
03	Batteries dead	The batteries died during the measurement. The remaining charge was not sufficient to continue the measurement.
04	Batteries replaced	The batteries were replaced during the ambulatory measurement.
09	External interference	External electrical interferences or static discharges caused an interruption of the measurement.
31	Cuff not connected	The cuff was not connected to the device when the blood pressure measurement was started.
32	Airway problem	There was a problem in the air tube or in the pneumatic system. In general, this means the air tube was blocked or pinched.
33	Cuff not airtight	The system was not able to maintain air pressure. In general, this means the cuff is not airtight.
34	Cuff not on the arm	The cuff was not on the arm or it was placed too loosely.
90, 99	Device error	Internal device error; please notify the service personnel.

Malfunction	Possible cause	Remedy
No blood pressure measurements available	Wrong time set	Check time on the display of PremoPort ***Four*** and the PC. Correct time on PC. (When transferring the measurement plan, the time on the PC is transmitted to PremoPort ***Four***).
	Wrong cuff type	Make sure that the cuff type used is identical to the one set in the measurement plan.
	Leaky or defective cuff	Check the cuff and, if necessary, use a new cuff.
	Air circulation problems	▪ Start a manual measurement and check its progression. ▪ Use “Receive and display” in Diagnostik*Suite* together with the measurement values to call up any error codes from PremoPort ***Four*** and check the event table.

Malfunction	Possible cause	Remedy
PremoPort *Four* is not communicating with the PC, no "PC" display during data transfer	PremoPort ***Four*** is not switched on	Switch on PremoPort ***Four***
	Fibre optic cable is not correctly connected	Check whether the connection cable on the PC and PremoPort ***Four*** is correctly inserted.
	Wrong interface set. Fibre optic cable or converter defective.	▪ Check whether the correct interface is set in Diagnostik*Suite*. ▪ Remove the fibre optic cable from PremoPort ***Four***. Start Diagnostik*Suite.* In the navigation area, open the "**New**" tab and, for a new ambulatory blood pressure measurement, select "Prepare measurement". Transfer the patient data and the measurement plan. When the connection is correct, a red light briefly blinks at the end of the fibre optic cable. Then reconnect the fibre optic cable to PremoPort ***Four***.
	Interface problem of the operating system	▪ Check in the Windows device manager whether there is a general problem with the interface. ▪ If necessary, use another interface. ▪ Check the functionality of the desired interface with another connected device.
	Battery capacity too low	Check the battery voltage and if necessary, replace the disposable batteries or insert newly charged rechargeable batteries. Disposable batteries need more than 3 V, rechargeable batteries need more than 2.5 V battery voltage.
PremoPort *Four* is not working correctly	External malfunction or device error	In Diagnostik*Suite,* start the function "Read in measurement" and thus call up any available error codes from PremoPort ***Four***. Then check the event table.

15.2 Disposal

Disposal

The device may only be returned to the factory in its original packaging. It must be disposed of by the factory in Neu-Ulm.

Disposable and rechargeable batteries should not be discarded in household waste under any circumstances. NiCd batteries are to be considered hazardous waste in any case. Disposable and rechargeable batteries are to be disposed of in accordance with the German Battery Act.

Note

In foreign (European) countries, disposal is handled by dealers authorised by Zimmer MedizinSysteme.

16. Manufacturer's EMC declaration

Medical electrical devices, such as PremoPort ***Four***, are subject to special precautionary measures with regard to EMC (electromagnetic compatibility) and must be installed and put into operation according to the EMC information in the instructions for use or accompanying documentation.

Portable and mobile HF communication devices (such as mobile phones, cell phones) can affect medical electrical devices.

PremoPort ***Four*** may only be operated with the original connection cable indicated in the list of the scope of delivery and accessories.
Operation of the device with a different connection cable can lead to increased emissions or reduced interference immunity of the device!

Guidelines and manufacturer's declaration – Electromagnetic emissions		
The PremoPort ***Four*** device is intended to be operated in an electromagnetic environment as indicated below. The customer or user of the PremoPort ***Four*** should ensure that it is operated in such an environment.		
Interference emission measurements	**Compliance**	**Electromagnetic environment - Guideline**
HF emissions according to CISPR 11	Group 1	The PremoPort ***Four*** device uses HF energy only for its internal functioning. This means that its HF emissions are very low, and it is very unlikely that adjacent electronic devices would suffer interference.
HF emissions according to CISPR 11	Class B	
Harmonic emissions according to IEC 61000-3-2	Not applicable	
Voltage fluctuations/flickers according to IEC 61000-3-3	Complies	The PremoPort ***Four*** is suitable for use in all facilities, including those in a residential area, and in those which are connected directly to the public grid which also supplies buildings used for residential purposes.

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The PremoPort ***Four*** device is intended to be operated in an electromagnetic - environment as indicated below. The customer or user of the PremoPort ***Four*** should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment – Guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV Contact discharge ± 8 kV Air - discharge	± 8 kV Air discharge	Floors should be made of wood or concrete or should be covered with ceramic tiles. If the floor is covered with synthetic material, the relative air humidity must be at least 30%.
Rapid transient electrical disturbances/bursts - according to IEC 61000-4-4	± 2 kV for power cables ± 1 kV for input and output - cables	Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV voltage external conductor-external conductor ± 2 kV voltage external conductor-ground	Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, brief interruptions and - fluctuations in the supply voltage according to EN 61000-4-11	<5% U_T (>95% dip in U_T) for ½ cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 cycles	Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the PremoPort ***Four*** requires continued function even if interruptions in the power supply occur, it is recommended to power PremoPort ***Four*** from an uninterruptible power supply or a battery.
Magnetic field at power supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should correspond to the typical values found in a business or hospital environment.
Note: U_T is the a.c. voltage prior to application of the test level.			

Key performance features of the PremoPort ***Four*** are: smooth recording of ambulatory blood pressure profiles, smooth operation of all functions.

<table>
<tr><th colspan="4">Guidelines and manufacturer's declaration – Electromagnetic immunity</th></tr>
<tr><td colspan="4">The PremoPort Four device is intended to be operated in an electromagnetic environment as indicated below. The customer or user of the PremoPort Four should ensure that it is used in such an environment.</td></tr>
<tr><th>Immunity tests</th><th>IEC 60601-test level</th><th>Compliance level</th><th>Electromagnetic environment – Guidelines</th></tr>
<tr><td>Conducted HF disturbances according to IEC 61000-4-6

Radiated HF disturbances according to IEC 61000-4-3</td><td>3 $V_{Effective\ value}$
150 KHz to 80 MHz

3 V/m
80 MHz to 2.5 GHz</td><td>Not applicable

3 V/m</td><td>Portable and mobile radio equipment should not be used at a distance away from the PremoPort Four, including the cables, that is less than the recommended safety distance which is calculated according to the equation applicable to the transmission frequency.

Recommended safety distance:

d= [3.5 / V1] √P

d= 1.17 √P for 80 MHz to 800 MHz

d= 2.33 √P for 800 MHz to 2.5 GHz

with P as the rated output of the transmitter in watts (w) according to the information of the manufacturer of the transmitter and d as the recommended safety distance in meters (m).

At all frequencies, the field strength of stationary radio transmitters should be less than the compliance level[b] according to on-site testing[a].

In the environment of devices which bear the following symbols, interferences are possible:

  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 Hz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is influenced by absorption and reflection from buildings, objects and people.</td></tr>
</table>

[a] The field strength of stationary transmitters, such as base stations for radio telephones and land mobile radios, amateur radio stations, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment with regard to the stationary transmitters, an electromagnetic site survey is to be recommended. If the measured field strength in the location in which the PremoPort ***Four*** device is used exceeds the above compliance level, the PremoPort ***Four*** device must be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PremoPort ***Four.***

[b] Above a frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Recommended safety distances between portable and mobile HF telecommunication devices and the PremoPort *Four* device

The PremoPort ***Four*** device is intended to be operated in an electromagnetic - environment in which the HF disturbances are controlled. The customer or user of the PremoPort ***Four*** device can help avoid electromagnetic interference by maintaining a minimum distance between portable and mobile HF telecommunication devices (transmitters) and the PremoPort ***Four*** device – depending on the output power of the communication device as indicated below.

Rated output of the transmitter W	**Safety distance depending on the transmission frequency** m		
	150 kHz to 80 MHz d= [3.5 / V1] √P	**80 MHz to 800 MHz** d= 1.17 √P	**800 MHz to 2.5 GHz** d= 2.33 √P
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.2	2.3
10	Not applicable	3.8	7.3
100	Not applicable	12	23

For transmitters whose maximum rated output is not listed in the table above, the recommended safety distance d in metres (m) can be determined using the equation applicable to the respective column, where P is the maximum rated output of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is influenced by absorption and reflection from buildings, objects and people.

17. Index

PremoPort*Four*

Instructions for Use

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