ABPM 7100
Ambulatory Blood Pressure Monitor

Directions for Use

The ABPM 7100 is distributed only by Welch Allyn, Inc.
To support the intended use of the product described in this publication, the purchaser of the product is permitted to copy this publication for internal distribution only, from the media provided by Welch Allyn.

Caution: Federal US law restricts sale of the device identified in this manual to, or on the order of, licensed physicians.

The manufacturer and Welch Allyn do not accept liability for injuries or unlawful or improper use of the product which may result from the fact that the product is not used in accordance with the instructions, cautions and warnings, as well as the indications for use published in this manual.

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Welch Allyn Technical Support:
http://www.welchallyn.com/about/company/locations.htm

REF 901050 AMBULATORY BLOOD PRESSURE MONITOR

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Distributed by Welch Allyn

Welch Allyn
Advancing Frontline Care™

Table of contents

Symbols

Documentation symbols

	**WARNING** The warning statement identifies an immediate threat. Non-adherence may lead to the most severe injuries and to death		**CAUTION** The caution statement identifies a possible hazard. Non-adherence may lead to minor or moderate injuries
Attention	The attention statement marks possible material damage. Non-adherence may lead to damage to the device or its accessories	**Note**	The note statement marks further information on the ABPM 7100 or its accessories
	**INTERNAL REFERENCE** Marks references within the document to further information		**EXTERNAL REFERENCE** Marks references to external documents containing further optional information
	Mandatory – Consult Directions for Use		Meets essential requirements of European Medical Device Directive 93/42/EEC
	Consult Directions for Use, Electronic version available at Welchallyn.com, or Hard copy DFU available from Welch Allyn within 7 days.		

Power symbols

	Battery symbol indicates the type of power supply		Nonionizing electromagnetic radiation

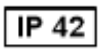
Connectivity symbols

	FCC ID and IC		Bluetooth Connectivity

Shipping, storing and environment symbols

	Separate the device from other disposables for recycling. See www.welchallyn.com/weee

Miscellaneous symbols

	Manufacturer		Date of manufacture
	Reference/Model number		Serial number
	Reorder/Catalog number		Batch code
	Global Trade Item Number		Protection class
	Regulatory Compliance Mark (RCM) for Australia		NRTL-Certification

Defibrillation-proof type BF applied part

MR Unsafe Poses unacceptable risks to the patient, medical staff or other persons within the MR (magnetic resonance) environment

Introduction

Preliminary note

With the ABPM 7100 24-hour blood pressure measuring device, you now have an Ambulatory Blood Pressure Monitoring System (ABPM System) at your disposal.

The ABPM 7100, also specified as ABP Monitor, can be prepared for a new patient in just a few minutes. This permits the optimum use of the ABP Monitor and allows you to process one 24-hour profile per day.

The ABPM 7100 can therefore be quickly integrated into everyday practice life. The recorded blood pressure values must be evaluated with the intended software.

In combination with the Hypertension Management Software and an appropriate license, the ABPM 7100 is also able to process a haemodynamic analysis of the recorded pulse waves.

About these directions for use

These directions for use will familiarize you with the use of the ABPM 7100 and its accessories.

The directions for use of the Hypertension Management Software are provided on the CD together with the HMS software.

The software CardioPerfect Workstation (CPWS) can be used for the evaluation of blood pressure measurements in regions, where Welch Allyn has registered and distributed the software for this purpose.

Upgrades for haemodynamic evaluation may also be purchased from Welch Allyn. Please contact Welch Allyn for further information.

With reference to specific version characteristics, only the parts relevant for your respective version will apply.

- Please refer to the software directions for use for software operating instructions.
- For the upgrades please refer to the respective directions for use to operate the Hypertension Management Software (HMS), version 5.0 and above.

Note These directions for use explain the ABPM 7100 and its accessories in the sequence in which you setup the device for a blood pressure measurement, followed by the installation, initial operation, measurement preparation, placement on the patient and the evaluation. Individual functions are only explained when they are needed. You will therefore be familiarized with the ABPM 7100 on a step-by-step basis.

This directions for use must be kept with the product for later use!

Clinical data

The blood pressure measuring device ABPM 7100 fulfills the requirements of the ESH (European Society of Hypertension), BHS (British Hypertension Society) and ISO 81060-2.

The device has not been tested on pregnant women, including preeclamptic patients.

CE Mark

The ABPM 7100 fulfills the requirements of the following directives:

- Directive 93/42/EEC (MDD)
- Directive 2014/53/EU (RED)
- Directive 2011/65/EU (RoHS)

The ABPM 7100 bears the CE mark.

Content

Standard

1. ABPM 7100 Monitor
2. Pressure Cuff – Size “Adult”
3. Carrying Pouch
4. PC Interface Cable
5. 4x AA Alkaline Batteries
6. ABPM 7100 Directions For Use
7. Calibration Notice
8. Pressure Cuff – Size “Adult Plus” (*dependent on set*)

HMS Option

1. HMS Software
2. Bluetooth®-Dongle
3. Quick Start Guide *(dependent on upgrade option)*
4. Version dependent 16 digit License Code *(dependent on upgrade option)*

Warning

Risk of injury posed by the use of other accessories. The use of unapproved accessories may lead to incorrect measurement results.

- Only use accessories approved and distributed by the manufacturer and Welch Allyn.
- Check the accessories regarding the manufacturer’s information before first use.

Direction for use

Intended use

The ABPM 7100 is intended for clarifying the blood pressure status and for use as a diagnostic aid for an individual patient (in the patient’s environment). The ABPM 7100 may only be used under medical supervision and after detailed instruction has been provided by the doctors or healthcare professionals. The ABPM 7100 in combination with the Hypertension Management Software (HMS) provides a derived ascending aortic blood pressure wave form and a range of central arterial indices. Analysis based on the recordings is in the sole responsibility of the medical professional.

Indications for use

- The ABPM 7100 is an automated, microprocessor controlled ambulatory blood pressure monitor (ABPM) which records, accumulates and stores: heart beat (rate), systolic and diastolic data of an individual patient (in the patient’s environment) for a session which may last 24 hours. Ambulatory monitoring is not supported for the 14-20 cm (5.5-7.9 in) cuff size.
- The ABPM 7100 is intended for use in domestic healthcare settings and in professional healthcare facilities, including, for example, vehicles, dental practices and first aid stations.
- It is used with a standard upper-arm cuff for blood pressure measurement.
- The ABPM 7100 in combination with the Hypertension Management Software (HMS) provides a derived ascending aortic blood pressure wave form and a range of central arterial indices. It is used in those adult patients, where information related to the ascending aortic blood pressure is desired, but in the opinion of the physician, the risk of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.

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Contraindications

- The ABPM 7100 must not be used on neonates and children under the age of 3 years!
- Due to the strangulation risk posed by tubing and cuff, the ABPM 7100 must not be placed within reach of unsupervised children, and must not be used on unsupervised patients with limited cognitive abilities, or patients under anesthetics!
- The ABPM 7100 is not intended for alarm triggering monitoring purposes in intensive care units, and must not be used for blood pressure monitoring purposes in intensive care units or during surgery!
- The ABPM 7100 must not be used in aircraft.
- The device has not been tested on pregnant women, including preeclamptic patients.

Essential Performance

The main performance features are defined as blood pressure measurement with:

- Error tolerances of the pressure gauge and measurement results are within required limits (IEC 80601-2-30).
- Maximum change value in blood pressure determination is as specified in IEC 80601-2-30.
- Cuff pressurization remains within specified limits (IEC 80601-2-30).
- An error is issued in the event that successful blood pressure measurement is impossible.

The ABPM 7100 does not issue ALARMS pursuant to IEC 60601-1-8 and is not intended for use in connection with HF surgical equipment or to clinically monitor patients in intensive care units.

Basic safety means that the patient cannot be endangered by any automatic device procedure. During any unclear conditions, the ABPM 7100 must therefore transfer into the safe **Standby** mode, during which the ABPM 7100 cannot automatically inflate the cuff, while this can be manually triggered by pushing the **START** button.

In this context, any interruption of a measurement or in automatic operation by an external influence, or the ability of the ABPM 7100 to test error conditions, is regarded as the retention or restoration of basic safety, and not as non-adherence to the main performance features.

Side effects of 24-hour blood pressure monitoring

As with occasional blood pressure measurements, petechiae, haemorrhages or subcutaneous haematoma may occur on the measured arm despite a correctly seated cuff. The innate patient-dependent risk resulting from treatment with anticoagulants or in patients with coagulations disorders arises irrespective of the type of monitoring device. Always check whether the patient displays coagulation disorders or is being treated with anticoagulants.

Product description

Introduction

The ABPM 7100 System consists of two main components:

- The ABPM 7100 with cuffs and accessories
- Patient management software for the doctor to evaluate the measurement results

With the software the ABPM 7100 can be prepared for measurement, transfer stored measurement results to the PC, display transferred measurements on the screen in various formats such as graphics, lists and statistics and print out measurement results. Optional is the possibility to evaluate the measurement results with upgrades.

The ABPM 7100 can be prepared immediately for the next patient. With little practice this procedure can be completed in just a few minutes. This allows the doctor to use the ABPM 7100 around the clock on each work day.

The ABPM 7100 is designed to allow recording and display of a blood pressure profile throughout the day and at night. Additional parameters such as nocturnal values and blood pressure fluctuations are recognized. This permits the doctor to prescribe optimal medical treatment for each individual.

Measurement with the ABPM 7100 can be either automated or be manually controlled by the user. In order to start a series of automatic measurement, the user must initiate the first measurement by pressing the **START** button and the doctor should check the reliability of the first measurement.

During the first measurement, the cuff is inflated in increments, to determine the cuff pressure required to measure the systolic blood pressure value. The maximum required inflation pressure is stored and applied by direct inflation during the subsequent automatic measurements. This procedure is called **AFL – Auto Feedback Logic.**

The ABPM 7100

Components

1	Cuff connection
2	ON/OFF button
3	LCD-Display
4	START button
5	DAY/NIGHT button
6	EVENT button
7	PC Interface cable port

9 - Product description

The Buttons

ON/OFF

The **ON/OFF** button turns the ABPM 7100 on and off. To prevent unintended activation, the ABPM 7100 turns on or turns off only when the button is pressed for more than 2 seconds.

START

The **START** button serves to

- initiate a manual measurement to ascertain whether the ABPM 7100 is working correctly.
- initiate a 24-hour measurement.
- perform a measurement outside the specified measurement cycle.

DAY/NIGHT

The **DAY/NIGHT** button is used to differentiate between waking and sleeping phases during the measurement, which is important for statistics and the graphic displays.

The patient is instructed to press the **DAY/NIGHT** button upon going to bed and again, when getting up in the morning. This individually adapts the measurement interval to the patient and assists you in the analysis of the blood pressure profile.

EVENT

The patient uses the **EVENT** button to document the time of medication or to record any events which may cause the blood pressure to rise or fall. Pressing the button will trigger a measurement, the patient should note the reason for pressing the **EVENT** button in the event log.

LCD Display

The LCD display is located on the front of the ABPM 7100 casing. It displays useful information for the doctor and the patient regarding measurement data, monitor settings and measurement errors. When the **START** button is pressed, the number of previously registered measurements will be shown before starting a manual measurement.

Audible signals

Individual or multiple beeps of audible signals are used. The following table explains the meaning of the beeps:

1 beep	• Switching ON/OFF • Starting and ending a measurement (except at night intervals) • Removal of the interface cable • Establishing and ending Bluetooth® communication • Measurement errors
3 beeps	• System errors
Continuous beeps	• Severe system errors (e.g. cuff pressure is higher than 15 mmHg for longer than 10 seconds outside the measurement)
Combined beeps	• Manual deletion of measurement, 1 beep followed by 5 beeps 2 seconds later

Cuff connection

- The cuff connection is located at the top of the ABPM 7100 casing.
- The cuff is connected to the ABPM 7100 via a metal connector.

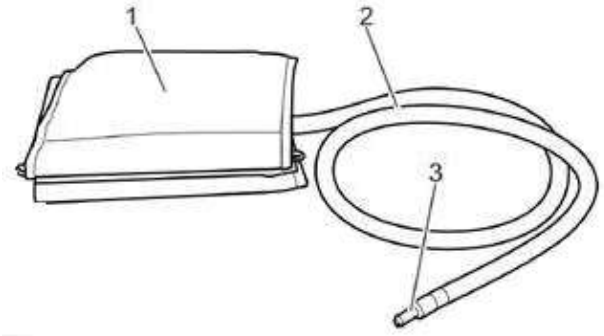
Attention

Measurement errors

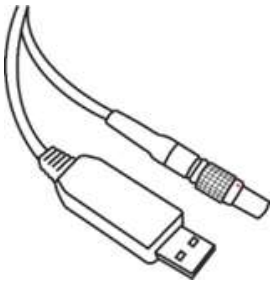
- The cuff connection must always engage with an audible "*CLICK*". A poor connection between the ABPM 7100 and cuff will result in measurement errors.

The Arm Cuff

1	The arm cuff
2	Air tube
3	Air tube connection

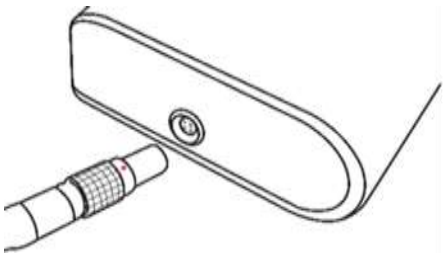


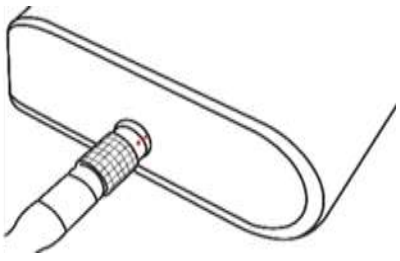
PC Interface Cable



In order to read data from the ABPM 7100, the interface cable must be connected to an USB slot on a PC.

PC Interface Cable Port





- The connecting port for the PC interface cable is located at the bottom of the ABPM 7100 casing.
- The red dot on the plug must align with the red dot on the port before plugging.
- To disconnect, pull on the knurled ring of the connector.

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Connecting the ABPM 7100 to the PC

To transfer the data from the ABPM 7100, ensure that the interface cable is connected correctly to an USB port on the PC and to the interface cable port on the device.

Technical Data

Measurement pressure range:	Systolic 60 to 290 mmHg Diastolic 30 to 195 mmHg
Accuracy:	+/- 3 mmHg in display range
Static pressure range:	0 to 300 mmHg
Pulse range:	30 to 240 beats per minute
Procedure:	oscillometric
Measurement intervals:	0, 1, 2, 3, 4, 5, 6, 10, 12, 15, 20 or 30 measurements per hour
Measurement logs:	4 adjustable interval groups
Memory capacity:	300 Measurements
Battery capacity:	> 300 Measurements
Operating temperatures:	+5°C to +40°C
Operating humidity:	15% to 93%
Storage environment:	-25°C to +70°C and 15% to 93% humidity
Ambient pressure	700-1060 hPa
Dimensions:	121 x 80 x 33 mm
Weight:	approx. 220 g excluding batteries
Power supply:	2 Ni-MH batteries with 1,2 V each and min. 1500 mAh (AA, Mignon) or 2 Alkali 1,5 V batteries (AA, Mignon, LR6)
Interfaces:	USB-Interface cable Bluetooth® (Class 1 / 350 m and max. 80 mW with 2,402 GHz to 2,480 GHz) only available with optional HMS software
Expected operational device life:	5 Years
Expected operational cuff life:	6 Months

Accessories

Accessories	Description
REUSE-09-ABPM	CUFF, WA, REUSE, CHILD, ABPM (arm circumference 14-20 cm (5.5-7.9 in))
REUSE-10-ABPM	CUFF, WA, REUSE, SMALLADULT, ABPM (arm circumference 20-24 cm (7.9-9.5 in))
REUSE-11-ABPM	CUFF, WA, REUSE, ADULT, ABPM (arm circumference 24-32 cm (9.5-12.6 in))
REUSE-11L-ABPM	CUFF, WA, REUSE, ADULTPLUS, ABPM (arm circumference 32-38 cm (12.6-15.0 in))
REUSE-12-ABPM	CUFF, WA, REUSE, LARGEADULT, ABPM (arm circumference 38-55 cm (15.0-21.7 in))
REUSE-091012-ABPM	CUFF, WA, REUSE, CSL, ABPM (pack of child, small adult and large adult cuffs)
REUSE-ALL-ABPM	CUFF, WA, REUSE, ALL, ABPM (pack of all five individual cuff sizes)
7100-21	ABPM 7100 Pouch and Shoulder Belt
7100-24	ABPM 7100 USB Interface Cable
7100-10	ABPM 7100 Battery Cover Replacement
ABPM 7100CBP UPGRA	ABPM 7100 UPGRADE KIT CBP (monitor serial number Is required)
ABPM 7100PWA UPGRA	ABPM 7100 UPGRADE KIT PWA (monitor serial number Is required)
CBP TO PWA UPGRADE	ABPM 7100 UPGRADE CBP TO PWA (monitor serial number Is required)

Preparing the ABPM 7100

Safety instructions

⚠ Warning

Risk of strangulation posed by the shoulder strap and cuff tubing.

- If the patient has limited cognitive abilities, the device may only be used under supervision.
- Do not place the shoulder strap and cuff tubing around the patient's neck.
- Always place the cuff tubing under the outer clothing (even at night).
- When used on children, the device must only be applied with special care and under permanent supervision.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)
- Measurement can be interrupted at any stage by pushing any of the buttons. This deflates the cuff and the device can be removed.

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⚠ Warning

In very rare cases materials used for and on the cuff may cause allergic reactions.

- Do not use the cuff on patients with a known hypersensitivity to epoxy resin.

⚠ Warning

The equipment must not be used in the vicinity of an MRI scanner!

⚠ Caution

Risk of injury caused by incorrect application of the device.

- The doctor must ensure that, due to the patient's medical condition, the use of the device and the cuff does not result in impaired blood circulation.
- If the patient has limited cognitive abilities, the device may only be used under supervision.
- When used on children, the device must only be applied with special care and under permanent supervision.
- While it is still attached to a patient, the device may never be connected to a PC or other device.
- Instruct the patient to place the device in such a way that, while the cuff is inflated, the tubing is not compressed or kinked, especially during sleep.
- Petechiae, haemorrhages or subcutaneous haematoma may occur in some patients.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)

⚠ Caution

Risk of injury caused by incorrect application of the cuff.

- The doctor must ensure that, due to the patient's medical condition, the use of the device and the cuff does not result in impaired blood circulation.
- If the patient is has limited cognitive abilities, the device may only be used under supervision.
- When used on children, the device must only be applied with special care and under permanent supervision.
- It is imperative that you instruct the patient in the correct seating of the cuff.
- Inform the patient that the cuff may only be used on the upper arm.
- Ensure that neither the shoulder strap nor the cuff tubing can ever wrap around the patient's neck. Always place the cuff tubing under the outer clothing (even at night).
- Instruct the patient to place the device in such a way that, while the cuff is inflated, the tubing is not compressed or kinked, especially during sleep.
- Petechiae, haemorrhages or subcutaneous haematoma may occur in some patients.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)

⚠ Caution

Intolerances caused by the use of disinfectants.

- Wash to remove residues.
- Wash the cuff sleeve with a mild detergent in the washing machine at max. 30°C without spinning.

Inserting the batteries

Attention

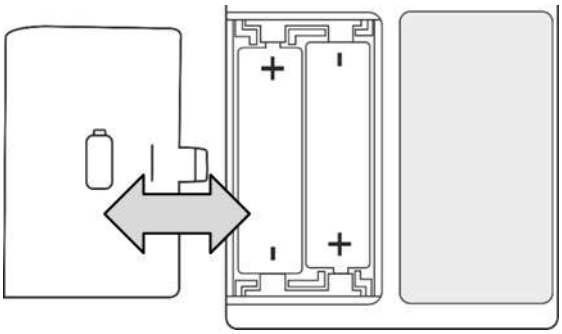
Device function

- Although zinc-carbon batteries may indicate sufficient voltage during a battery test, their output is frequently insufficient to perform 24-hour measurements. Ensure sufficient battery voltage. At least 2.6 volts for NiMH batteries and at least 3.10 volts for alkaline batteries!

Attention

Damage to device

- Do not open the casing. Once the device is opened, all warranties will lapse.



Open the batteries compartment on the rear of the ABPM 7100 casing to insert the batteries into the ABPM 7100 according to the battery polarities (+ / -) and close the compartment.

Note

- Always use fully charged batteries for a new measurement
- Only use undamaged batteries
- Please remove the batteries if the device has not been used for a longer period
- When inserting the batteries, please ensure correct polarity

Attention

Internal memory battery

- If after changing the external battery the display shows “rEboot”, the internal memory battery may be empty. Please contact your dealer.

Activating the device

Attention

Damage to device

- Do not wear the ABPM 7100 while showering. If you suspect that liquid has entered the device while cleaning or using it, the device shall no longer be used on the patient.
- If the device was exposed to moisture, switch off the device and remove the batteries.
- Inform your service immediately and send the device in for inspection.
- The device may not be operated around MRI scanners or in the immediate vicinity of other medical electrical equipment.
- During a defibrillator discharge, the device shall not be in contact with the patient. Such a discharge may damage the ABPM 7100 and cause it to display incorrect values.
- This device should not be used directly adjacent to other devices or stacked with other devices, as this may result in malfunction. If it is nonetheless necessary to operate the device in the manner described above, you should observe this and the other devices during use and convince yourself that they are working properly.
- The ABPM 7100 is not suitable for simultaneous use with HF surgical equipment.
- Measurement can be interrupted at any stage by pushing a random button. This deflates the cuff and the device can be removed.

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Attention

Hygiene

- Ensure hygiene in accordance with the maintenance schedule.

Always check the condition of the ABPM 7100 by observing the initial display shown on the device shortly after turning it on and before handing it to a patient. The ABPM 7100 performs a self-test. In addition, a beep sounds to check the speaker. The following should be displayed in this sequence:

Test	Display	Comment
Battery condition (volts)	2.85	(At least 2.6 volts for NiMH batteries and at least 3.10 volts for alkaline batteries)
Display Segment Test	999:999 to 000:000	The display of the figures (999:999 to 000:000) is accompanied by all other symbols of the LCD in succession. Check whether all segments are correctly and fully displayed (the complete program code is checked for correctness in the background)
Current 24h time	21:45	hh:mm

If the internal test detects an error, the ABPM 7100 will indicate "**E004**" on the display and emit an audible signal. For safety reasons, the use of the ABPM 7100 will be locked. The faulty ABPM 7100 unit should be send back immediately for repairs to your dealer or to Welch Allyn.

Setting the time / date

The ABPM 7100 has an internal buffer battery allowing the time to continue even if the batteries have been removed. Nevertheless the time and the date should be checked before every measurement series.

The time and date can be set automatically with the patient management software.

Alternatively the time and date can be set manually. Press and hold the **START** button and then press the **EVENT** buttons to enter the **Set Time** mode. Use the **START** button to select the appropriate item and use the **EVENT** button to jump to the next display item.

Clearing the memory

The device memory must be cleared before every measurement series, i.e. blood pressure data form the previous patient must not remain in the memory.

If there are existing data, the memory can be cleared with the delete function of the analysis software.

Alternatively the data can be cleared manually. Press and hold the **START** button for a minimum of 5 seconds until "**cLr**" is displayed. Within the next 5 seconds press and hold the **EVENT** button for at least 2 seconds to confirm the deletion of the stored measurements. The device emits a single beep to indicate that the memory is cleared.

Transferring patient data (ID)

The ABPM 7100 must be prepared by transferring patient data (ID) with the help of the patient management software, so that correct data allocation is possible when it is read out after measurement. Please refer to the respective patient management software manual for how to transfer patient data (ID) to the ABPM 7100.

Setting measurement logs

In the patient management software you can optionally choose between eleven (1-11) logs. A log serves to set the measurement intervals. As soon as you have conducted a measurement, the log can only be changed once you have fully deleted all data.

Manual log settings

For manual log setting, press and hold the **DAY/NIGHT** button while simultaneously pressing the **EVENT** button. Use the **START** button to change the log and confirm with the **EVENT** button.

Log	Day-Time	Night-Time	Measurements per hour	Audible signal	Display of measured values
1	08:00 00:00	23:59 07:59	4 2	YES NO	YES
2	08:00 23:00	22:59 07:59	4 1	YES NO	YES
3	07:00 22:00	21:59 06:59	4 2	YES NO	NO
4	08:00 00:00	23:59 07:59	4 2	YES NO	NO
5	18:00 10:00	09:59 17:59	4 2	YES NO	YES
6	07:00 00:00	23:59 06:59	4 2	YES NO	YES
7	06:00 23:00	22:59 05:59	4 2	YES NO	NO
8	07:00 09:00 00:00	08:59 23:59 06:59	6 4 2	YES YES NO	YES
9	09:00	08:59	30	NO	YES
10	08:00	07:59	30	YES	NO
11	08:00 00:00	23:59 07:59	4 2	YES NO	YES

Setting the logs via software

To set the logs via software please refer to the respective patient management software manual.

Note

- Logs 1, 2, 10 and 11 are set by default but can be changed via the patient management software.
- Log 5 is suitable for nighttime activities (night shift).
- Log 9 is designated as “Schellong-Test”.
- Log 10 automatically sends the measurement values to your doctor’s PC via Bluetooth®. Bluetooth® communication is not supported with the CPWS software.
- Log 11 is only available to upgraded ABPM 7100 systems in connection with HMS from version 5.0. Blood pressure measurement intervals and the 24h PWA can be set separately here. Please contact Welch Allyn for further information.

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Selecting a suitable cuff

⚠ Caution

Risk of injury caused by incorrect application of the cuff.

- The doctor must ensure that, due to the patient's medical condition, the use of the device and the cuff does not result in impaired blood circulation.
- If the patient is has limited cognitive abilities, the device may only be used under supervision.
- When used on children, the device must only be applied with special care and under permanent supervision.
- It is imperative that you instruct the patient in the correct seating of the cuff.
- Inform the patient that the cuff may only be used on the upper arm.
- Ensure that neither the shoulder strap nor the cuff tubing can ever wrap around the patient's neck. Always place the cuff tubing under the outer clothing (even at night).
- Instruct the patient to place the device in such a way that, while the cuff is inflated, the tubing is not compressed or kinked, especially during sleep.
- Petechiae, haemorrhages or subcutaneous haematoma may occur in some patients.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)

⚠ Caution

Intolerances caused by the use of disinfectants.

- Wash to remove residues.
- Wash the cuff sleeve with a mild detergent in the washing machine at max. 30°C without spinning.

The correct cuff size is important for correct blood pressure measurement. To obtain reproducible measurements, standardized measuring conditions are needed. Measure the circumference of the upper arm and select the appropriate cuff:

Welch Allyn Size Number	Upper Arm Circumference	Cuff
09	14 – 20 cm (5.5-7.9 in)	Child
10	20 – 24 cm (7.9-9.5 in)	Small Adult
11	24 – 32 cm (9.5-12.6 in)	Adult
11L	32 – 38 cm (12.6-15.0 in)	Adult Plus
12	38 – 55 cm (15.0-21.7 in)	Large Adult

Applying the ABP Monitor and cuff

⚠ Warning

Risk of strangulation posed by the shoulder strap and cuff tubing.

- If the patient is has limited cognitive abilities, the device may only be used under supervision.
- Do not place the shoulder strap and cuff tubing around the patient's neck.
- Always place the cuff tubing under the outer clothing (even at night).
- When used on children, the device must only be applied with special care and under permanent supervision.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)
- Measurement can be interrupted at any stage by pushing any of the buttons. This automatically deflates the cuff and the device can be removed.

⚠ Warning

Poor circulation caused by continuous cuff pressure.

- Do not kink the connecting tubing.
- If the patient has limited cognitive abilities, the device may only be used under supervision.
- Ensure the correct placement of the shoulder strap and cuff tubing.
- Always place the cuff tubing under the outer clothing (even at night).
- When used on children, the device must only be applied with special care and under permanent supervision.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)

⚠ Warning

Placement and inflation of the cuff over a wound may lead to further injuries.
Placement and inflation of the cuff on any limb with an intravascular access or under intravascular treatment or an arteriovenous (A-V) shunt may lead to temporary interruption of circulation and therefore to further patient injury.
Placement and inflation of the cuff on the arm at the side of a breast amputation may lead to further injury.

- Examine the patient for wounds, bandages, etc.
- Question the patient regarding previous treatments.
- Observe the patient closely.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)

⚠ Warning

In very rare cases materials used for and on the cuff may cause allergic reactions.

- Do not use the cuff on patients with a known hypersensitivity to epoxy resin.

⚠ Caution

Intolerances caused by the use of disinfectants.

- Wash to remove residues.
- Wash the cuff sleeve with a mild detergent in the washing machine at max. 30°C without spinning.

19 - Preparing the ABPM 7100

⚠ **Caution**

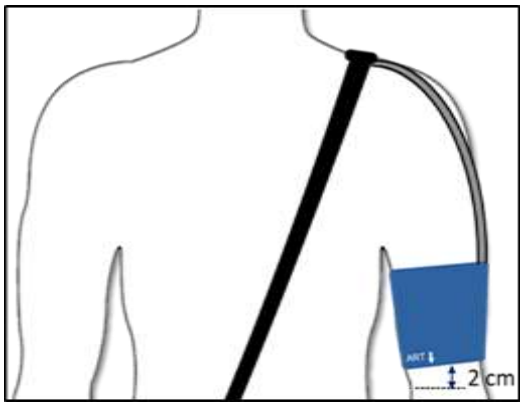
Risk of injury caused by incorrect application of the cuff.

- The doctor must ensure that, due to the patient's medical condition, the use of the device and the cuff does not result in impaired blood circulation.
- If the patient has limited cognitive abilities, the device may only be used under supervision.
- When used on children, the device must only be applied with special care and under permanent supervision.
- It is imperative that you instruct the patient in the correct seating of the cuff.
- Inform the patient that the cuff may only be used on the upper arm.
- Ensure that neither the shoulder strap nor the cuff tubing can ever wrap around the patient's neck. Always place the cuff tubing under the outer clothing (even at night).
- Instruct the patient to place the device in such a way that, while the cuff is inflated, the tubing is not compressed or kinked, especially during sleep.
- Petechiae, haemorrhages or subcutaneous haematoma may occur in some patients.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)

⚠ **Caution**

Risk of injury caused by incorrect application of the device.

- The doctor must ensure that, due to the patient's medical condition, the use of the device and the cuff does not result in impaired blood circulation.
- If the patient has limited cognitive abilities, the device may only be used under supervision.
- When used on children, the device must only be applied with special care and under permanent supervision.
- While it is still attached to a patient, the device may never be connected to a PC or other device.
- Instruct the patient to place the device in such a way that, while the cuff is inflated, the tubing is not compressed or kinked, especially during sleep.
- Petechiae, haemorrhages or subcutaneous haematoma may occur in some patients.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)



Applying the ABP Monitor and cuff:

1. Position the carrying pouch on the right side of the patient. By varying the length of the pouch strap, it can be worn around the hips or around the shoulders.
2. Alternatively a normal belt matching the clothes can be used.
3. Fit the cuff onto the patient.
   The correct cuff seating is very important for correct blood pressure measurement.
4. Align the cuff so that no part of the cuff tubing is kinked. In this regard, the tube connection on the cuff must face upwards.

5. Align the cuff so that the lower edge of the cuff is approximately 2 cm (0.8 in) above the inside of the patient's elbow.
6. Tighten the cuff around the upper arm until one finger can be introduced under the cuff.
7. It is imperative that the artery symbol is positioned on the brachial artery. If you have aligned the cuff correctly, the metal bar will lie on the outside of the upper arm (on the elbow side), whereby the cuff sleeve must cover the skin under the metal bar.
8. Guide the tubing through the shirt's row of buttons and out of the clothing, behind the nape of the neck to the ABPM 7100 on the right side of the body.
9. The cuff can be worn on the naked upper arm or over a thin shirt sleeve.
10. The placement of the pressure tube must guarantee the upper arm's free motion.

Connecting the cuff tubing to the ABPM 7100

1. Push the tube firmly onto the connection, with the cuff tubing engaging with an audible "*CLICK*" (to detach, simply pull back the knurled ring).
2. Before measurement, check to ensure that tubing, ABPM 7100 and cuff are positioned correctly. The ABPM 7100 is ready for measurement only once this is ensured.

Positioning the patient for measurement

The patient should take the following position during blood pressure measurement:

- Comfortably seated
- Legs uncrossed
- Feet flat on the ground
- With support to the back and the arms
- With the cuff center at one level with the right atrium

Note

- During measurement, the patient should be as relaxed as possible and may not speak unless he wants to report any discomfort!
- Allow for 5 minutes of relaxation before recording the first measurement value.
- Blood pressure measurements can be influenced by the patient's position (standing, sitting, lying), by exertion or the patient's physiological state. Exclude these influencing factors to the greatest possible degree!

Measurement process

Safety instructions

⚠ Warning

Risk of strangulation posed by the shoulder strap and cuff tubing.

- If the patient has limited cognitive abilities, the device may only be used under supervision.
- Do not place the shoulder strap and cuff tubing around the patient's neck.
- Always place the cuff tubing under the outer clothing (even at night).
- When used on children, the device must only be applied with special care and under permanent supervision.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)
- Measurement can be interrupted at any stage by pushing any of the buttons. This automatically deflates the cuff and the device can be removed.

21 - Measurement process

⚠ Warning

Poor circulation caused by continuous cuff pressure.

- Do not kink the connecting tubing.
- If the patient has limited cognitive abilities, the device may only be used under supervision.
- Ensure the correct placement of the shoulder strap and cuff tubing.
- Always place the cuff tubing under the outer clothing (even at night).
- When used on children, the device must only be applied with special care and under permanent supervision.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)

⚠ Warning

Poor circulation due to overly frequent measurements.

- Check the date of the last measurement.
- Inform the patient about this warning.
- If the patient has limited cognitive abilities, the device may only be used under supervision.
- Observe the patient closely.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)

⚠ Warning

If the patient is wearing an additional ME device on the same limb for monitoring purposes, the placement and inflation of the cuff may trigger the temporary loss of the existing ME device's function.

Operation and use of the automated non-invasive blood pressure monitoring device may result in prolonged impairment to the patient's circulation or to circulation in the relevant limb.

- Examine the patient.
- Question the patient regarding previous treatments.
- Observe the patient closely.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)

⚠ Caution

Risk of injury caused by incorrect application of the cuff.

- The doctor must ensure that, due to the patient's medical condition, the use of the device and the cuff does not result in impaired blood circulation.
- If the patient has limited cognitive abilities, the device may only be used under supervision.
- When used on children, the device must only be applied with special care and under permanent supervision.
- It is imperative that you instruct the patient in the correct seating of the cuff.
- Inform the patient that the cuff may only be used on the upper arm.
- Ensure that neither the shoulder strap nor the cuff tubing can ever wrap around the patient's neck. Always place the cuff tubing under the outer clothing (even at night).
- Instruct the patient to place the device in such a way that, while the cuff is inflated, the tubing is not compressed or kinked, especially during sleep.
- Petechiae, haemorrhages or subcutaneous haematoma may occur in some patients.
- Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement.)

⚠ Caution

Intolerances caused by the use of disinfectants.

- Wash to remove residues.
- Wash the cuff sleeve with a mild detergent in the washing machine at max. 30°C without spinning.

Attention

Damage to device

- Do not wear the ABPM 7100 while showering. If you suspect that liquid has entered the device while cleaning or using it, the device shall no longer be used on the patient.
- In the device was exposed to moisture, switch off the device and remove the batteries.
- Inform your service immediately and send the device in for inspection.
- This device should not be used directly adjacent to other devices or stacked with other devices, as this may result in malfunction. If it is nonetheless necessary to operate the device in the manner described above, you should observe this and the other devices during use and convince yourself that they are working properly.
- The device may not be operated around MRI scanners or in the immediate vicinity of other medical electrical equipment.
- During a defibrillator discharge, the device shall not be in contact with the patient. Such a discharge may damage the ABPM 7100 and cause it to display incorrect values.
- The ABPM 7100 is not suitable for simultaneous use with HF surgical equipment.
- Measurement can be interrupted at any stage by pushing a random button. This deflates the cuff and the device can be removed.

Attention

Hygiene

- Ensure hygiene in accordance with the maintenance schedule.

23 - Measurement process

Attention

Measurement errors

- The use of components other than those supplied with the product may lead to measurement errors, as alternative transformers and cables (for example) may increase electromagnetic interference emissions or reduce electromagnetic immunity. You should therefore use Welch Allyn accessories only.
- Although the ABPM 7100 meets all EMC standards, you should nonetheless avoid exposing it to strong electromagnetic fields, as this may cause malfunctions outside the tolerances for the device. You should therefore ensure that the ABPM 7100 is at least 30 cm (12 inches) from any portable RF communications equipment.
- Medical electrical equipment is subject to special EMC precautions. Please observe the directives attached.
- The cuff tubing between the ABPM 7100 and the cuff may not be knotted, compressed or pulled apart.
- The cuff connection must always engage with an audible "*CLICK*". A loose connection between the tubing and the device leads to measurement errors.

Note

- Severe malfunctions are indicated by a continuous beep.
- In the event of a continuous beep, switch off the device, remove the cuff and inform your doctor.
- Hand the data sheet "Patient information – operation of the ABPM 7100" to each patient. The data sheet is attached as a copy template.
- Portable and mobile RF communication equipment may influence medical electrical devices.
- Extreme temperatures, humidity or air pressure can influence measurement accuracy. Please observe the operating conditions.
- There are currently no clinical studies against reference methods available at respect to the application of pulse wave analysis on children.
- The pulse wave analysis provides additional indicators for possible risks, but is not permissible as a sufficient indicator for individual illness or as a treatment recommendation.
- An internal reboot may occur.
  This may be caused by internal or external influences, such as electrostatic discharges from clothing, or because the internal memory battery is empty. If the internal memory battery is empty, this error will occur when the external battery is replaced. You should therefore please contact your dealer.

Initial measurement

Note An initial measurement is required for starting the measurement log. The initial measurement must be checked by a physician for plausibility!

24-hour measurement

1. Ensure sufficient battery voltage. At least 2.6 volts for NiMH batteries and at least 3.10 volts for alkaline batteries!
2. The doctor must go through these instructions together with the patient before a 24-hour measurement.
3. The doctor must explain the possible hazards in detail on the basis of the warnings above!
4. Ensure that the patient has understood all functions and observable points!

Safety:

For your own safety during the following steps, please observe the safety instructions at the start of this chapter, as well as the functional overview.

Performing a measurement

1. To trigger a measurement, press the **START** button.
   - The number of stored measurements will be shown on the LCD display.
   - An audio beep will announce the upcoming measurement.
   - Manual measurement will start.
2. The patient should stay calm during the measurement process, until the measurement is completed. Allow your arm to hang loose, or place your lower arm loosely on the table or on a support whilst sitting. Avoid any movement!
3. Doctor: Please check the values of the first measurement for plausibility, so that subsequent automatic measurements can be processed correctly and correct cuff position is ensured.
4. In the event of an error measurement, please follow the instructions in sections **Measurement preparations** and **Troubleshooting**.

Cancelling a measurement

A measurement will be cancelled by pressing any buttons during the measurement process. The LCD display will then show **-StoP-** and the ABPM 7100 will beep 5 times. This cancellation will be stored in the measurement value table under **Cancel**.

Unsuccessful measurement

1. If the display shows errors, reexamine the correct procedure during set-up and positioning of the device.
2. Dismiss the patient only after a successful manual measurement!
   Inform the patient sufficiently in order to explain the situation!
3. Repeat the measurement.
4. If the display still shows errors, repeat the initial operation process.
5. For further troubleshooting measures and faults removal, please refer to the **Troubleshooting** section.

Note

- Severe malfunctions are indicated by a continuous beep.
- In the event of a continuous beep, switch off the device, remove the cuff and inform your doctor.

Care and Maintenance

To ensure the optimal functionality of the ABPM 7100 regular care and maintenance of the unit is required.

Attention

Damage to device

- Do not open the casing. Once the device is opened, all warranties will lapse.

Cleaning

Cleaning the ABP Monitor and carrying pouch

1. Read the safety instructions carefully and observe them closely before cleaning.
2. Only use a cotton cloth moistened with lukewarm water and mild detergents to clean the ABPM 7100 and the pouch.

Attention

Damage to the ABP Monitor and carrying pouch caused by the use of solvents

- Do not use strong or solvent-based additives.
- Ensure that no liquid enters the device.
- If liquid does penetrate the device, switch if off immediately and return it to your Welch Allyn specialist for inspection.

25 - Care and Maintenance

Cleaning the cuff sleeve, bladder and tubing

1. Read the safety instructions carefully and observe them closely before cleaning.
2. Before washing, carefully remove the bladder and tubing from the cuff sleeve.
3. When cleaning the cuff sleeve, bladder and tubing, use only mild detergents in lukewarm water without fabric softener.

Attention

Damage to the cuff sleeve during washing

- Always close the Velcro strip before washing!
- It is possible to wash the cuff sleeve in the washing machine at max. 30°C. Do not spin.
- Do not use fabric softeners or other washing aids (e.g. hygiene rinses, textile deodorants). These agents can leave behind residues and damage the material.
- The cuff sleeve is not suitable for drying in a dryer.

Disinfection

⚠ Caution

Intolerances caused by the use of disinfectants: Some patients display intolerance (e.g. allergies) to disinfectants or their components.

- Never use disinfectants which leave residues on the product or which are not suitable for contact with the skin.
- Carefully wash the cuff to remove residues.

Attention

Damage to the cuff sleeve, bladder and tubing caused by disinfectants

- Do not submerge the cuff sleeve in disinfectants.
- Avoid disinfecting the cuff bladder and connected rubber tubing.
- The bladder and tubing can be damaged by disinfectants. Wipe down the bladder with lukewarm water and add a mild detergent, if necessary.
- Ensure that no liquid enters the tube opening.

The user (doctor) decides whether and when the ABP Monitor and the cuff sleeve should be disinfected for hygienic reasons (e.g. after every use).

The following agents are recommended for disinfecting the ABP Monitor and the cuff sleeve:

- Terralin Liquid (Manufacturer: Schülke & Mayr)
- Isopropyl alcohol (70%)

For full effectiveness, moisten the ABPM 7100 and cuff sleeve with the disinfectant for at least 5 minutes.

The use of disinfectants not recommended in the directions for use shall render the user responsible for proof of safe application.

Note It is imperative that you observe the manufacturer's information regarding the use of these products. Allow the agents to dry off completely.

Maintenance plan

Attention

Damage to device

- Do not open the casing. Once the device is opened, all warranties will lapse.

Weekly Maintenance

Analysis review:

1. Review the print-out of your measurement analysis for:
   - Correctly entered times and intervals in accordance with the log.
   - Times of day/night transitions.
   - Correct standard values (nocturnal decrease).
2. Check the device, cuff and the cuff tubing for superficial soiling and clean it as specified in the **Cleaning** section.
3. Check the cuff and the cuff tubing for superficial damage. In the event of damages return it to your Welch Allyn specialist for inspection.

Checking battery voltage:

Always use fully charged or new batteries.
The battery voltage appears on the display of the ABPM 7100 for approximately 3 seconds after the device is switched on. The battery voltage must be at least 2.6 volt to ensure a 24-hour measurement.

Maintenance every 2 years

As proof of continuous compliance to “Basic Requirements” pursuant to Directive 93/42/EEC, the ABPM 7100 must be subjected to calibration checks every two years. In certain countries, this requirement may be regulated by national laws or regulations.

Welch Allyn offers to provide calibration checks and the servicing comprising of the following:

- Calibration check
- Software updates (if required)
- Functional check: Electronics, pump and pneumatic circuit

Except the calibration check, no further maintenance work for electronic compatibility are necessary.

Troubleshooting

Attention

Damage to device

- Do not open the casing. Once the device is opened, all warranties will lapse.

Basic error sources

The following may cause error measurements or unintended events:

- The patient’s arm movement during measurement
- Incorrect cuff size
- Cuff displacement while wearing it
- Omitted successful initial measurement by the doctor
- Wrong log set by the user
- Empty, incorrectly charged or outdated batteries
- Kinked or knotted cuff tubing
- Severe arrhythmia

Transmission error

The ABPM 7100 reviews the transmitted data to prevent errors. If an error occurs, "**E004"** will be shown on the display.

Checklist

Please review the following checklist for any errors occurring during the operation of the ABPM 7100. Many errors have simple causes:

- Check to see that all cables are connected correctly.
- Check to see whether the ABPM 7100 and the computer are switched on.
- Check to see whether the batteries have sufficiently voltage.

Note Some errors are combined with a continuous alarm for safety reasons. The continuous alarm can be cancelled by pressing any button. If there is residual pressure inside the cuff, open the cuff immediately.

Error codes

Error description of the ABPM 7100

Error symptom	Possible cause	Remedy
Time and date are not updated following a longer period without power supply from power packs or batteries.	The internal buffer battery is depleted.	Date and time can be reset after every power pack or battery replacement. Send the device to your Welch Allyn specialist.
Measurement data can no longer be called up/displayed.	An error occurred during patient data storage.	Delete the respective patient (menu bar) and recreate it.
The connection between the ABPM 7100 and the PC is faulty.	The incorrect COM interface is set.	Set the correct interface in the service programs.
	Cable plug or socket is defective.	Inspect the plug and the socket on the ABPM 7100. Ensure that the pins are straight to guarantee contact.
	The ABPM 7100 is not in transmitting mode (the displays shows the time).	Switch the ABPM 7100 off and then on again without removing the connecting cable.
No patient number.	The ABP Monitor is not initialized, i.e. the patient number was not transferred during the preparation for a 24-hour measurement.	The patient number can also be transmitted after the measurement. This does not influence the measurement data.
No measurements were conducted during the nocturnal phase.	The battery packs or batteries were prematurely depleted.	The power packs or batteries may be defective (please contact your Welch Allyn specialist).
	The patient has switched off the ABPM 7100.	Draw the patient's attention to the urgency of a complete 24-hour measurement.
The display does not show "**co**" or "**bt**".	You are not in transmitting mode.	Communication via cable: Switch the ABPM 7100 off and then on again without pulling the plug.
		Communication via BT: Press and hold the **START** button and then press the **DAY/NIGHT** button. Select "**bt**" using the **START** button.
No automatic measurements will be performed.	No manual measurements performed after application.	Valid manual measurement must always be performed after the device has been positioned.
	Incorrect log set.	Set log 1 or 2.
The measurement interval does not meet your expectations.	Incorrect log set.	The programmed log does not correspond with the set log in the ABPM 7100. Check the log manually on the device.
	No manual measurements performed after application.	Conduct manual measurement to activate the set log

29 - Troubleshooting

Error symptom	Possible cause	Remedy
Err 1	The patient displays severe arrhythmia.	ABP Monitor not applicable.
	The arm was moved during measurement.	Keep the arm still during measurement.
	Insufficient valid pulse rate detected.	Place the cuff on your arm again.
Err 2	The arm was moved during measurement.	Keep the arm still during measurement.
	Cuff does not fit the arm snugly.	Check the seating of the cuff and that of the device.
Err 3	Blood pressure beyond the measurement range.	Permanent notification renders the ABP Monitor unsuitable for the patient.
	Strong arm movements.	Keep the arm still during measurement.
	Problems with the pneumatics.	If the error persists permanently, send the device to your Welch Allyn specialist.
Err 4	Data transmission cable incorrectly inserted in ABP Monitor.	Insert the cable into the ABP Monitor correctly.
	Pins in the plug of the data transmission cable are mechanically damaged.	Check the plug to see whether the pins on the inside are damaged. If they are, contact your Welch Allyn specialist.
	Measurement value was not correctly transmitted.	Restart the transmission.
Err 5 **bAtt**	Power pack or battery voltage too low.	Replace the power packs or batteries.
	Power packs or batteries are defective.	The power pack or battery voltage is correct but "**bAtt**" is displayed during cuff inflation. Replace the power packs.
	Battery contacts are corroded.	Clean the battery contacts with a cotton cloth and a little alcohol.
Err 6 + Possible continuous alarm until a button is pressed.	Build-up 29 fair.	Check the cuff for a build-up of air or a kink in the tubing. If the cuff tubing is kinked, straighten the tubing. Otherwise send the device in for inspection immediately.
	Blood pressure cuff incorrectly connected.	Connect the cuff to the device.
	Leaky points in the cuff or the cuff tubing.	If necessary, replace the cuff.
Err 7	The memory of the blood pressure measurement device is full. (a maximum of 300 measurements and events can be stored)	Delete the data in the ABP Monitor but ensure that the data was stored on your PC first.
Err 8	Measurement cancelled with a pressed button.	
Err 9 + Possible continuous alarm until a button is pressed.	Residual pressure inside the cuff	Wait for the cuff to deflate completely.
	Zero point comparison was unsuccessful.	Send the device to your specialist for inspection immediately or directly to your Welch Allyn specialist.

Error symptom	Possible cause	Remedy
Err 10 + Continuous alarm until a button is pressed.	Severe error caused by accumulated pressure outside the measurement process.	Send the device to your specialist for inspection and repair immediately or directly to your Welch Allyn specialist.
	These error messages all show a severe error in the program code.	
The analysis unit does not react to data transmission but the display shows "**co**".	Data transmission cable not correctly inserted in the PC. (also refer to Err 4)	Check whether the 9-pin plug of the data transmission cable is securely seated in the device's interface socket. (also refer to Err 4)
The ABPM 7100 measures every two minutes.	Log 9 is set in the ABPM 7100.	Set log 1 or 2.
The desired log cannot be set with the button combination.	The last patient's measurement values are still contained in the memory.	Delete the data in the ABP Monitor but ensure that the data was stored first.
The ABP Monitor cannot be switched on.	The battery packs or batteries were incorrectly inserted.	Reinsert either power packs or batteries and ensure correct polarity.
	Power pack or battery voltage too low.	Replace the power packs or batteries.
	Defective display.	Send the device to your specialist for repair or directly to your Welch Allyn specialist.
An error occurs during the first measurement.	The cuff size is not suitable for the patient's arm circumference.	Measure the patient's arm circumference and compare this with the imprint on the cuff. You may require a different cuff size.

Communication error ABPM 7100 Bluetooth Interface

Error symptom	Possible cause	Remedy
Code 1	Bluetooth® interface of the ABPM 7100 was not started correctly. Possible hardware fault.	Send the device to your Welch Allyn specialist for inspection.
Code 2	Bluetooth® interface of the ABPM 7100 could not be configured correctly. (Communication problem between ABPM 7100 and the Bluetooth® module.)	Try again. If the error persists, send the device to your Welch Allyn specialist for inspection.
Code 3	The status of the Bluetooth® interface of the ABPM 7100 could not be determined. (Communication problem between ABPM 7100 and the Bluetooth® module.)	Try again. If the error persists, send the device to your Welch Allyn specialist for inspection.
Code 4	The Bluetooth® interface of the ABPM 7100 has not yet been paired with the analysis software.	Reconnect the device via Bluetooth®.
Code 5	The Bluetooth® interface of the ABPM 7100 could not connect to the Bluetooth dongle on the computer.	Try again. If the error persists, send the device to your Welch Allyn specialist for inspection.
Code 6	The measurement value memory of the ABPM 7100 contains unsent blood pressure values.	These will be sent once further measurements have been performed.
Code 7	The ABPM 7100 is paired with a cell phone or GSM modem, which is technically incapable of transmitting measurement values, is outside the network range or is incorrectly configured.	Try again. If the error persists, contact your Welch Allyn specialist.

Limited Warranty

Welch Allyn warrants the product to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for the period of one year from the date of purchase from Welch Allyn or its authorized distributors or agents.

The warranty period shall start on the date of purchase. The date of purchase is: 1) the invoiced ship date if the device was purchased directly from Welch Allyn, 2) the date specified during product registration, 3) the date of purchase of the product from a Welch Allyn authorized distributor as documented from a receipt from said distributor.

This warranty does not cover damage caused by: 1) handling during shipping, 2) use or maintenance contrary to labeled instructions, 3) alteration or repair by anyone not authorized by Welch Allyn, and 4) accidents.

The product warranty is also subject to the following terms and limitations: Accessories are not covered by the warranty. Refer to the directions for use provided with individual accessories for warranty information.

Shipping cost to return a device to a Welch Allyn Service center is not included.

A service notification number must be obtained from Welch Allyn prior to returning any products or accessories to Welch Allyn's designated service centers for repair. To obtain a service notification number, contact Welch Allyn Technical Support.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILTY AND FITNESS FOR A PARTICULAR PURPOSE. WELCH ALLYN’S OBLIGATION UNDER THIS WARRANTY IS LIMITED TO REPAIR OR REPLACEMENT OF PRODUCTS CONTAINING A DEFECT. WELCH ALLYN IS NOT RESPONSIBLE FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM A PRODUCT DEFECT COVERED BY THE WARRANTY.

Service Policy

All repairs on products under warranty must be performed by Welch Allyn or by a service provider authorized by Welch Allyn. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair should be performed exclusively by Welch Allyn or by a service provider that has been authorized by Welch Allyn.

If the product fails to function properly - or if you need assistance, service, or spare parts - contact the nearest Welch Allyn Technical Support Center.

Before contacting Welch Allyn, try to duplicate the problem, and check all accessories to ensure that they are not causing the problem. When calling, please be prepared to provide:

- Product name, model number, and serial number of your product.
- Complete description of the problem.
- Complete name, address and phone number of your facility.
- For out-of-warranty repairs or spare parts orders, a purchase order (or credit card) number.
- For parts orders, the required spare or replacement part numbers.

If your product requires warranty, extended warranty, or non-warranty repair service, please call first the nearest Welch Allyn Technical Support Center. A representative will assist you troubleshooting the problem and will make every effort to solve it over the phone, avoiding potential unnecessary return of your product.

In case a return cannot be avoided, the representative will record all necessary information and will provide a Return Material Authorization (RMA) number, as well as the appropriate return address. An RMA number must be obtained prior to any return.

If you have to return your product for service, follow these recommended packing instructions:

- Remove all hoses, cables, sensors, power cords, and other accessories (as appropriate) before packing, unless you suspect they are associated with the problem.
- Wherever possible use the original shipping carton and packing materials.
- Include a packing list and the Welch Allyn Return Material Authorization (RMA) number.

It is recommended that all returned goods be insured. Claims for loss or damage to the product must be initiated by the sender.

EMC Guidelines and Manufacturer Declaration

Table 1 – Guidelines and Manufacturer Declaration
Electromagnetic emission for all ME devices and ME systems

Guidelines and Manufacturer Declaration - Electromagnetic emissions		
The ABPM 7100 is intended for operation in an electromagnetic environment as specified below. The customer or user of the ABPM 7100 should ensure it is used in such an environment.		
Emission measurement	Compliance	Electromagnetic Environment Guideline
RF Emissions according to CISPR 11	Group 1	The ABPM 7100 utilizes RF power for its internal function only. Its RF emission is therefore very low and it is improbable that neighbouring electronic device experience any interference.
RF Emissions according to CISPR 11	Class B	The ABPM 7100 is suitable for use in other facilities than the living area and those immediately connected to the public supply network, which also supplies buildings used for residential purposes.
RF Emissions according to CISPR 25	Not applicable	
Emission of harmonics according to IEC 61000-3-2	Not applicable	
Emission of voltage fluctuations/ flickers according to IEC 61000-3-3	Not applicable	

33 - EMC Guidelines and Manufacturer Declaration

Table 2 – Guidelines and Manufacturer Declaration
Electromagnetic immunity – for all ME devices and ME systems

Guidelines and Manufacturer Declaration - Electromagnetic immunity			
The ABPM 7100 is intended for operation in an electromagnetic environment as specified below. The customer or user of the ABPM 7100 should ensure it is used in such an environment.			
Immunity tests	**IEC 60601-test levels**	**Compliance levels**	**Electromagnetic Environment - Guidelines**
Electrostatic discharge (SD) according to IEC 61000-4-2	± 8 kV Contact discharge ± 15 kV Air discharge	± 8 kV Contact discharge ± 15 kV Air discharge	Floors should consist of wood or cement or ceramic tiles. If the floor consists of synthetic materials, relative humidity must be at least 30%.
Rapid transient electrical disturbance/bursts according to IEC 61000-4-4	± 1 kV 100 kHz repetition rate	± 1 kV 100 kHz repetition rate	
Surges according to IEC 61000-4-5	± 1 kV Line-to-line voltage ± 2 kV Line-to-earth voltage	Not applicable Not applicable	The ABPM 7100 does not have an AC power supply.
Magnetic field in supply frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Magnet fields in network frequency should correspond with the typical values found in business and hospital environments.
Voltage drops, short interruptions and fluctuations in supply voltage according to IEC 61000-4-11	0% UT for 0.5 cycles 0% UT for 1 cycle 70% UT for 25/30 cycles 0% UT for 250/300 cycles	Not applicable Not applicable Not applicable Not applicable	The ABPM 7100 does not have an AC power supply.
NOTE UT is the AC voltage before the application of the test levels.			

Table 3 - Electromagnetic immunity for casings designed to shield against high-frequency wireless communication devices

Guidelines and manufacturer declaration – electromagnetic immunity		
The ABPM 7100 is intended to be operated in the electromagnetic environment specified below. The customer or the ABPM 7100 user should ensure that it is used in such an environment.		
Emitted interference measurement	**IEC 60601-1 test level**	**Compliance level**
HF radiated disturbances in accordance with IEC 61000-4-3	380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHz 9 V/m; PM 50%; 217 Hz 800 - 960 MHz 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHz 9 V/m; PM 50%; 217 Hz 800 - 960 MHz 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz

Table 4 – Guidelines and Manufacturer Declaration
Electromagnetic immunity for ME devices or ME systems that are not life-supporting

Guidelines and Manufacturer Declaration - Electromagnetic immunity		
The ABPM 7100 is intended for operation in an electromagnetic environment as specified below. The customer or user of the ABPM 7100 should ensure it is used in such an environment.		
Immunity tests	**IEC 60601-test levels**	**Compliance level**
Radiated disturbance variables according to IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m
Conducted disturbance variables according to IEC 61000-4-6		Not applicable

Compliance

General radio compliance

The wireless features of this monitor must be used in strict accordance with the manufacturer's instructions as described in the user documentation that comes with the product.

This device complies with Part 15 of the FCC rules and with the rules of the Canadian ICES-003 as described below.

Federal Communication Commission (FCC) Interference Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Consult the dealer or an experienced radio/TV technician for help.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

Industry Canada (IC) emissions

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This radio transmitter (IC ID: 5123A-WT11U) has been approved by Industry Canada to operate with the antenna listed in the specification table.

This Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe B est conform à la norme NMB-003 du Canada.

European Union

Hereby IEM GmbH declares that this ABPM 7100 is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

The complete text of the RE-D Declaration of Conformity (DoC) is available at the following website address: www.welchallyn.com.

Bluetooth®

Category	Feature	Implementation
Wireless specification	Bluetooth	v2.1 / v.2.1 + EDR
	Transmit Power	Class 1, +17 dBm
	Range	350 meters line-of-sight
Coexistence	802.11	IEEE 802.11
Antenna	Internal, chip antenna	Max. gain 2.14dBi
Environmental	Operating Temperature	-40C to +85C
Approvals	Bluetooth FCC / IC / CE / MIC	Registered Approved

This device is a 2.4 GHz wideband transmission system (transceiver), intended for use in all EU member states and EFTA countries, except in **France** and **Italy** where restrictive use applies.

In Italy the end-user should apply for a license at the national spectrum authorities in order to obtain authorization to use the device for setting up outdoor radio links and/or for supplying public access to telecommunications and/or network services.

This device may not be used for setting up outdoor radio links in **France** and in some areas the RF output power may be limited to 10 mW EIRP in the frequency range of 2454 – 2483.5 MHz.

For detailed information the end-user should contact the national spectrum authority in **France**.

Norway — Do not operate the ABPM 7100 Bluetooth function in the geographical area within a radius of 20 km from the center of Ny-Ålesund.

United Arab Emirates

TRA

REGISTERED No:
ER65942/18

DEALER No:
DA44647/18

Brazil

ANATEL MODELO: WT11U 07154-18-03402

“Este equipamento opera em caráter secundário, isto é, não tem direito a proteção contra interferência prejudicial, mesmo de estações do mesmo tipo, e não pode causar interferência a sistemas operando em caráter primário.”

Japan

R 209- J00232

Mexico

This product contains an Approved module, Model No. WT11U IFETEL No. RCPWEWT18-1544

Patient Information - operation of the ABPM 7100

Safety instructions

⚠ Warning

Risk of strangulation posed by the shoulder strap and cuff tubing.

- If the patient has limited cognitive abilities, the device may only be used under supervision.
- Do not place the shoulder strap and cuff tubing around the patient's neck.
- Always place the cuff tubing under the outer clothing (even at night).
- When used on children, the device must only be applied with special care and under permanent supervision.
- Turn off the device, remove the cuff, and notify the doctor in the event of experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that some mild to moderate discomfort may be experienced during a blood pressure measurement.)
- Measurement can be interrupted at any stage by pushing a random button. This deflates the cuff and the device can be removed.

⚠ Warning

Poor circulation caused by continuous cuff pressure.

- Do not kink the connecting tubing.
- If the patient has limited cognitive abilities, the device may only be used under supervision.
- Ensure the correct placement of the shoulder strap and cuff tubing.
- Always place the cuff tubing under the outer clothing (even at night).
- When used on children, the device must only be applied with special care and under permanent supervision.
- Turn off the device, remove the cuff, and notify the doctor in the event of experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that some mild to moderate discomfort may be experienced during a blood pressure measurement.)

⚠ Warning

Placement and inflation of the cuff over a wound may lead to further injuries.

Placement and inflation of the cuff on any limb with an intravascular access or under intravascular treatment or an arteriovenous (A-V) shunt may lead to temporary interruption of circulation and therefore to further patient injury.

Placement and inflation of the cuff on the arm at the side of a breast amputation may lead to further injury.

- Turn off the device, remove the cuff, and notify the doctor in the event of experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that some mild to moderate discomfort may be experienced during a blood pressure measurement.)

⚠ Warning

If the patient is wearing an additional ME device on the same limb for monitoring purposes, the placement and inflation of the cuff may trigger the temporary loss of the existing ME device's function.

The operation and use of the automated non-invasive blood pressure monitoring device may lead to longer impaired blood circulation in the patient or respective limb.

- Turn off the device, remove the cuff, and notify the doctor in the event of experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that some mild to moderate discomfort may be experienced during a blood pressure measurement.)

⚠ Warning

Poor circulation due to overly frequent measurements.

- If the patient has limited cognitive abilities, the device may only be used under supervision.
- Turn off the device, remove the cuff, and notify the doctor in the event of experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that some mild to moderate discomfort may be experienced during a blood pressure measurement.)

⚠ Warning

In very rare cases materials used for and on the cuff may cause allergic reactions.

- Do not use the cuff on patients with a known hypersensitivity to epoxy resin.

⚠ Caution

Risk of injury caused by incorrect application of the cuff.

- If the patient has limited cognitive abilities, the device may only be used under supervision.
- When used on children, the device must only be applied with special care and under permanent supervision.
- Ensure that neither the shoulder strap nor the cuff tubing can ever wrap around the patient's neck. Always place the cuff tubing under the outer clothing (even at night).
- Place the device in such a way that, while the cuff is inflated, the tubing is not compressed or kinked, especially during sleep.
- Petechiae, haemorrhages or subcutaneous haematoma may occur in some patients.
- Turn off the device, remove the cuff, and notify the doctor in the event of experiencing pain, swelling, redness or numbness in the limb where the cuff is placed. (It is expected that some mild to moderate discomfort may be experienced during a blood pressure measurement.)

Attention

Damage to device

- Do not open the casing. Once the device is opened, all warranties will lapse.

Attention

Damage to device

- Do not wear the ABPM 7100 while showering. If you suspect that liquid has entered the device while cleaning or using it, the device shall no longer be used on the patient.
- In the device was exposed to moisture, switch off the device and remove the batteries.
- The device may not be operated around MRI scanners or in the immediate vicinity of other medical electrical equipment.
- During a defibrillator discharge, the device shall not be in contact with the patient. Such a discharge may damage the ABPM 7100 and cause it to display incorrect values.
- The ABPM 7100 must not be used in aircraft.
- Measurement can be interrupted at any stage by pushing a random button. This deflates the cuff and the device can be removed.

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Attention

Measurement errors

- Although the ABPM 7100 meets all EMC standards, you should nonetheless avoid exposing it to strong electromagnetic fields, as this may cause malfunctions outside the tolerances for the device. You should therefore ensure that the ABPM 7100 is at least 30 cm (12 inches) from any portable RF communications equipment.
- The cuff tubing between the ABPM 7100 and the cuff may not be knotted, compressed or pulled apart.
- The cuff connection must always engage with an audible "*CLICK"*. A loose connection between the tubing and the device leads to measurement errors.

Note

- Severe malfunctions are indicated by a continuous beep.
- In the event of a continuous beep, switch off the device, remove the cuff and inform your doctor.

24-hour measurement

1. Before a 24-hour measurement, go through these instructions together with your doctor.
2. Let your doctor explain possible hazards in detail on the basis of the warnings above.
3. Ensure that you have understood all functions and observable points.
4. Turn the device off when it is not being worn (e.g. during x-ray screening at airports). When the device is applied again, ensure that it is turned on with the **ON/OFF** button.

Safety:

For your own safety during the following steps, please observe the safety instructions at the start of this chapter.

Position of the cuff

It is imperative that the artery symbol is positioned on the brachial artery. If the cuff is aligned correctly, the metal bar will lie on the outside of the upper arm (on the elbow side), whereby the fabric bag must cover the skin under the metal bar.

The Buttons

ON/OFF

The **ON/OFF** button turns on and off the ABPM 7100 when the button is pressed for more than 2 seconds.

START

The **START** button serves to

- initiate the automatic protocol.
- trigger a measurement in addition to the automatic protocol.

DAY/NIGHT

The **DAY/NIGHT** button is used to differentiate between waking and sleeping phases during the measurement. Press the **DAY/NIGHT** button immediately before going to bed and upon waking.

EVENT

Press the **EVENT** button to record an event which may affect the blood pressure and to trigger an additional measurement. Note the reason for pressing the **EVENT** button in the event log.

Measurement process

During the first measurement, the cuff is inflated in increments, to determine the cuff pressure required to measure the systolic blood pressure value. This maximum required inflation pressure is stored and applied by direct inflation during the subsequent automatic measurements. The patient should stay calm during the measurement process, until the measurement is completed. Allow your arm to hang loose, or place your lower arm loosely on the table or on a support whilst sitting. Avoid any movement! In the event of a failed measurement a new measurement is performed automatically according to the measurement process described above.

Cancelling a measurement

A measurement will be cancelled by pressing any buttons during the measurement process causing the cuff to be quickly deflated automatically. The LCD display will then show "-**StoP-**" and the ABPM 7100 will beep 5 times. This cancellation will be stored in the measurement value table under **Cancel**.

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