

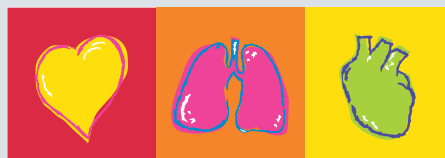


BR-102 plus / BR-102 plus PWA

24/48 Hour Ambulatory Blood Pressure Recorder



User Guide



SCHILLER
The Art of Diagnostics



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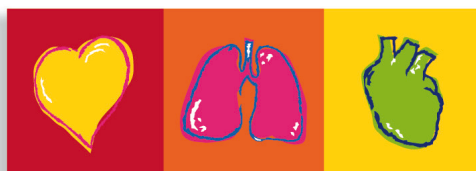
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CE 0123

BR-102 plus / BR-102 plus PWA bears the CE-0123 mark (Notified Body TÜV-SÜD Produkte Service GmbH, Ridlerstr. 65, 80339 Munich, Germany), indicating its compliance with the essential requirements of the Annex I of the Medical Device Directive 93/42/EE regarding safety, functionality and labelling. The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use.



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1 Safety Precautions

1.1 User Profile

Medical Personnel (Operator, User)

This blood pressure recorder as well as the analysis program are provided for the exclusive use of qualified physicians or trained medical personnel under their direct supervision.

Patient, Caregiver (for use in home environment)

After thorough instruction from the attending physician, the patient or his/her caregiver may use the device on their own (see chapter 4 [Patient Information](#) and chapter 9 [Patient Diary](#)).

1.2 Intended Use



- ▲ The BR-102 plus / BR-102 plus PWA is a non-invasive ambulatory blood pressure recorder. It uses auscultatoric and oscillometric signals, or purely oscillometric signals to measure the blood pressure of human beings. Systolic, diastolic, mean arterial pressure and heart rate are measured. The BR-102 plus / BR-102 plus PWA is intended as an aid to diagnosis and treatment when it is necessary to measure an adult or adolescent patient's blood pressure over an extended period of time (up to 24 48 hours). Further, with each measurement, the PWA data will be saved for subsequent external assessments.
- ▲ The BR-102 plus / BR-102 plus PWA can be used for adults and children (3 years old onwards) of both sexes and all ethnic origins.
- ▲ This blood pressure recorder can be used on pregnant patients or patients suffering from pre-eclampsia.
- ▲ Patients with special needs such as children, the elderly, the disabled, or people lacking the capacity for judgement must be accompanied by a caregiver who will supervise the actions as well as monitor the recording.

1.3 Contraindications



- ▲ The BR-102 plus / BR-102 plus PWA has **not** been designed for, and must not be used for the following patients:
 - neonates and children under the age of 3.
 - patients who must undergo invasive blood pressure monitoring.

1.4 Responsibility of the User



- ▲ The numerical and graphical results as well as any interpretation suggested by the device must be examined with respect to the patient's overall clinical condition and the quality of the recorded data.
- ▲ The indications given by this equipment are not a substitute for regular checking of vital functions.
- ▲ The responsibilities of the personnel for the operation and maintenance of the device must be specified.
- ▲ Ensure that personnel have read and understood these operating instructions. In particular this section safety notes must be read and understood.
- ▲ Damaged or missing components must be replaced immediately.
- ▲ The operator is responsible for compliance with all applicable accident prevention regulations and safety regulations.
- ▲ The safety, reliability and performance of the unit can only be guaranteed when the maintenance intervals, as stated in the Maintenance section of this user guide, are observed.
- ▲ No modification of this equipment is allowed.

1.5 Organisational Measures



- ▲ Before using the unit, ensure that an introduction regarding the recording functions and the safety precautions has been provided by a medical product representative.
- ▲ Observe the operating instructions and maintenance instructions and keep these operating instructions in an accessible place for reference when required. Make sure that they are always complete and legible.
- ▲ These operating instructions do not override any statutory or local regulations, or procedures for the prevention of accidents and environmental protection.

1.6 Maintenance



- ▲ No serviceable parts inside. Refer servicing to qualified technician authorised by SCHILLER only.
- ▲ Do not use high temperature sterilisation processes (such as autoclaving). Do not use e-beam or gamma radiation sterilisation.
- ▲ Do not use aggressive or abrasive cleaners.
- ▲ Do not, under any circumstances, immerse the device or cable assemblies in liquid.

1.7 Hygiene



- ▲ For cleaning and disinfection observe the legal requirements applicable.
- ▲ Only use cleaning agents and disinfectants recommended by SCHILLER. Unsuitable agents can damage the device. Clean and disinfect the device in accordance with the instructions given in this book.

1.8 Safety Conscious Operation



- ▲ Make sure that the staff have read and understood the operating instructions - particularly this Safety Notes section.
- ▲ Immediately report any changes that impair safety (including operating behaviour) to the person responsible.
- ▲ Only use accessories and other parts recommended or supplied by SCHILLER AG. Use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the recorder.

1.9 Safety Facilities



- ▲ Connecting the unit to a PC with defective cables may constitute a danger to life. Therefore:
 - Do not connect the BR-102 plus / BR-102 plus PWA to any PC if the earth connection is suspect or if the mains lead is damaged or suspected of being damaged.
 - Damaged cable connections and connectors must be replaced immediately.

1.10 Operation with other Devices



- ▲ Only use accessories and other parts recommended or supplied by SCHILLER AG. The use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the device.
- ▲ Accessory equipment must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the system standard IEC/EN 60601-1. Everyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult the technical service department or your local representative.
- ▲ The BR-102 plus / BR-102 plus PWA is safe during defibrillation. However, as a safety precaution remove the cable assembly between the recorder and the PC and when possible, remove the BR-102 plus from the patient before defibrillation.
- ▲ The BR-102 plus / BR-102 plus PWA complies with EMC regulations for medical products which afford protection against emissions and immunity. However, the possibility exists that high frequency disturbance from other devices can affect the recorder's operation.

1.11 Safety Symbols and Pictograms

1.11.1 Symbols used in this Document

The safety level is classified according ANSI Z535.4. The following overview shows the safety symbols and pictograms used in this manual.



For a direct danger which could lead to severe personal injury or to death.



For a possibly dangerous situation, which could lead to serious bodily injury or to death.



For a possibly dangerous situation which could lead to personal injury. This symbol is also used to indicate possible damage to property.



For general safety notes as listed in this chapter.



Note For possibly dangerous situations, which could lead to damages to property or system failure. **Important** or helpful user information.



Reference to other guidelines.

1.11.2 Symbols on the Device, Batteries, and Accessories



The recorder/component can be recycled.



Notified body of the CE certification (TÜV P.S.).



Manufacturer: SCHILLER AG, CH-6341, Baar.



Type BF equipment, safe for external applications.



Symbol for the recognition of electrical and electronic equipment.

Recycle the recorder and batteries separately from other waste. Equipment/components and accessories no longer required must be disposed of in a municipally approved collection point or recycling centre. Alternatively, you can return the equipment to your supplier or SCHILLER AG for disposal. Improper disposal can harm the environment and human health.



BR-102 plus / BR-102 plus PWA battery type 2 x AA 1.2 V / 2700 mAh, NiMH. Use NiMH charger only.

Do not disassemble, mutilate, incinerate, or heat. Do not short circuit a battery. May cause burns. At the end of a battery's life, do not dispose in household waste. Batteries must be disposed of in a municipally approved collection point or recycling centre. To prevent the possibility of battery leakage, always remove the batteries from the device when not used for prolonged periods.

IP42

According DIN VDE 0470 PART 1 /EN 60529 / IEC 529

Protection against deposits of dust and protection against spray water. (The first digit indicates the protection of the equipment against ingress of solid foreign bodies and dust and the second digit indicates the degree of protection of the equipment inside the enclosure from ingress of water).



Read and follow the instructions in the accompanying documentation.



- Do not tumble dry
- Do not use bleach to clean the pouch
- Do not iron



- Dry Clean
- Wash at a temperature of 30° C
- Select 'gentle or delicate cycle'.

2 Introduction

The SCHILLER BR-102 plus / BR-102 plus PWA is an Ambulatory Blood Pressure Recorder used for single and long-term recordings. The device can take up to 100 measurements over a 24 hour recording period, and up to 200 measurements over a 48 hour recording period. All recorded data is stored in an internal memory and can be uploaded to the medilogDARWIN2 program. The recorder has four recording programs that can be defined by the user with individual time and interval settings for each program. This enables long-term blood pressure measurements to be taken at pre-set intervals for different patients and conditions.



BR-102 plus PWA



Standard

- BR-102 plus Ambulatory Blood Pressure recorder Standard, or BR-102 plus PWA (Pulse Wave Analysis)
- Four rechargeable AA NiMH batteries
- Battery charger unit
- Cuff size 'M' (medium) adult, and pressure hose with microphone
- Securing pouch with belt
- medilogDARWIN2 software
- USB cable
- BR-102 plus / BR-102 plus PWA user guide
- Premium accessories case
- Single use pouches (x5)

Cuffs and Accessories

Cuffs are available in sizes 'XS' (extra small, Osc. only), 'S' (small), 'M' (medium), 'L' (large), and 'XL' (extra large). A list of these and other accessories are given at the end of this book ([see Accessories, page 62](#))

2.1 BR-102 plus / BR-102 plus PWA

The recorders are available as follows:

2.1.1 BR-102 plus



The Standard BR-102 plus is identified by the black front casing. There are two measurement methods available as follows:

- Option 1 employs the auscultatory (Riva-Rocci, Korotkoff) method of measurement, with an oscillometric method as back-up. This means that when a clear measurement cannot be obtained with the auscultatory method, the oscillometric value is used. If a clear measurement cannot be obtained with either method the BP measurement is retaken. It is not possible to define oscillometric as the primary measurement method.
- Option 2 employs the oscillometric method only. Note that with this recorder no microphone is provided with the cuff.

2.1.2 BR-102 plus PWA



The BR-102 plus PWA (Pulse Wave Analysis) is identified by the white front casing and takes measurements using the auscultatory (Riva-Rocci, Korotkoff) method with oscillometric as back-up.

The setup and settings of the BR-102 plus PWA, measurement interval, cuff application, and start and stop procedure are all identical to the standard unit.

To obtain the extra data needed for PWA, the measurement cycle differs from standard BP measurement. After every individual measurement (and the SYS and DIA values recorded), the cuff is again inflated to the diastolic pressure. This pressure is then held for 10 seconds while the PWA data is obtained. After 10 seconds the cuff is again deflated and ready for the next programmed measurement.

An outline of PWA principal is given at the end of this book ([see BR-102 plus PWA, page 64](#)).

2.2 The medilog®DARWIN2 Program

The medilogDARWIN2 program supplied with the recorder is used to display, save, edit, analyse and print recordings. In addition to blood pressure recordings, the medilogDARWIN2 can upload and view Holter ECG recordings and SpO₂ recordings. Details of the program are given in the medilogDARWIN2 user guide (see [Documentation, page 62](#)).

2.3 Inserting/Changing the Batteries



- ▲ Use **NiMH rechargeable batteries** supplied or recommended by SCHILLER. Full capacity of new NIMH batteries are only reached after three charge/discharge cycles.
- ▲ **Energizer Ultimate Lithium** batteries (ENERGIZER L91-FR6) may also be used.
- ▲ **Do not mix batteries.** Only use two batteries of the same type.
- ▲ **Do not use any other type of battery** - the capacity of other battery types may not be sufficient for a 24 hour recording and the battery capacity symbol can be incorrect.

1. Open the battery compartment by pressing and sliding the battery cover away from the recorder.
2. Use the battery removal ribbon to remove the two batteries.
3. Insert two fully charged batteries.
 - Ensure that the battery removal ribbon is positioned under the batteries so that the batteries can be removed from the recorder when depleted.
 - Ensure that the batteries are inserted with the correct polarity as shown.

Art. no.: 2.511076 Rev. d



4. Position the battery cover in the cover slides and slide back in place until it clicks to secure.

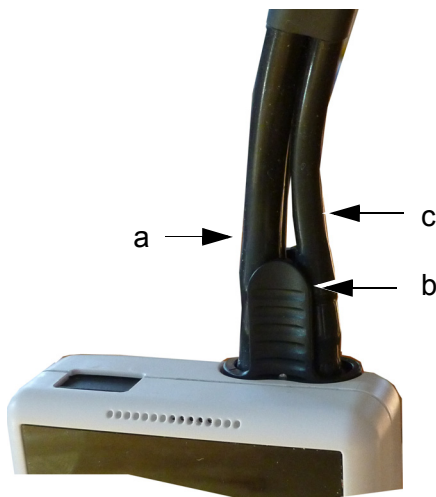


- The battery capacity indicator is detailed in the operating section ([see Battery Status for NiMH Rechargeable Batteries, page 19](#)).
- Battery charging details, disposal, and safety relevant precautions are detailed in the maintenance section ([see Battery Maintenance, page 42](#)).
- Battery and battery charger part numbers are detailed at the end of this book ([see Accessories, page 62](#)).

2.4 Connecting the Pressure Hose and Microphone



The hose / microphone assembly can only be inserted in one direction. Take care when positioning the assembly not to damage any connectors. Do not pull directly on the hose or microphone cable.

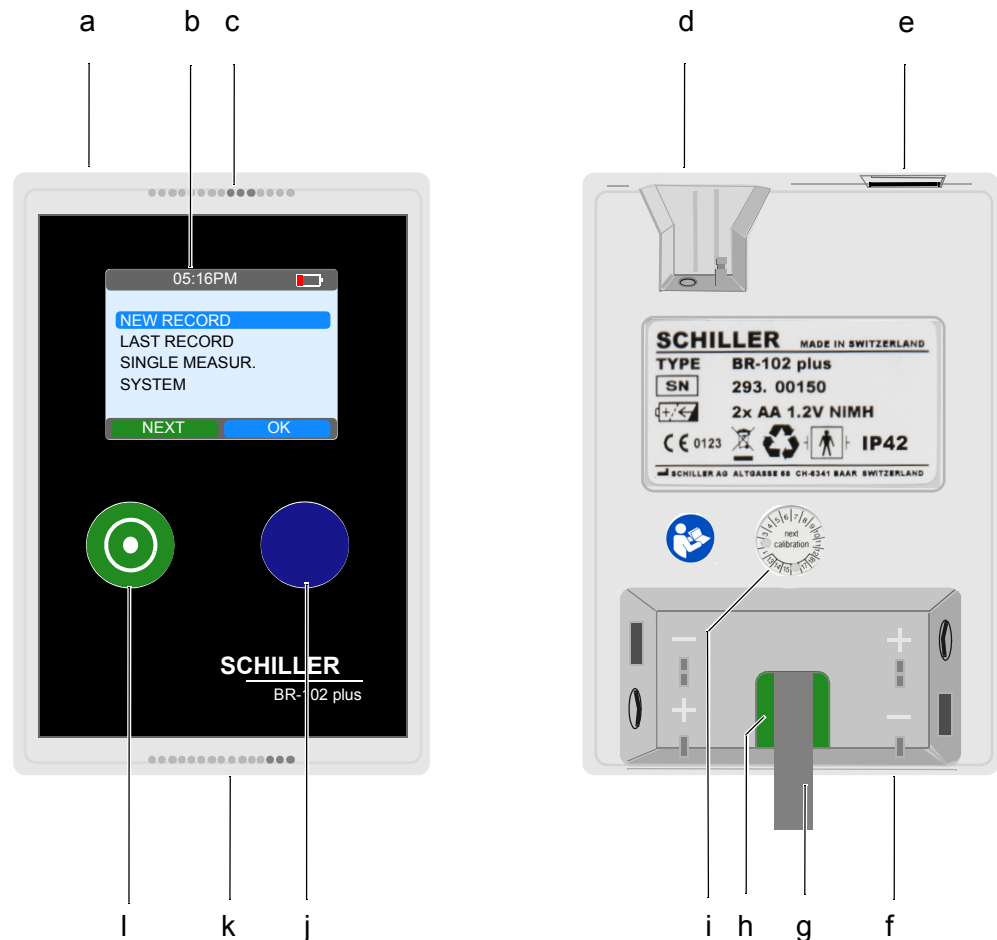


Position the pressure hose connector **(a)** and attach to the BR-102 plus / BR-102 plus PWA by gently pressing until the connector clicks in place. If the version is with a microphone **(c)**, the plug attached is combined with the hose and the assembly is inserted into the BR-102 plus / BR-102 plus PWA socket at the same time.

Removing the Pressure Hose

Gently press the securing catch **(b)** to release and remove the hose connector (and microphone jack plug) from the BR-102 plus / BR-102 plus PWA.

2.5 Main Components of the Device



- (a) USB-cable connection
- (b) OLED display
- (c) Loudspeaker
- (d) Microphone connector jack plug and patient cuff connection recess
- (e) USB connector
- (f) Battery recess (battery cover removed)
- (g) Battery removal ribbon.
- (h) Micro SD card recess (under battery removal ribbon)



The micro SD memory card is for service only and is used for software updates or storage of raw data for test purposes.

- (i) Calibration label
- (j) Programming function key
- (k) Microphone for recording patient identification
- (l) Programming function key and ON/OFF key

2.5.1 Operating and Display Elements

Menu option selection and control of the BR-102 plus / BR-102 plus PWA is with two function keys. The **green and blue function information boxes** at the bottom of the screen indicate the function that will be carried out when the **green and blue function keys** are pressed:

Left Green Key Functions:

ON/OFF: (Switch-Off from main menu only)

Next: (next menu item)

No: (do not confirm selection)

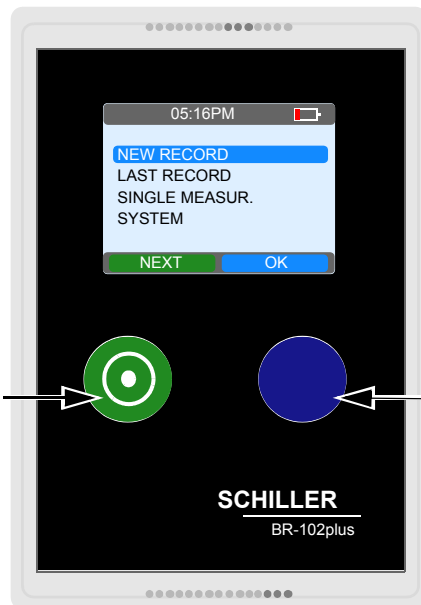
Meas: initiate a measurement (during the recording)

Holding the key stops the recording

Break: Halts an ongoing measurement

Stop: Stops a recording in progress.

Back: Back to last menu



Right Blue Key Functions:

OK: (confirm menu selection)

Change: (toggle through options)

Yes: (confirm selection)

Meas: initiate a measurement (during the recording)

Start: Starts the acoustic record of the patient ID

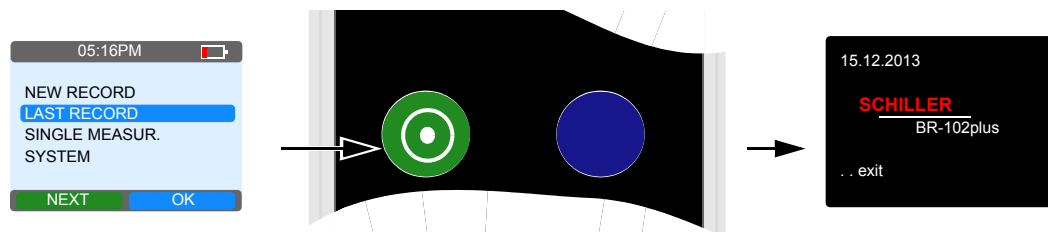
Stop: Stops a recording in progress

2.5.2 Switching On

Press the green ON/OFF key. The display shows an introduction screen and copyright message for a few seconds and then the main menu is displayed. If an unformatted micro SD card is installed, you are prompted to format the card when the recorder is switched on, and again when a recording is started.

2.5.3 Switching Off

With the **main menu displayed** and the cursor at any position, press and hold the **Green control button for 4 seconds**. When the button is released, the device is switched off.



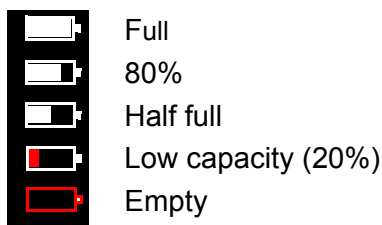
If a recording is running, first stop the recording by holding the **Green control button for 4 seconds** and confirming that the recording will be stopped ([see Stopping the Recording, page 36](#)). Then enter the main menu and switch off as described above. Any recorded data is saved when the recorder is switched off.



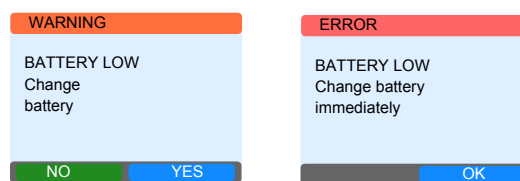
When no recording is running, the recorder switches off automatically after 5 minutes if no keys are pressed.

2.5.4 Battery Status for NiMH Rechargeable Batteries

The battery status display is a guide to battery capacity when using **NiMH rechargeable batteries** supplied or recommended by SCHILLER. If **Energizer Ultimate Lithium Batteries** are used, a different battery symbol is displayed (see next page).



The battery symbol in the upper right of the screen, indicates the battery status. When the battery is full, the symbol is filled and gives an indication of current battery capacity as it reduces during the recording. The empty symbol indicates that the capacity is limited and that the batteries should be changed. If the batteries are not changed during this period a warning message is given that the batteries must be changed. If the batteries are still not changed an error message is displayed before the recorder switches off (see next page).



i

- An audible and visual indication is given during recording when battery capacity is limited. When the indication is given and the recording is to be continued, we recommend that the batteries are replaced at the first opportunity.
- When recording is stopped because of low battery capacity, and the batteries are replaced within 5 hours of the recorder switching off, the recording will continue (see [Changing the Batteries During a 48 Hr Recording, page 35](#))

Battery Condition

Batteries deteriorate over time and must be replaced. An indication of battery condition is given when batteries are first placed in the recorder after a full charge, as follows:

Battery Indicator	Battery Recording Capacity
Full (100%)	24-hour recording is possible.
80%	24-hour recording should be possible.
Half full (50%)	Single measurements only will be possible. The batteries should be replaced.
Low capacity or empty	A 24-hour recording is not possible. Replace batteries.

2.5.5 Battery Display for Energizer Ultimate Lithium Battery



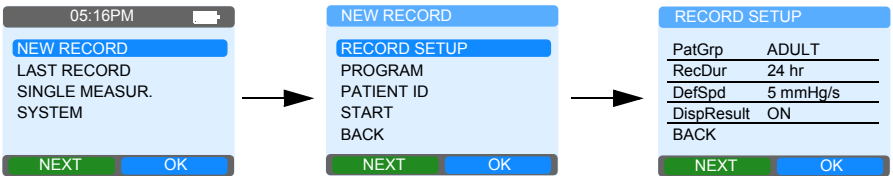
If **Energizer Ultimate Lithium** batteries are used, the battery status display is shown blue and always 'full'. This is because the voltage hysteresis curve for these types of battery is not linear and the device cannot accurately determine battery capacity. When battery capacity is very limited the change battery messages (shown above) are still displayed but the time interval between the messages is reduced.

2.5.6 Time Display

The current time is displayed in the top line of the display. The format of the time display can be set to 24 hour or 12 hour display (am/pm displayed) - this setting is defined in System setup (see [DATE /TIME, page 24](#)).

2.6 Menu Structure

The menus are selected with the green function key (**Next**). A selected menu is opened with the blue function key (**OK**) and values selected with the blue function key (**Change**). Depending on the selected menu, the button functions will change.



The position in the menu is indicated on the top line as shown in the example above for new record. Select the item with the green button and confirm with the blue key.



In all displays, the top line is colour coded to give an indication of the type of message that is displayed as follows:

<div>05:16 PM</div>	Grey: Main menu screen.
<div>RECORD SETUP</div>	Light Blue: Information or setup screen.
<div>ERROR</div>	Red: Error message (for example, battery capacity limited, no data available when requested, etc.).
<div>WARNING</div>	Orange: Warning message or question (for example, battery capacity critical, Format SD card).
<div>CONFIRMATION</div>	Green: Confirmation message (for example, SD card formatted successfully).

2.6.1 Menu Overview

Main Menu	Sub Menu 1	Value/Info	Sub Menu 2	Value/Info	Sub Menu 3	Value/Info
NEW RECORD	RECORD SETUP	Defines the recording parameters	Patient Group	Adult / Child - Maximum initial pressure for adult is 300mmHg and for a child 210mmHg.		
			Record Duration	24/48 Hours		
			Deflation Speed	2, 3, 4, 5, 6, 7, 8, 9 mmHg/s or Auto (3mmHg / heart beat).		
			Display Result	ON / OFF. Displays the cuff pressure during a measurement and displays the result on the screen after a measurement has been taken. When Off is selected measurements are not displayed during, nor after a measurement. NOTE: When Off is selected, the first two measurements taken are always displayed to enable checking. The recommended setting is Off to prevent patient concern during the recording.		
	PROGRAM	Defines the program parameters	Select program A, B, C, D	Select one of four individual recording programs A, B, C, D. The programs are defined in Program Setup below.		
			Program Setup	A, B, C, D - Four individual BP measurement programs (A, B, C and D) can be defined. Each individual program has up to 8 cycles with separate start time BP measurement interval for each cycle.	Change / Next 1. Define the start time by pressing change . The time counts up in 10 minute intervals. 2. When the desired start time is shown press next . The measurement interval is highlighted. 3. Press change to select a BP measurement interval of: 5, 10, 15, 20, 30, 60, or 120 minutes. 4. Press next to define the next start time. 5. Continue until all desired start times (with measurement interval) are defined for the selected program.	
					When less than 8 cycles are required pressing next twice returns to the previous menu.	

Main Menu	Sub Menu 1	Value/Info	Sub Menu 2	Value/Info	Sub Menu 3	Value/Info
	PATIENT ID		Record Voice		Start	Start Voice Recording.
					Stop	Stop Voice Recording.
			Play Voice	Plays recorded patient identification.	Stop	Stop Playing Voice.
	START		Do you want to start a BP Recording?	Yes / No - Confirm Recording start. Confirmation of recording start is given. Followed by REC: BP recording and the time of the next measurement (this is displayed for approximately 5 seconds).	BP Recording . Next Meas. .. 09.15	Press either of the two function keys for approximately a second to take an extra measurement during the recording. Press either of the two function keys when a measurement is being taken to interrupt a measurement being taken during the recording.
	BACK	Return to main menu.				
LAST RECORD	RECORD DATA	Date and time, patient group, record duration, deflation speed, number of measurements.	OK	Press OK to return to previous menu.		
	PATIENT DATA	Play voice ID. Note: If started from a PC the patient data is also displayed.	Stop	Stops voice		
	MEASUREMENTS	Displays results of stored recording.	Back / Next	Press back / next to go back to last record, forward to next record. Press and hold the back / next for approximately 2 seconds to return to the last record menu.		
	BACK	Return to main menu.				

Main Menu	Sub Menu 1	Value/Info	Sub Menu 2	Value/Info	Sub Menu 3	Value/Info
SINGLE MEAS- UREMENT	PATIENT GROUP	Adult/Child - Maximum initial pressure for adult is 300mmHg and for a child 210mmHg.				
	DEFLATION SPEED	2, 3, 4, 5, 6, 7, 8, 9 mmHg/s or Auto (3mmHg / heart beat).				
	PULSE BEEP	Audible beep with detected heart rate.	On / Off			
	START	Measurement starts and value displayed.	OK	Measurement is displayed (or an error message is given). Press OK again to return to the previous menu.		
			Break	Interrupt measurement: Press the break button when a measurement is being taken to interrupt the measurement.		
SYSTEM	SETTINGS		Language	ENG, DEU, FRA, ITA, SPA, POR, SWE, RUS.		
	DATE / TIME		Date format	<ul style="list-style-type: none">• dd.mm.yyyy• mm/dd/yyyy• yyyyMMdd• ddmmyyyy• yyyy-mm-dd• yyyyMMdd	Set date	Set current date in the format defined.
			Time format	12, 24 hour	Set time	Set current time in the format defined.
	SYSTEM INFO	Serial number, Hardware and pneumatic index, software version, control (date that the next test (MTK) is due), SD card capacity (if inserted)				
	SERVICE AREA	Service information and check screens	Test Calibration	In this menu option the BP measurement can be checked against a calibrated manometer (see Measurement Check, page 52).		
			Hardware Setup	This is an information screen for Factory use only and requires a password to enter.		
			Logbook	This details the number of measurements made and the number or errors registered.		
	BACK	Return to main menu.				

3 BP Recording

3.1 Safety

WARNING

- ▲ Danger of unnoticed necrosis especially in patients with decreased pain sensitivity (due to medication), or with older patients with decreased blood circulation of the extremities. Only carry out long-term measurement with these patients under constant medical supervision.
- ▲ Possibility of strangulation especially in young or older patients, patients with reduced mobility, or patients susceptible to drowsiness due to drugs, etc. The danger increases at night. Only carry out long-term measurement with these patients under constant medical supervision.
- ▲ In some patients petechiae, haemorrhages or subcutaneous haematomas may occur. All patients must be told when putting on the cuff that if they experience pain during the recording they should switch off the equipment and inform the doctor.
- ▲ The cuff must not be attached to a limb that is already used for interventions such as:
 - infusions
 - SpO₂ measurement (loss of data can occur during cuff inflation)
 - an arterio-venous shunt is present.
- ▲ When a five minute measurement interval is defined for recordings of 24h duration or more, bruising or decreased blood circulation can occur in the arm. Only carry out recordings with 5 minute measurement intervals under constant medical supervision.
- ▲ It must be certain that, according to the health of the patient, the use of the device will not damage blood circulation in the arm.

! CAUTION

- ▲ To prevent excessive pressure, it is important to choose the correct cuff size and to check that the correct setting is used in the menu setup (**Record Setup > Patient Group > Adult / Child**).
- ▲ The cuff must not be placed over or near a wound that could cause further injury.
- ▲ As with occasional blood pressure measurement, petechial bleeding can occur in patients with coagulation disorders or having anticoagulant treatment even with the correct cuff size.
- ▲ In patients that have had a single mastectomy the cuff can be placed on the opposite arm.
- ▲ When the patient is monitored by an ME unit, loss of data can occur from the arm during cuff inflation at the ME equipment.
- ▲ During long term recording, the area where the cuff is attached must be checked regularly for signs of ischaemia, purpuras and/or neuropathy.
- ▲ To prevent incorrect measurement results, ensure that the tube is not pinched or compressed.
- ▲ A cuff that is applied to a patient in the recumbent or sitting position is normally located at the same level as the heart. However, if the cuff is located at a level higher than the heart (for instance if the arm of a patient in bed is lifted), this may result in lower-than-actual measurement readings (approx. 7.5 mmHg per 10 cm rise).
- ▲ The unit is safe during defibrillation. However, as a safety precaution, when possible remove the cuff and microphone before defibrillation and, if connected remove the USB connector from the recorder and the PC.
- ▲ Do not touch the unit casing during defibrillation.
- ▲ If the unit gets wet accidentally, switch off and dry with a cloth.
- ▲ If the unit is accidentally immersed in liquid, remove the batteries and return to SCHILLER for checking.

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A list of BR-102 plus error messages is given in the Maintenance section ([see Error Messages, page 55](#)).

3.2 Applying the Cuff

The BR-102 plus is supplied with one of two cuff types. Both are applied in the same way. The buckle cuff instructions detailed here give general guidelines and apply to both types of cuff.

3.2.1 Cuff Type with Buckle

1. Instruct the patient to remove upper clothing.
2. Select the appropriate cuff size according to the patient's upper arm. Five cuff sizes are available as follows:

To fit arm size Midpoint Arm Circumference [cm]	Cuff Designation
7.5 - 13	XS (Extra small, Child, Osc only)
18 - 26	S (Small Adult, Child)
25 - 35	M (Adult)
35 - 45	L (Large Adult)
35 - 45	XL (Extra Large, Wide, Adult)

Note: A cuff that is too small for the patient may give over measurements. Similarly, a cuff that is too large for the patient may give under measurements.



2 cm



3. Uncover the **left** upper arm of the patient. (The cuff is designed to fit the left upper arm, but can be placed on the right arm if required).
4. Locate the brachial artery above the elbow bend inside the upper arm.
5. Position the microphone (marked **Micro**) and indicated by the red strip, over the brachial artery and secure cuff.



- Wrap the cuff around the upper arm in such a way that the patient can still bend arm (the bottom edge of the cuff should be 2 cm away from the elbow bend).
 - Tighten the cuff and secure with the velcro strip. The cuff must be tightened to such an extent that it fits properly on the upper arm and is prevented from moving.
 - To avoid a venous congestion don't tighten the cuff too firmly.
 - The pressure hose and microphone cable must point to the patient's shoulder.
6. Place the pressure hose so that it is loosely positioned behind the patients neck.

7. Connect the pressure hose and microphone cable (if not already connected) to the recorder ([see Connecting the Pressure Hose and Microphone, page 16](#)).
8. Secure BR-102 plus / BR-102 plus PWA to the right or left side of the patient for preference using the holding pouch and belt
 - Ensure that there is enough slack not to strain the hose when the patient moves. Ensure that the patient is comfortable.
 - Tape can be used to secure the tubing to the body if required.
9. When the cuff and device are comfortably positioned, the patient can replace upper clothing.



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- The oscillometric version does not contain a microphone however, the cuff is placed in the same manner.
- It is recommended that the patient wears a t-shirt over the tubing to help hold the tubing in place. This can be covered with for example, a loose fitting shirt.

⚠ CAUTION

- ▲ To help keep the hose in position and prevent strangulation, the T-shirt and/or outer clothing must remain on at night or be replaced by the patient's normal night wear over the hose.

3.2.2 Cuff Type without Buckle

The cuff is positioned, and the hose routing and unit positioning is the same as for the cuff with the buckle.



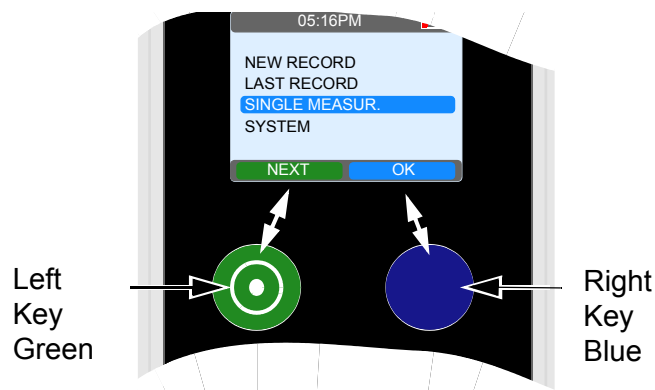
3.2.3 Patient Comfort Sleeve

If the Patient comfort sleeve is to be used, the sleeve can be positioned on the patients arm and then the cuff applied. Alternatively attach the sleeve to the cuff with the velcro strip before applying to the patient and then apply the cuff and sleeve together to the patient.



3.3 Taking a Single Measurement

1. Apply the cuff as previously described.
2. Select **Single measurement** from the main menu:

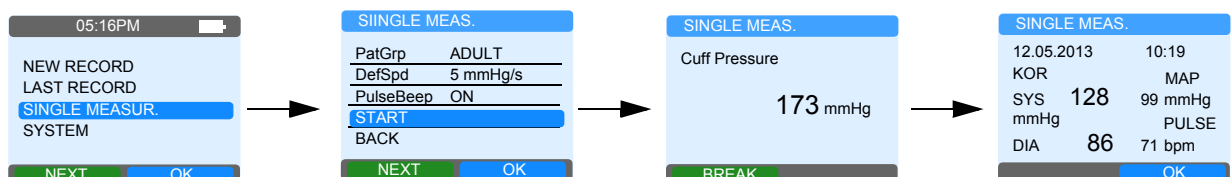


3. Using the buttons on the recorder, select:
 - Patient Group - **Adult / child**
 - Deflation Speed - **2 to 9 mmHg** in 1 mmHg steps, or **Auto**.
 - **Pulse beep** - on or off. The recorder gives an audible beep with the detected heart rate.



When **auto** setting is defined, the deflation rate is set for the detected heart rate at 3 mmHg per heart beat. The heart rate is ascertained when the cuff is inflating.

4. Select **Start**.



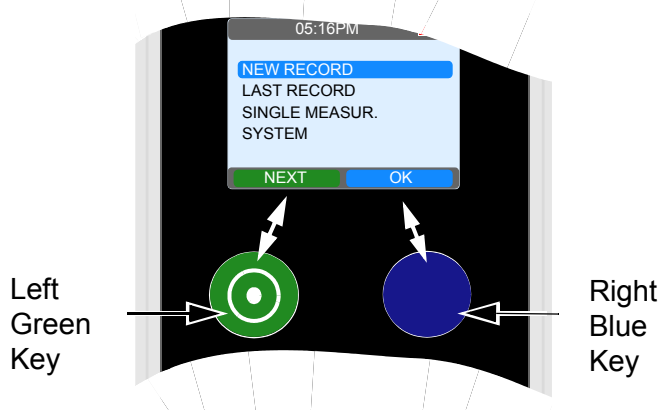
5. The cuff pressure is displayed when the measurement is being taken.
6. On completion the single measurement is displayed with the following information:
 - Date and time of the measurement
 - Recording method used:
 - KOR = Auscultatoric (Korotkoff/Riva-Rocci)
 - OSC = Oscillometric
 - Measurement:
 - SYS = Systolic Pressure [mmHg]
 - DIA = Diastolic Pressure [mmHg]
 - MAP = Mean Arterial Pressure (MAP) in mmHg.
 - Pulse = Pulse rate [bpm] (beats per minute)

3.4 Long Term Recording

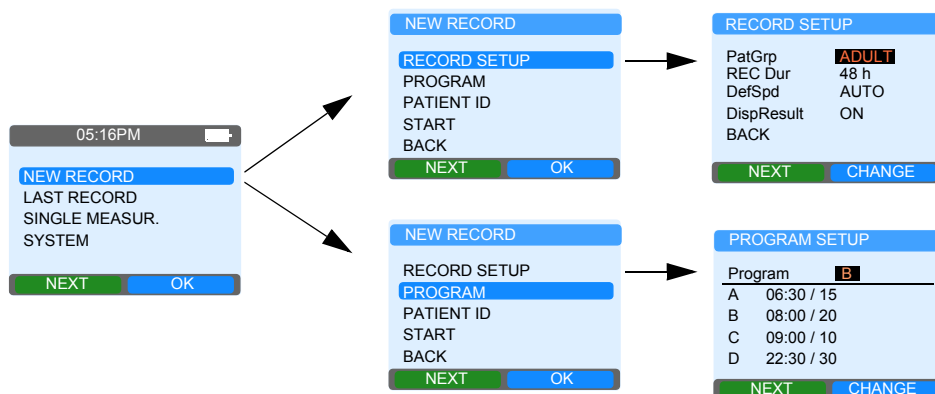


A long term recording can also be started and the recording times defined from the medilogDARWIN2 program. See the user guide for details.

Use the function keys on the recorder to select all settings



Settings are made for patient group (adult or child), recording duration, and deflation speed. In addition four recording time and measurement interval programs are defined (A, B, C and D). Each program has up to eight start times when measurement intervals can be defined.



3.4.1 Record Setup

Select **Record Setup** to define the following settings:

- Patient group: **adult or child**
- Duration: **24 hours or 48 hours**
- Deflation speed: **2, 3, 4, 5, 6, 7, 8, 9 mmHg/s, or Auto.** The **Auto** setting sets the deflation speed according the heart rate.

3.4.2 Program

Selecting a Program

Enter program setup and select **Change** to select the program (A, B, C or D). The recording program defined is used when a long term record is started.

Defining the Recording Programs

Enter the program setup start times, sleep times and duration for the four programs.

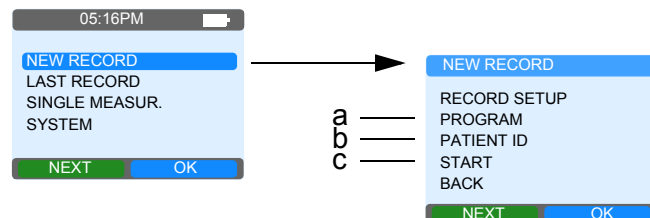
Highlight the recording program to be set and set the start time and measurement duration for each entry. Up to 8 separate start times can be defined with the BP measurement interval defined for each start time.

1. Define the start time by pressing **change**. The time counts up in 10 minute intervals.
2. When the desired start time is shown press **next**. The measurement interval is highlighted.
3. Press **change** to select a BP measurement interval of: 5, 10, 15, 20, 30, 60, or 120 minutes.
4. Press **next** to define the next start time.
5. Continue until all desired start times (with measurement interval) are defined for the selected program.

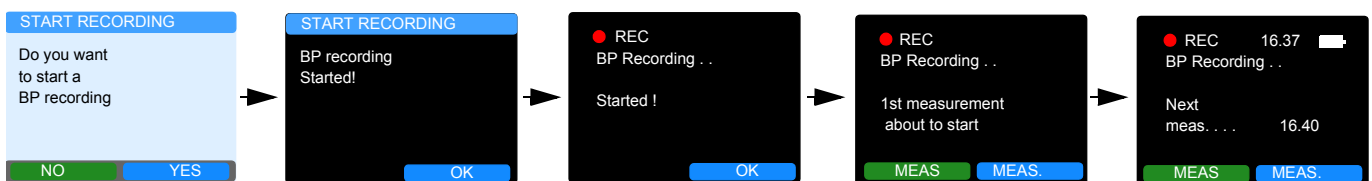
When less than 8 starts are required pressing next twice returns to the previous menu. A minimum of 2 start times must be defined.

3.4.3 Starting a Recording

1. Position cuff on the patient (see [Applying the Cuff, page 27](#)).
2. Insert fully charged batteries in the BR-102 plus / BR-102 plus PWA (see [Inserting/Changing the Batteries, page 15](#)).
3. Check that the correct time (and date) is displayed. These can be changed in **System Setup**.
4. Select **NEW RECORD**.



5. Select **Program (a)** - check/set recording and program setup (see [previous page](#)).
6. Select **Patient ID (b)** to record or listen to the audible Patient ID.
 - The audible patient ID can be played back at the end of the recording and registered when the recording is uploaded to the DARWIN2 program.
 - Select **Start Recording** and speak the patient data into the device.
 - Speak clearly into the microphone. Hold the unit approximately 15 - 20 cm distant. To ensure recording clarity, do not hold the unit too far away.
 - Select **Stop Recording** when the Patient ID has been stated.
 - The recording time allowed for Patient ID is up to 30 seconds.
7. Select **Start (c)** to start the recording. You are prompted to confirm.



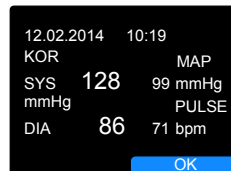
8. After confirming the recording screen is displayed. The initial measurement will be taken within a minute.

9. Check that the initial measurement is successful.



Initial Measurement Check

After the first measurement (on the resting patient), it is recommended that the following is checked to help ensure that the recording is successful:



- Ensure that a BP reading has been obtained and is displayed on the BR-102 plus / BR-102 plus PWA.
- Check that the measurement has been taken using the auscultatory method (**KOR** displayed next to the measurement, below the time). Note: If the cuff does not have a microphone (or an unsuccessful auscultatory measurement has been taken) **OSC** is displayed.
- If the measurement has not been taken correctly check the cuff placement and microphone position.
- Check the battery display and ensure that it still shows full capacity.

10. After checking the first measurement and battery display, position the BR-102 plus / BR-102 plus PWA in the pouch and secure.

- Subsequent measurements are taken as defined for the program selected.
- During BP measurement, the ascending/descending cuff pressure is shown. After a measurement has been taken, the result is displayed for approximately one minute ([see Displaying a Recording, page 36](#)).

3.4.4 Changing the Batteries During a 48 Hr Recording

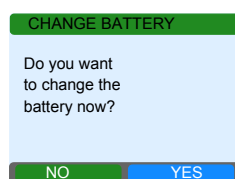


An interrupted recording during battery change (unit is switched off), is automatically continued when battery replacement occurs within 5 hours and the unit is switched on again.

For a 48 hour recording the batteries must be changed. An audible alarm and visual indication is given when the batteries must be changed.

Preventive changing the batteries after 24 hours

1. Press the blue button for 4 seconds. Confirm message **“Change battery”** again with the blue button.

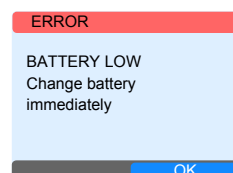
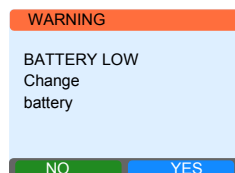


2. Remove the batteries and replace with the fully charged batteries supplied. Observe correct polarity.
3. Press the green button to switch the unit on. The following message is displayed:

BP recording . . Next meas . . xx:xx

Changing batteries when following audible and messages are displayed:

The batteries must be changed when an audible indication is given and the message **Battery LOW - change battery** is displayed.



Proceed as follows:

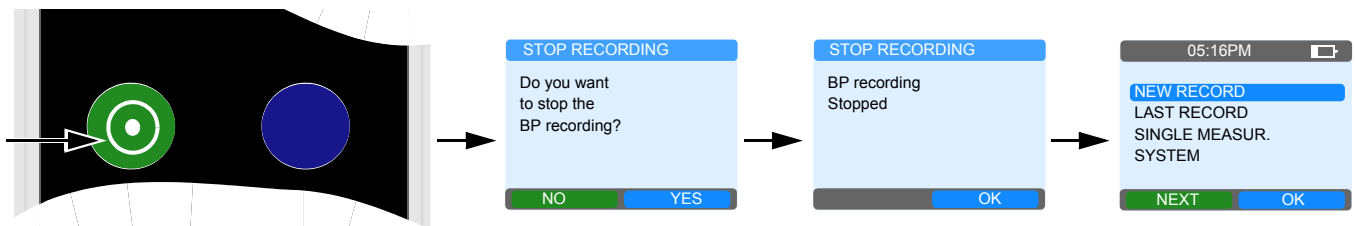
1. Confirm **“Change battery”** with the blue button.
2. Remove the batteries and replace with the fully charged batteries supplied. Observe correct polarity ([see Inserting/Changing the Batteries, page 15](#)).
3. Press the green button to switch the unit on. The following message is displayed:

BP recording . . Next meas . . xx:xx

3.4.5 Stopping the Recording

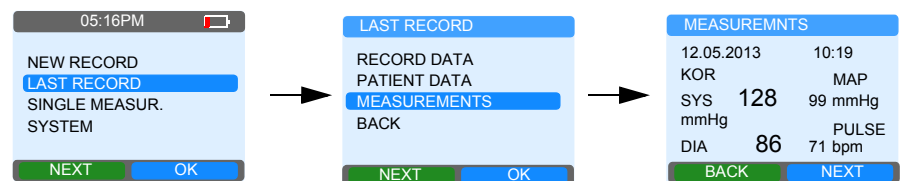
The recording will stop automatically after 24 or 48 hours and no user intervention is required. The recorder can however, be stopped manually if required. Do this as follows:

Press and hold left green **Function** key for 4 seconds and confirm with **YES - blue right Function** key.



If no confirmation is received within 30 seconds, the recording continues.

3.4.6 Displaying a Recording



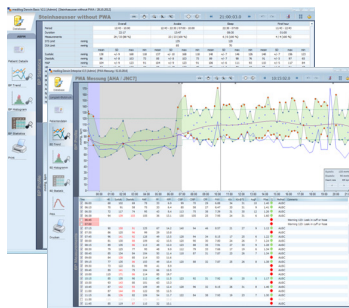
1. Select **Last Record** from the main menu.
2. Select **Measurements** to display all measurements.
3. The measurements are displayed giving:
 - Date and time.
 - Measurement method:
KOR = auscultatory (Riva-Rocci, Korotkoff).
OSC = oscillometric.
 - Systolic Pressure in mmHg.
 - Diastolic Pressure in mmHg.
 - Mean Arterial Pressure (MAP) in mmHg.
 - Pulse rate (PULS) in beats / minute (bpm).
4. **Next** continues to the following measurement and **Back** returns to the previous measurement.
5. To return to the main menu press **Back** for approximately 4 seconds. The recorder also returns to the menu automatically when no key is pressed for approximately one minute.

3.4.7 Uploading the Recording to the medilogDARWIN2

The recording can be reviewed, analysed and a report created with the medilogDARWIN2 program.



Connect BR-102 plus /
BR-102 plus PWA to PC.



Use medilogDARWIN2 to
retrieve data, analyse and edit.



Print report or save as
PDF file.

Details of uploading a BP recording to the medilogDARWIN2 program is described in the medilogDARWIN2 user guide.

4 Patient Information

WARNING

- ▲ Danger of strangulation. The shoulder strap or cuff tube can become entangled around the patient's neck and lead to strangulation. The danger increases at night. Ensure the patient is aware of the danger. The doctor should draw the patient's attention to the fact that the cuff must be worn on the upper arm only and care must always be taken to ensure that neither the shoulder strap nor the air tube ever become wrapped around the neck. The air tube must be positioned under a T-shirt or outer clothing that must continue to be worn at night over the tubing to help keep it secure.
- ▲ Tell the patient that if any numbness in the arm, chafing, pain or discomfort is experienced, the cuff must be removed and to contact the surgery.

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- ▲ Tell the patient not to get the unit wet - the unit is not waterproof and must remain dry. If the patient is permitted to take a bath or shower during the recording (e.g. when taking a 48 hour recording) it must be emphasised that the recorder and the cuff must be removed before taking a bath or shower. Instruction should be given on re-applying the cuff and attaching the device.

4.1 General

Inform the patient about the use of the BR-102 plus / BR-102 plus PWA and instruct the patient on the following points:

- Explain to the patient how to place the cuff correctly and the times and intervals that measurements will be taken.
- The equipment must not be used in the vicinity of an MRI scanner.
- The performance of the BR-102 plus / BR-102 plus PWA can be affected by extremes of temperature, humidity and altitude.
- If taking a 48 hour recording, inform the patient how to change the batteries. Instruct the patient to keep replacement batteries in the bag or box provided and not to dispose of the old batteries. Spent batteries must be returned in the bag or container provided.
- Tell the patient that during the measurement:
 - Noisy places should be avoided.
 - Not to move the arm during the measurements and a recommendation that where possible, the patient relaxes during the measurement process and does not speak.
 - Entries must be made in the patient diary during the long-term measurement.

- The pressure tube and cuff must not be knotted or stretched or subject to compression or restriction. The air tube may kink when inflated. It should be explained that particularly when sleeping, the equipment should be positioned in such a way that the tube cannot be compressed. If the patient is not fully competent, the equipment should be worn only under supervision.
- After an invalid measurement a second measurement will be initiated immediately.
- The recorder should not be turned off during the recording.

4.2 Taking an Extra Measurement

To take an extra BP measurement during the recording, press either of the **control buttons to display the recording screen**. Then with the recording screen displayed, press either of the control buttons again for approximately one second to start a measurement. Record the measurement in the patient diary.

4.3 Interrupting a Measurement During the Recording

To interrupt a measurement, press either of the **control buttons** during the measurement. This will deflate the cuff. An interrupted measurement will be recorded with an error and will not be repeated. The next measurement will take place according to the schedule.



Every extra measurement or interrupted measurement should be entered in the patient diary together with the time, reason, activities being undertaken at the time of occurrence, and the symptoms.

The template for the patient diary is stored on the software CD as a Word file and as a pdf file. An example is given at the end of the book.

4.4 Extended 48-Hour Recording

The patient must be instructed how to change the batteries for an extended recording ([see Changing the Batteries During a 48 Hr Recording, page 35](#)).

It is recommended that the patient receives two fully charged batteries that can be used for replacement. These must be placed in a small box or plastic bag to help prevent a short circuit of the battery. The patient should return the spent batteries in the same container.

If the patient is old or in any way confused, consider asking the patient to return to the surgery for battery replacement.

4.5 BR-102 plus PWA Unit Measurements

The BP measure interval, cuff application, and the start and stop procedure are identical to the standard unit. However, after every individual measurement, the cuff is again inflated to the diastolic pressure and held at that pressure for 10 seconds while PWA data is obtained. After this time the cuff again deflated and ready for the next programmed measurement.

5 Maintenance and Cleaning



All maintenance work must be carried out by a qualified technician authorised by SCHILLER AG. Only maintenance procedures given in this book may be carried out by the user.

The following table indicates the maintenance intervals, the maintenance requirement, and the person authorised to carry out the procedure.

Interval	Service	Responsible
Every 6 months	• Visual inspection of the monitor, cables and tubes and cuff (see below).	→ User
Every 24 months	• Measurement calibration.	→ SCHILLER AG authorised service centre.

5.1 Visual Inspection

Visually inspect the unit, cables, connectors, tubing and cuff for the following:

- Device casing not broken or cracked.
- Display not broken or cracked.
- Microphone cable sheathing and connectors undamaged. No kinks in the cable.
- No kinks, abrasion or wear in the tubing assembly.
- Pressure bladder and tube connector in good condition.
- Cuff and velcro connector in good condition. No excessive soiling or damage.



- ▲ Do not use if the unit, or any cable assembly or accessory, is damaged.
- ▲ Defective units, damaged cables, or damaged accessories must be replaced immediately.

5.2 Battery Maintenance

- The batteries require no maintenance during their life.
- The life cycle of the batteries is approximately 500 charge / discharge cycles.
- To prevent the possibility of battery leakage, always remove the batteries from the device when not used for prolonged periods.

5.2.1 Charging the Batteries



- Full capacity of new NIMH batteries are only reached after three charge/discharge cycles.
- Totally discharged batteries require approximately three hours to be fully charged (with two batteries in charger), or six hours (with four batteries in charger).
- Charged batteries lose their charge when removed from the charger unit. Therefore to ensure full capacity only remove the batteries from the charger immediately before taking a recording.
- No harm will be done to the batteries by leaving them in the charger unit.

Remove the batteries from the BR-102 plus / BR-102 plus PWA ([see Inserting/Changing the Batteries, page 15](#)), and place in the battery charger unit. Leave the batteries in the charger unit until fully charged (see battery charger operating instructions).

5.2.2 Battery Disposal



- ▲ Danger of explosion! batteries must not be burned or disposed of in domestic rubbish.
- ▲ Danger of acid burns! Do not open the batteries.



The batteries must be disposed of in municipally approved areas or sent back to SCHILLER AG.

5.3 Cleaning the Casing and Hose Assembly

CAUTION

- Some patients have intolerances (e.g. allergies) to disinfectants or their components. If you have such a patient or you are not sure, remove possible residues with careful washing.

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- Do not autoclave the unit or any accessories.
- Do not immerse in liquid when cleaning. If liquid does penetrate the unit, switch it off immediately and send it to SCHILLER for testing.
- Use of cleaning solutions which have a high acid content or are otherwise inappropriate can cause damage to the equipment, including cracking and deterioration of the plastic case.
- Always follow the mixing/diluting instructions provided by the manufacturer of the cleaning solution.
- Never use any of the following solutions or similar products to clean the equipment: ethyl alcohol, ethanol, acetone, hexane, abrasive or scouring powder or material, any cleaning material that damages plastic.
- The pressure tube and microphone cable must not be exposed to excessive mechanical stress. Whenever disconnecting, hold the plug/connector and not the cable.
- When cleaning, ensure that all labels and safety statements, whether etched, printed or stuck to the unit, remain in place and remain readable.

5.3.1 Cleaning the Device

Before cleaning the unit or any accessories, thoroughly inspect them. Look for any signs of damage and any improper mechanical function of buttons or connectors.

The casing of the BR-102 plus / BR-102 plus PWA and the cable assemblies can be cleaned with a cloth slightly moistened (not wet) on the surface only. Where necessary a domestic non-caustic cleaner or 70% alcohol solution can be used for grease and finger marks. Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved cleaning solutions. Thoroughly wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, latches, or crevices. If liquid gets into connectors, dry the area with warm air, and then check the equipment to confirm that it operates properly.

5.3.2 Cleaning the Pressure Hose/Microphone Cable Assembly

1. Before cleaning, inspect the hose/cable for damage. Gently bend and flex all parts of the assembly. Inspect for splits in the sheathing, damage or extreme wear, exposed wires, or bent connectors.
2. Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved solutions listed below. Gently grip the cable with the damp cloth in the centre of the cable and slide the cable through the cloth 20 cm at a time until clean.

CAUTION

- Do not clean the whole length in one single action as this may cause bunching of the sheathing.
- Wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, latches, or crevices. If liquid gets into connectors, dry the area with warm air

5.3.3 Approved Cleaning Solutions

- 70% solution isopropyl alcohol
- Neutral mild detergent solution
- All products designed for cleaning plastic.

5.3.4 Cleaning Materials that must not be Used

Never use products containing the following:

- Ethyl alcohol
- Acetone
- Hexane
- Abrasive cleaning powder
- Plastic-dissolving products

5.4 Cleaning the Cuff and Pouch

5.4.1 Cleaning the Cuff



- Do not use bleach
- Do not iron
- Do not tumble dry
- Do not spin dry
- Observe the following when washing:
 - Program setting of 30°C (86°F) for cuff without buckle.
 - Program setting of 60°C (140 °F) for cuff with buckle.
 - Select gentle or delicate cycle.
 - Use a mild washing powder. Do not use biological powder because of possible allergic reactions.
 - Do not use fabric softeners, disinfectant rinses, textile deodorants or any other additives - these solutions may leave residues and damage the material.
- Leave cuff to dry naturally.

The cuff must be washed or disinfected after every long-term measurement using any of the following methods:

In a Standard Washing Machine

- Prepare Cuff:
 - Buckle type cuff ([see Cuff Preparation - Cuff Type With Buckle, page 46](#)).
 - Cuff without buckle ([see Cuff Preparation - Cuff Type Without Buckle, page 48](#)).
- Fold the cuff and secure the cuff with the velcro strip.
- Place the cuff in a cleaning bag.

Dry Clean

- Prepare the cuff in the same way as for washing.

Disinfect

- Disinfect by gently wiping the cuff with an approved hospital grade disinfectant ([see Sterilisation, page 51](#)).

5.4.2 Cuff Preparation - Cuff Type With Buckle



Before cleaning or washing the cuff, the microphone must be removed from the cuff and the pressure hose disconnected.

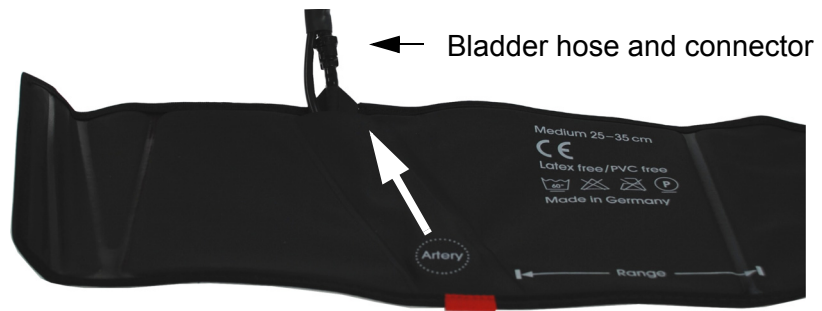
1. Disconnect the pressure hose from the cuff inflation bladder connector by twisting the connector a quarter turn.
2. Gently remove the microphone from the microphone pouch by pushing on the outside of the cuff to move the microphone along the pouch channel until it can be removed from the cuff
3. Insert the bladder plug in the bladder hose to prevent ingress of water. Insert and gently twist a quarter turn to secure to the hose connector.
4. Fold the cuff and secure the cuff with the velcro strip.
5. Place the cuff in a cleaning bag and wash.

CAUTION

- ▲ Do not pull on the microphone lead when removing the microphone as this can cause damage to the connections.
- ▲ Danger of water ingress in the bladder during washing. Ensure the bladder plug is inserted in the bladder hose before washing or dry cleaning.
- ▲ After washing ensure that the bladder plug is still in place and that no water has got into the bladder.
- ▲ If water has got into the bladder do not use. Water in the bladder can cause damage to the BR-102 plus / BR-102 plus PWA.

Re-inserting the Microphone Connecting the Pressure Hose

1. Remove the bladder plug and check that there has been no ingress of water in the bladder.
2. Gently slide the microphone in the microphone pouch and push fully home from the outside of the cuff. Ensure the microphone is fully home and occupies the area indicated by the micro designation printed on the cuff.
 - The metallic (yellow) side of the microphone must be facing upwards when inserting in the cuff (the metallic side faces the patient).
 - Ensure that the microphone is correctly inserted in the cuff. It must fully reach the bottom of the pouch.
3. Remove the bladder plug and connect and secure the pressure hose to the cuff bladder connector with a quarter turn



Gently push the microphone out of the cuff and disconnect the pressure hose from the bladder (connector quarter twist).



Connect the bladder plug to the bladder connector for washing.

After washing, disconnect the bladder plug and reinsert the microphone in the microphone pouch.



Reconnect the pressure hose to the cuff bladder.



5.4.3 Cuff Preparation - Cuff Type Without Buckle



Disconnecting the Pressure Hose and Removing the Microphone and Bladder

Before cleaning, the microphone and the bladder must be removed from the cuff and the pressure hose disconnected.

1. Disconnect the pressure hose from the cuff inflation bladder connector by twisting the connector a quarter turn.
2. Gently remove the microphone from the microphone pouch by pushing on the outside of the cuff to move the microphone along the pouch channel until it can be removed from the cuff.

⚠ CAUTION

- ▲ Do not pull on the microphone lead when removing the microphone as this can cause damage to the connections.

3. Place hand in the bladder pouch and remove the cuff bladder.
4. Fold the cuff and secure the cuff with the velcro strip.
5. Place the cuff in a cleaning bag and wash.

Re-inserting the Microphone and the Bladder and Connecting the Pressure Hose

1. Gently slide the microphone in the microphone pouch and push fully home from the outside of the cuff. Ensure the microphone is fully home and occupies the area indicated by the micro designation printed on the cuff.
 - The metallic (yellow) side of the microphone must be facing upwards when inserting in the cuff (the metallic side faces the patient).
 - Ensure that the microphone is correctly inserted in the cuff. It must fully reach the bottom of the pouch.
2. Replace the bladder in the cuff - ensure that the bladder is flat and not twisted in the cuff.
3. Connect and secure the pressure hose to the cuff bladder connector with a quarter turn.

Bladder hose and connector →

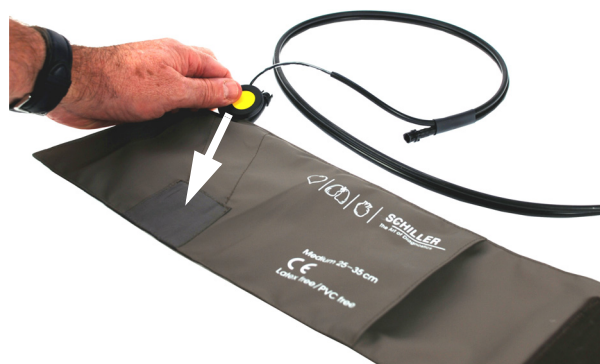


Gently push the microphone out of the cuff and disconnect the pressure hose from the bladder (connector quarter twist).



Remove the bladder from the cuff.

After washing re-insert the bladder in the cuff.



Push the microphone until home in the micro pouch.

Reconnect the pressure hose to the cuff bladder.



5.4.4 Cleaning the Pouch (and shoulder and waist strap)



Clean the pouch with a damp cotton cloth (do not use corrosive liquids or solvents) or can be washed in a washing machine at 30°C using a mild washing powder (do not spin). Do not use fabric softeners or other aids (e.g. disinfectant rinses). These solutions may leave residues and damage the material. The Pouch is not suitable for drying in a tumble dryer.



- Do not use bleach
- Do not iron
- Do not Tumble dry
- Do not expose neoprene pouch to direct sun light



Wash the pouch at a temperature of 30° C with a normal washing powder. Select 'gentle or delicate cycle'. Leave to dry naturally.

5.4.5 Disinfection

The user (doctor) decides, whether and when disinfection of the cuff sleeve is necessary for reasons of hygiene. Use commercially available disinfectants intended for clinics, hospitals and practices to disinfect the device. Disinfect the unit in the same way as described for cleaning ([see Cleaning the Device, page 44](#)). For cleaning and disinfecting the cuff, wipe with a damp cloth. SCHILLER has tested and recommends the following solutions:

- Terralin Liquid (manufacturer: Schuelke & Mayr)
- Promanum N (manufacturer: B. Braun)

Additionally, the cuff can be disinfected with the following:

- Cidex
- Sporicidin
- Mikrozid
- Isopropyl alcohol 70%
- Ethanol 70%
- Buraton fluid

It is vital to observe the manufacturer's instructions for the use of these products. Always leave the cuff to dry completely.

When using other disinfectants not recommended by SCHILLER, the user is responsible for proving harmless application. Never use disinfectants that leave a residue on the product or which are unsuitable for use in contact with skin.

5.4.6 Admissible Disinfectants for the Casing

- Isopropyl alcohol 70%
- Propanol (70-80%)
- Ethyl hexanal
- Aldehyde (2-4%)
- Ethanol (70-80%)
- All products that are suitable for ABS plastic

5.4.7 Non-admissible Disinfectants

Never use products containing the following:

- Organic solvents
- Ammonia-based detergent
- Abrasive cleaning agents
- 100% alcohol, Virex, Sani-Master
- Sani-Cloth®, Ascepti® or Clorox® wipes
- HB Quat®
- Conventional cleaner (e.g. Fantastic®, Tilex® etc.)
- Conductive solution
- Solutions or products containing the following ingredients:
 - Acetone
 - Ammonium chloride
 - Betadine
 - Chlorine, wax or wax compound
 - Ketone
 - Sodium salt

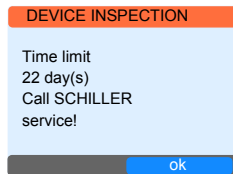
5.4.8 Sterilisation

The cuff can be sterilised with Ethylene oxide gas. Prepare the cuff as detailed previously. After sterilisation the parts that were exposed to the gas must be aired.



- ▲ All relevant regulations and safety precautions must be complied with.

5.5 Calibration



The unit must be returned to a SCHILLER approved centre for calibration at the interval defined by local regulations or at least every two years. A reminder message is displayed 30 days before calibration is due and counts down the subsequent days every time the unit is switched on.

The message is displayed for approximately 60 seconds before the main BR-102 plus / BR-102 plus PWA menu is displayed. Select OK to display the main menu immediately for normal use.

5.6 Measurement Check

A service option is incorporated in the BR-102 plus / BR-102 plus PWA to check the measurement accuracy and the correct functioning of the overpressure valve. This option can be performed at any time to check the unit's integrity.

5.6.1 Equipment Required



- Calibrated Manometer (purchased locally).
- BR-102 plus / BR-102 plus PWA connector and hose assembly.

5.6.2 Setup



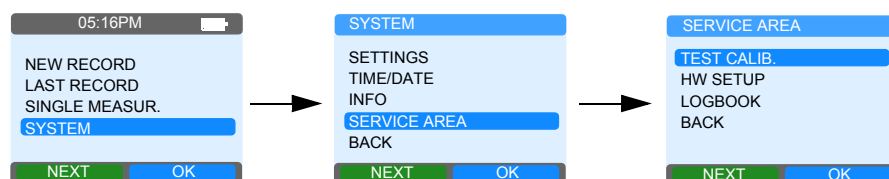
5.6.3 Measurement Accuracy

1. Remove the pressure hose and microphone from the BR-102 plus / BR-102 plus PWA and connect to the manometer as shown.

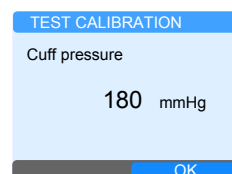


The setup shown is an example connection only. Dependent on the type of manometer and hose connector used, the cuff connector can be removed from the BR-102 plus / BR-102 plus PWA and connected directly to the manometer.

2. Select **System > Service Area > Test Calibration**.



3. Pump once or twice to pressurise to approximately 200 mmHg.



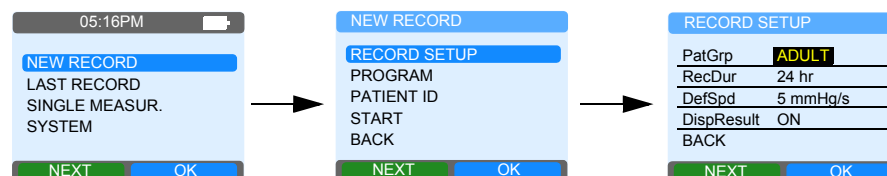
4. The pressure will slowly drop. Check the reading on the BR-102 plus / BR-102 plus PWA against the calibrated pressure gauge. The two measurements should be within 3 mmHg. After 120 seconds the BR-102 plus / BR-102 plus PWA releases the pressure.

5.6.4 Overpressure Relieve Valve

The overpressure relieve valve can be checked for correct release for both the adult settings and paediatric setting.

Adult

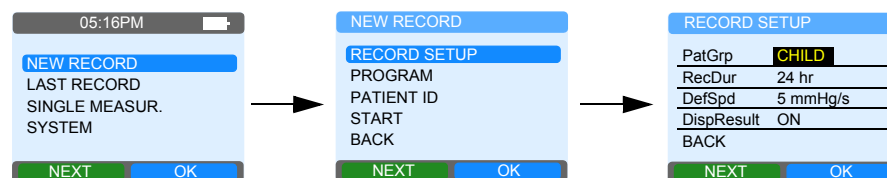
1. Set / check that Adult is set in the record setup. This can be done for single measurement or new record:



2. Setup and enter the calibration screen as detailed on the previous page.
3. Pump to 300 mmHg. Slowly continue to pump and check that the overpressure valve activates (a pressure hiss is heard and the cuff rapidly deflates) at **320 mmHg ± 10 mmHg**.

Paediatric

1. Set the record setup to Child. This can be done for single measurement or new record:



2. Setup and enter the calibration screen as detailed on the previous page.
3. Pump to 200 mmHg. Slowly continue to pump and check that the overpressure valve activates (a pressure hiss is heard and the cuff rapidly deflates) at **225 mmHg ± 5 mmHg**.

5.7 Error Messages

The following is a list of the error message that can appear on the device. A common occurrence of errors is movement or a noisy environment during measurement. In most cases checking the hose connections and cuff placement, and then retaking the measurement without moving the arm will solve the error.

5.7.1 Error Message Table

No.	Message	Cause	Remedy
51	Battery low	• Battery voltage too low to take a measurement.	→ Replace with fully charged batteries.
52	Valve/pump	• Valve or pump is defective; air leak.	→ Check pneumatic system. Check that tube is secured and that the connectors at both ends are securely in place. Check for holes or air leaks in the cuff bladder and pressure hose; contact service department.
120	Signal Disturbed	• Disturbances in measurement signal.	→ Perform measurement in quiet environment; avoid moving the arm during a measurement.
122	Cuff pressure	• Too much residual air in cuff bladder.	→ Ensure that cuff is completely decompressed before commencing a measurement.
123	No cuff	• No pressure (<3 mmHg) 10 sec after inflation; leak in the cuff or hose.	→ Connect cuff; check hose connections.
124	Measur. break	• Measurement stopped manually.	→
126	Measurement time	• Measurement time too long; hose, cuff or pump is defective.	→ Check hose connections. Check hose and bladder for defects. Contact service department.
127	Cuff loose	• Pressure too low (<10 mmHg) 10 sec after inflation.	→ Check cuff; if necessary tighten it more firmly.
128	Pump time	• Pump-up time too long (50/60 sec, depending on patient type, C/A); hose, cuff or pump is defective.	→ Check cuff and hose. Contact technical service.
130	Overpressure	• Device automatically shut off by relief valve.	→ Maximum pressure reached.
140	Meas. invalid	• Evaluation impossible (KOR).	→ Check position of microphone; repeat measurement.
150	Meas. invalid	• Evaluation impossible (OSC).	→ Check cuff; avoid moving the arm.
180	No signal	• Pressure reached 70 mmHg and no Korotkoff signal detected.	→ Connect microphone. Check position of microphone.
181	Weak signal	• Pressure reached 50 mmHg and no Korotkoff signal detected.	→ Place microphone over brachial artery; ensure that the microphone is correctly orientated (metallic side towards arm).

No.	Message	Cause	Remedy
182	Signal disturbed	• Too much interference in Korotkoff signal.	→ Perform measurement in quiet environment; avoid moving the arm during measurement.
190	No signal	• Pressure reached 50 mmHg and no pulse detected (OSC).	→ Check cuff.
191	Weak signal	• Less than 8 pulse beats detected (OSC).	→ Check cuff.
192	Signal disturbed	• More than 200 pulse beats detected (OSC).	→ Avoid moving the arm during measurement.
198	DIA not detected	• Minimum pressure reached without diastolic value detected (OSC).	→ Avoid moving the arm during measurement.
199	SYS not detected	• Minimum pressure reached without systolic value detected (OSC).	→ Avoid moving the arm during measurement.
200	No pulse	• No pulse detected (OSC).	→ Repeat measurement; check cuff.
201	Pulse > max.	• Too many pulse beats detected (OSC).	→ Perform measurement in quiet environment; avoid moving the arm during measurement.
202	Pulse < min.	• Too few pulse beats detected (OSC).	→ Repeat measurement; check cuff.
210	No pulse	• No pulse detected (KOR).	→ Connect microphone; Check position of microphone. Ensure that the microphone is correctly orientated (metallic (yellow) side towards arm).
211	Pulse > max.	• Too many pulse beats detected (KOR).	→ Perform measurement in quiet environment; avoid moving the arm during measurement.
212	Pulse < min.	• Too few pulse beats detected (KOR).	→ Place microphone over brachial artery; ensure that the microphone is correctly orientated (metallic (yellow) side towards arm).
238	Min. pressure	• Minimum pressure reached without measurement result.	→ Repeat measurement.
239	Max. pressure	• Maximum pressure reached without measurement result.	→ Repeat measurement.
255	Unit error	• Device is defective.	→ Contact technical service.
322	No measurements available	• No recording stored. • No recording has been made. • Incorrect initialisation of a recording. • Error in the recording storage.	→ Take/ retake a recording.
323	No patient data available	• No patient data has been recorded.	→ Enter patient data.
324	SD- card missing	• SD card not inserted. For PWA recording an SD card is necessary.	→ Insert an SD card.

6 Technical Data

Device Name	BR-102 plus / BR-102 plus PWA
Dimensions	100 x 68 x 28 mm (l x w x h)
Weight	200 grams (including rechargeable batteries)
Display	Graphical colour OLED with multi-language menu
Power Supply	
Power consumption	2.4 V, 4.0 VA
Batteries	Type AA, 2 rechargeable NiMH, 1.2 V, 2700 mAh
Capacity	24 hours (approximately 100 measurements can be performed) Battery capacity indicated on the display
Data Storage	Flash memory with capacity for over 400 measurements and 30 sec. of voice recording Additionally Storage: micro SD card
Interface	USB 2.0 interface for data transfer
Programming	Menu guidance; 2 buttons
Recording Protocols	Four programmable interval groups (each group has 8 measurements)
Measurements	
Methods of measurement	BR-102 plus Auscultatory (Korotkoff / Riva-Rocci) with additional oscillometric method as backup or only oscillometric, both with linear adjustable deflation rate. BR-102 plus PWA Same as BR-102 plus but with additional 10 second oscillometric signal recording for PWA.
Measurement duration	24 or 48 hr
Measuring range	
Blood pressure	25 to 300 mmHg (± 3 mmHg)
Heart rate	25 to 300 bpm (25 to 100 bpm $\leq \pm 2\%$) (100 to 200 bpm $\leq \pm 4\%$) (200 to 300 bpm $\leq \pm 5\%$)
Deflation rate	2 to 9 mmHg/s, automatic (3 mmHg / heart beat)
Measurement intervals	5 to 120 min

Safety Standards	IEC 60601-1 ISO 81060-1 IEC 80601-2-30 IEC 60601-1-2 (EMC)
Protection Class	Internal power supply
Applied Part	BF according to IEC/EN 60601-1
Conformity	CE 0123 according to Annex II 93/42/EEC (medical devices)
Classification	Ila according to MDD 93/42/EEC
Trusted Accuracy	<p>The BR-102 plus / BR-102 plus PWA is clinically validated to all internationally recognised organisations:</p> <ul style="list-style-type: none">– BHS (in progress)– ESH (2002)– AAMI SP10:2002
Environmental Conditions (Operation)	
Operating temperature	• + 10°C to + 40°C (+ 50°F to + 104°F)
Relative humidity	• 15 % to 95 % (non-condensing)
Pressure during operation	• 700 hPa to 1060 hPa
Environmental Conditions (storage and transport)	
Temperature transport	• - 10°C to + 50°C (+ 14°F to + 122°F)
Temperature storage	• + 5°C to + 50°C (+ 41°F to + 122°F)
Relative humidity (storage and transport)	• 10 % to 95 % (non-condensing)
Pressure (storage and transport)	• 500 hPa to 1060 hPa

6.1 Electromagnetic Radiation



"Non-ionic electromagnetic radiation"

The user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the BR-102 plus / BR-102 plus PWA. The distance depends on the output performance of the communication device as indicated below.

HF source	Transmitter frequency [MHz]	Power P [W]	Distance d [m]
Radio telephone (microcellular) CT1+, CT2, CT3	885-887	0.010	0.23
Cordless DECT telephone, WLAN, UMTS phone	1880-2500	0.25	1.17
Mobile phone USA	850/1900	0.6	1.8
Mobile phone			
- GSM900	900	2	3.3
- GSM850, NMT900, DCS 1800	850,900,1800	1	2.3
Walkie-talkie (rescue service, police, fire brigade, service)	81-470	5	2.6
Mobile telephone system (rescue service, police, fire brigade)	81-470	100	11.7



It can be deducted from the table that portable HF telecommunication devices must not be used within a radius of 3 metres from the BR-102 plus / BR-102 plus PWA.

Further measures to prevent electromagnetic interferences:

The user can take the following measures to prevent electromagnetic interferences:

- Increase distance to the source of interference.
- Turn the device to change the angle of radiation.
- Only use original accessories.



For more information on the use in an electromagnetic environment in accordance with IEC/EN 60601-1-2, tables 201, 202 and 204, please consult the service handbook.

6.2 Classification

6.2.1 Clinical Tests

The BR-102 plus / BR-102 plus PWA fulfils the requirements of the ESH (European Society of Hypertension). Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, Manual, electronic or automated Sphygmomanometers.

The blood pressure classification is according to standards specified by the World Health Organisation (WHO) and the Guidelines for management of hypertension: report of the fourth Working Party of the British Hypertension Society, 2004 BHS IV, B Williams et al: J Hum Hyp (2004); 18: 139-185.

6.2.2 Classification of Blood Pressure Levels in Adults

Category	Systolic blood pressure [mm Hg]	Diastolic blood pressure [mm Hg]
Blood pressure		
Optimal	<120	<80
Normal	<130	<85
High normal	130-139	85-89
Hypertension		
Grade 1 (mild)	140-159	90-99
Grade 2 (moderate)	160-179	≥110
Grade 3 (severe)	≥180	≥110
Isolated systolic hypertension		
Grade 1	140-159	<90
Grade 2	>160	<90

- Based on clinic blood pressure and not values for ambulatory blood pressure measurement.
- Threshold blood pressure levels for the diagnosis of hypertension using self/home monitoring are greater than 135/85 mm Hg.
- For ambulatory monitoring 24 hour values are greater than 125/80 mmHg.
- If systolic blood pressure and diastolic blood pressure fall into different categories the higher value should be taken for classification.

6.2.3 Hypertension in Children / Adolescents

Age		High to Normal [mm Hg]	Significant Hypertension [mm Hg]	Severe Hypertension [mm Hg]
6 - 9 years	Sys	114 - 121	122 - 129	≥130
	Dia	74 - 77	78 - 85	86
10 - 12 years	Sys	122 - 125	126 - 133	≥134
	Dia	78 - 81	82 - 89	90
13 - 15 years	Sys	130 - 135	136 - 143	≥144
	Dia	80 - 85	86 - 91	92
16 - 18 years	Sys	136 - 141	142 - 149	≥150
	Dia	84 - 91	92 - 97	98

Adapted from the Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents. Paediatrics 2004 Aug;114(Suppl 2:):555-76

7 Accessories



- ▲ Always use SCHILLER replacement parts and disposables, or products approved by SCHILLER. Failure to do so may endanger life and invalidate the guarantee.

Your local representative stocks all the disposables and accessories available for the BR-102 plus / BR-102 plus PWA. A full list of all SCHILLER representatives can be found on the SCHILLER website (www.schiller.ch).

7.1 Documentation

Part Number	Description
2.511043	medilogDARWIN2 User Guide DE
2.511044	medilogDARWIN2 User Guide EN
2.511045	medilogDARWIN2 User Guide FR
2.511064	medilogDARWIN2 User Guide ES
2.511065	medilogDARWIN2 User Guide SV
2.511066	medilogDARWIN2 User Guide RU
2.511067	medilogDARWIN2 User Guide ZH-S
2.540045	BR-102 plus / BR-102 plus PWA Recurrent test and service handbook

7.2 General Accessories

Part Number	Description
2.156077	Premium reusable pouch red BR-102 plus / BR-102 plus PWA.
2.156079	Premium accessories case red including reusable pouch red.
2.156086	Holter pouch single use, white, set of 50
2.156088	Shoulder and waist strap for premium reusable pouch red BR-102 plus / BR-102 plus PWA.
2.200119	Battery Ni-MH AA BR-102 plus / BR-102 plus PWA, BP-200 plus, rechargeable.
2.200179	Charging unit BR-102 plus / BR-102 plus PWA, BP-200 plus, MS-12blue, 90-264 VAC (4 batteries can be charged at the same time).
2.310215	USB / mini USB cable for MT-101, BR-102 plus / BR-102 plus PWA, BP-200plus, TM-1.

7.3 Cuff and Cuff Accessories

Part Number	Description
2.100325	Velcro plaster for BR-102, BR-102 plus / BR-102 plus PWA, BP-200plus, set of 10.
2.100326	Adhesive plaster for microphone, BR-102, BR-102 plus / BR-102 plus PWA and BP-200 plus, set of 10.
2.120053	Blood pressure cuff 2008 with bladder, size XS, 7.5-13 cm, BR-102 plus / BR-102 plus PWA for oscillometric measurement only.
2.120057	BP buckle cuff 2014 with bladder, size S, 18-26cm, for BR-102 plus / BR-102 plus PWA, BP-200 plus.
2.120058	BP buckle cuff 2014 with bladder, size M, 25-35cm for BR-102 plus / BR-102 plus PWA, BP-200 plus.
2.120059	BP buckle cuff 2014 with bladder, size L, 35-45cm, for BR-102 plus / BR-102 plus PWA, BP-200 plus.
2.120062	BP buckle cuff 2014 & buckle, Size M, complete with microphone and tube BR-102 plus / BR-102 plus PWA for auscultatory measurement.
2.120061	BP buckle cuff 2014, Size M, with tube for oscillometric measurement only
2.120054	Tube for BP cuffs 2008 and 2014 BR-102 plus for oscillometric measurement only
2.120063	BP velcro cuff 2014, size XS, BR-102 plus for oscillometric measurement only
2.120064	BP velcro cuff 2014, size S, BR-102 plus, BP-200 plus
2.120065	BP velcro cuff 2014, size M, BR-102 plus, BP-200 plus
2.120066	BP velcro cuff 2014, size L, BR-102 plus, BP-200 plus
2.120067	BP velcro cuff 2014, size XL, BR-102 plus, BP-200 plus
2.120068	Comfort fleece size XS, package of 10, for BP cuff 2.120063
2.120069	Comfort fleece size S, package of 10, for BP cuff 2.120064
2.120070	Comfort fleece size M, package of 10, for BP cuff 2.120065
2.120071	Comfort fleece size L, package of 10, for BP cuff 2.120066
2.120072	Comfort fleece size XL, package of 10, for BP cuff 2.120067

8 BR-102 plus PWA

8.1 Overview

The clinical usefulness of central blood pressure (BP) as an index of risk for cardiovascular disease and the augmentation index (AIx) is often cited with relation to sex, age and heart rate. Arterial stiffness is an important determinant of cardiovascular risk and the augmentation index (AIx) is a measure of wave reflection and thus systemic arterial stiffness derived from the ascending aortic pressure waveform.

The central arterial pulse wave is the sum of the forward pressure wave generated by left ventricular ejection and a backward propagating wave that is subsequently reflected from the peripheral site. The time point at which these forward and backward propagating waves merge and the amplitude of the reflected (backward) wave affect the level of central BP.

8.2 Measurements

After every BP measurement, the cuff is again inflated to the diastolic pressure and held for 10 seconds while PWA data is obtained ([see BR-102 plus PWA Unit Measurements, page 40](#)).

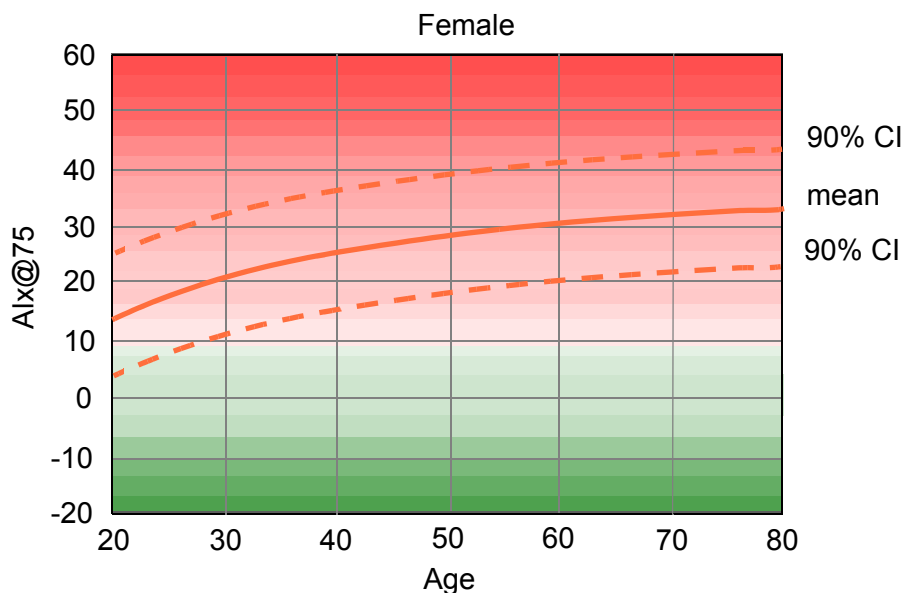
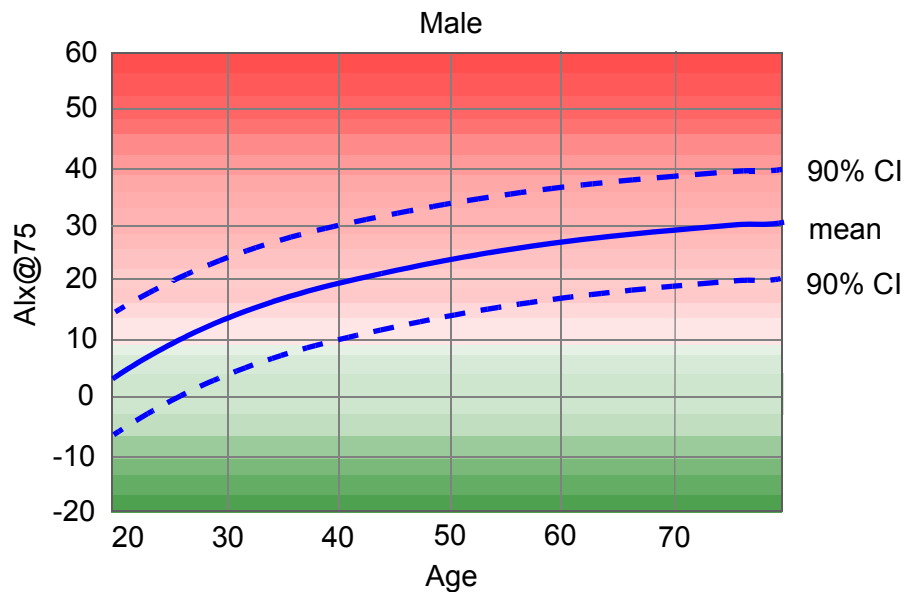
8.3 Display of Pulse Wave Analysis

Pulse wave analysis is based on arterial blood pressure curve containing haemodynamic information that exceeds peripherally measured blood pressure. This is used to analyse the central aortic pulse wave. The medilogDARWIN2 displays the following values:

- Central blood pressure
- Central pulse pressure
- Augmentation pressure
- Augmentation index
- AIx@75 [90% confidence interval]
- Peripheral resistance
- Pulse Wave Velocity [PWV]

8.4 Method Overview

Ten pulse waves are filtered and averaged to determine the central arterial pulse wave. The augmentation index is standardised for a pulse rate of 75 bpm (see reference [1]). This parameter is then described as $Alx@75$.



Average value and 90% confidence interval for the $Alx@75$

$Alx@75$ has been analysed in a representative cross-section of the population (see reference [2]), and an age-dependent estimate for the $Alx@75$ plus the respective confidence interval have been assessed. These relevant analyses have also shown that there is a significant difference for the average $Alx@75$ between men and women.

Based on research with a surveyed cross-section of the population of about 2,000 people average values and 90% confidence interval were determined. An increase of the Alx until the 55th year has been identified and after the 55th year the increase slows for both sexes. The level difference of the Alx between the sexes is about 8 to 10%. If the measured values exceed the sex- and age-specific interval, further examinations according to the European examination guidelines for hypertension [3] are recommended in order to detect the reason for the dysfunction.

1. Wilkinson I.B. et al. Heart Rate Dependency of Pulse Pressure Amplification and Arterial Stiffness. *American Journal of Hypertension* 2002;15:24-30.
2. Fantin F. et al. Is augmentation index a good measure of vascular stiffness in the elderly? *Age and Ageing* 2007; 36: 43-48.
3. The Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and the European Society of Cardiology (ESC). 2007 Guidelines for the management of arterial hypertension. *European Heart Journal* 2007; 28: 1462-1536.
4. *European Heart Journal* (2010) 31, 2338–2350 doi:10.1093/eurheartj/ehq165. Determinants of pulse wave velocity in healthy people and in the presence of cardiovascular risk factors: 'establishing normal and reference values'.

9 Patient Diary

9.1 Patient Diary Example

SCHILLER BR-102 plus / BR-102 PWA

Patient Diary

Patient ID:

Patient name:

Date: Recording start time:

WARNING

- If you experience any numbness in the arm, chafing, pain or discomfort remove the cuff and contact your doctor immediately.
- Danger of strangulation from the hose. Ensure a T-shirt or outer clothing is worn over the hose and unit at night.

CAUTION

- The unit is not waterproof, do not get wet - remove the recorder and cuff if you take a bath or shower.

DURING THE RECORDING

- Do not to move the arm during the measurements.
- Avoid noisy areas when a measurement is being taken.
- If an invalid measurement is made, a second measurement will be initiated immediately.
- The unit must continue to be worn during the night time period. Wear a T-shirt or continue to wear normal outer clothing over the tubing at night to help keep it secure

Control buttons →

BR-102 plus Standard



- If you have a PWA monitor a second phase is initiated after every measurement: the cuff is again re-inflated and remains inflated for approximately 10 seconds before deflating ready for the next measurement.

BR-102 plus PWA



Taking an extra measurement during the recording

The unit takes measurements at predetermined intervals. Extra measurements can be taken at any time, press either the green or the blue control button to display the measurement screen and press again to take an extra measurement.

Interrupting a measurement during the recording

To interrupt a measurement, press either of the control buttons during the measurement. The next measurement will take place according to the schedule.



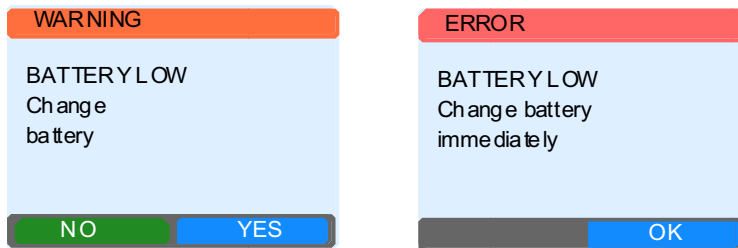
Battery compartment cover. Position in grooves and slide until clicked secure.

SCHILLER BR-102 plus / BR-102 PWA

Patient Diary

Changing the batteries during a 48 hours recording

- Preventive changing the batteries after 24 hours:
 1. Press the blue button for 4 seconds. Confirm message **“Change battery”** again with the blue button.
 2. Remove the batteries and replace with the fully charged batteries supplied. Observe correct polarity.
 3. Press the green button to switch the unit on. The following message is displayed:
BP recording . . Next meas . . xx:xx
 4. Make an entry in the patient diary.
- Or when the audible beep is heard and one of the following messages are displayed:



1. Confirm the Change battery message with the blue button.
2. Remove the batteries and replace with the fully charged batteries supplied. Observe correct polarity.
3. Press the green button to switch the unit on. The following message is displayed:
BP recording . . Next meas . . xx:xx
4. Make an entry in the patient diary.

Do not dispose of the old batteries - return to the surgery.

Cuff placement

The cuff should be placed on the left upper arm approximately 2cm above the elbow so that the forearm can move. Position the red flap (indicating the position of microphone) on the inside of the arm. The pressure tube points towards the shoulder. Tape can be used to hold the tubing to the body if required. Place the device in the pouch and secure with the pouch straps. Wear a t-shirt over the tubing to help secure the tubing in position.



Make an entry in this diary (next page) if you experience any dizziness, palpitations, chest pain, etc. Also make an entry when the batteries are changed, an extra measurement is taken, or for any other event.

SCHILLER BR-102 plus / BR-102 PWA Patient Diary

[illegible]

SCHILLER BR-102 plus / BR-102 PWA Patient Diary

[illegible]

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