



Digital Wrist Blood Pressure Monitor SC 6400



CE 0197



- Instructions for use -

Introduction

Thank you for deciding for the blood pressure monitor SC 6400 from SCALA Electronic GmbH. To be able to utilise all advantages of the blood pressure monitor to the fullest, you should carefully read these instructions before using the monitor. Keep the instruction leaflet in a safe place.

Safety instructions

The blood pressure monitor SC 6400 enables you to monitor your blood pressure regularly. However, you should never change the treatment which your doctor has prescribed

Self-measurement means monitoring, it does not imply diagnosis or treatment.

Discuss unusual values with your doctor.

Do not change the medication prescribed by your doctor.

The heart rate is not a useful indicator of the frequency of a cardiac pace maker. Patients with cardiac arrhythmia should use the blood pressure monitor only after consulting a doctor.

Features of the SC 6400


- The blood pressure monitor has fuzzy logic to identify the pumping pressure. If the pumping pressure set in the factory is not sufficient, the device identifies this and continues pumping.
- The device has 85 memory locations.
- The date and time are displayed and stored together with every blood pressure value.
- If the battery icon is displayed, the batteries are discharged and the device cannot be used until new batteries are inserted.
- WHO-Interpretation of blood pressure readings with colored band (See description at page 7).

- The handcuff is suitable for wrists from 135 to 195 mm circumference.

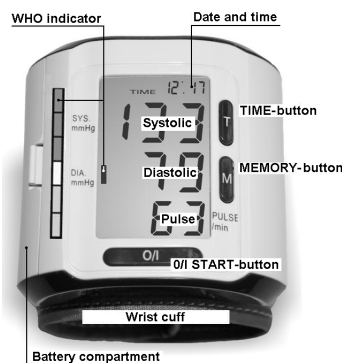
Preparing the monitor for measurement / changing batteries

Insert the two supplied batteries in the battery compartment at the side of the blood pressure monitor as shown.

Use only alkali batteries (LR03).

If the batteries are depleted, the battery icon  is displayed in the top left corner of the LC display. The battery needs urgent replacement because you cannot use the monitor with depleted batteries.

Device description



Setting the clock

After you have inserted the two batteries, you should set the clock.

To set the clock, hold the TIME button pressed for about 5 seconds. The year blinks in the top right corner of the display.

Set the year with the O/I-START button.

When the correct year is set, press the TIME button again. Now the 1 blinks in the top right corner of the LCD. It stands for the month.

Set the month with the O/I-START button.

Another press of the TIME button sets another 1 blinking. It stands for the first day in the month.

Set the day with the O/I-START button.

Another press of the TIME button takes you to the clock setting – the hours blink. As earlier, *set the clock with the O/I-START button.*

Pressing the TIME button advances to the minutes setting.

Set the minutes with the O/I-START button.

A final press of the TIME button completes the setting of the date and time.

How to obtain correct measuring results

To obtain correct readings, measure the blood pressure always under the same conditions, at rest, not under the effect of alcohol, not during meals, not after heavy physical or mental stress. If possible, sit down at a table for the measurement.



Please note: The blood pressure monitor must be at heart level during the measurement, otherwise wrong readings are obtained.

The measuring method

Put the cuff around your **left** wrist making sure that the device rests on the artery and the top edge of the device is about 1 cm away from the wrist joint (Please see the enclosed photo).



The cuff should be applied with moderate tightness.

Pressing the O/I-START button starts the automatic measurement. The cuff inflates to approx. 190 mmHg pressure.

The automatic deflation starts the measurement. After about 3 seconds, a heart icon starts blinking in the LC display. If a Korotkoff's sound is detected already at that time, it means a systolic pressure of more than 150 mmHg. Then the monitor re-inflates (to about 220 mmHg). At the end of the measurement, the result is displayed in the LCD and the cuff deflates.

Aborting a measurement

You can stop the measurement at any time by pressing the O/I-START button. The BP monitor deflates the cuff instantly.

The memory function

The SC 6400 can store up to 85 measurements in the memory area. Together with each measurement (systolic, diastolic and heart rate), the date and time are also saved. The measurement with the longest residence time in the memory is assigned number 1. All other measurements increment by one until number 85. Then the memory is full. The next measurement occupies memory location 85. The measurement formerly at location 85 changes to location 84 (etc., 83→82 2→1). The oldest measurement formerly at location 1 is lost.

Memory recall

With the MEMORY button you can recall the memories.

Delete a blood pressure value from the memory

Press the MEMORY button to view the blood pressure value you want to delete. Pressing the 0/I-START button instantly (and holding it for at least 4 secs.) displays:

dEL (for "delete") and the number of the memory location.

Press the 0/I-START button instantly and the value will be deleted.

Delete all blood pressure values in the memory

Press the MEMORY button to display any blood pressure value. Pressing the POWRER key instantly (and holding it for at least 4 secs.) displays:

dEL (for "delete") and the number of the memory location

Press the MEMORY button instantly and the LCD displays:

dEL (for "delete") and ALL (for all memory locations).

Press the 0/I-START button instantly and

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all values will be deleted. Time and date are not deleted.

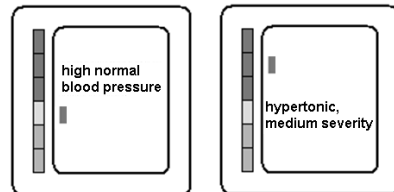
WHO*-Interpretation of blood pressure readings

29.12.2007

Meaning	Systolic / mmHg	Diastolic / mmHg
optimal	< 120	< 80
normal	< 130	< 85
high-normal	130 - 139	85 - 89
mildly hypertonic	140 - 159	90 - 99
hypertonic, medium severity	160 - 179	100 - 109
severly hypertonic	≥ 180	≥ 110

The World Health Organization (WHO) recommends medical treatment, when the blood pressure value exceeds 140/90 mmHg.

Examples:



Cleaning and maintenance

♥ Do not expose the BP monitor to extreme temperature, moisture, dust or direct sunlight.

♥ The cuff contains a sensitive airtight bulb. Treat it with care and avoid any stress by torsion or kinking.

♥ Clean the BP monitor with a soft, dry cloth. Do not use fuel, thinner or other solvent. Remove specks on the cuff carefully with a wet cloth and soap water.

Do not wash the cuff.

♥ Do not drop the BP monitor or treat it with force.


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♥ Do not try to open the BP monitor. This will make the factory calibration invalid

Troubleshooting and remedies

If a fault is detected during a measurement, the BM monitor displays „Err“ and a symbol (code for service personnel).

From many years of experience we know that most faults are the consequence of wrong use. The most frequent causes of faults are excessive movement during the measurement, wrong application of the cuff, use of wrong batteries or use of a rechargeable battery.

Message	Error description	Correction
LL Err	The pressure measured was lower than 20mmHg.	Please measure again.
UU Err	The pressure measured was higher than 300mmHg.	Please measure again.
P Err	Pumping error.	Please check cuff and try again.
rrErr	The pressure can not be measured due to signal noise.	Please measure again.
HI	The pumping pressure is higher than 300mmHg.	Please measure again.
 or no display	Low batteries.	Please check and replace the batteries if necessary.

Wait at least 5 minutes before repeating the measurement.

Periodic re-calibration

We recommend periodic checks of the pressure indication every 2 years.

Referenced norms

For registration, a defined number of blood pressure monitors was subjected to stringent clinical testing. These monitors

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used the same program for blood pressure measurement as your monitor uses. Thus, this program is also regarded as clinically tested.

The manufacture of the blood pressure monitor complies with the European norms for blood pressure monitors: EN 60601-1, EN 1060-1 to EN 1060-3.

Electromagnetic compatibility:

The blood pressure monitor complies with the requirements of European norm EN 60601-1-2.

The requirements of EU directive 93/42/EEC concerning medical devices, class IIa are complied with.

Warranty

We grant a warranty of two years for the blood pressure monitor SC 6400. Within this period, defects of the BP monitor will be repaired free of charge. You can also have your BP monitor repaired by our customer service after the warranty period. We will provide you with a free cost estimate for the repair.

The warranty does not cover damage due to improper handling, accident, natural wear and tear (cuff), non-compliance with the instructions for use or unauthorized modifications of the monitor.

Excluded from the warranty are: the packaging, batteries and the instructions for use.



Disposal note

The disposal of batteries is regulated. Spent batteries are collected at collection points provided by battery dealers and the communities.

Dispose of the blood pressure monitor as prescribed. i.e., at a collection point for electrical scrap.

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Specifications

Measuring method: Oscillometric
 Measuring range: Pressure: 20 to 300mmHg
 Heart rate: 40 to 200/min
 Measuring accuracy: stat. pressure: +/- 3mmHg
 Heart rate: +/- 5 %

Measuring value memory: memory with 85 locations for systolic / diastolic / heart rate, date and time
 Display: LC display

Automatic switch-off: after approx. 1 minute of inactivity

Voltage supply: 2 x LR03 (alkali batteries),
 Working temperature range: +10°C - +40°C

Storage temperature range: - 10°C - +50°C

Weight (without batteries): approx. 100 g
 Cuff length: for wrist circumference from 135mm to 195mm

Specifications may change as technical improvements take place

*WHO – World Health Organization










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Explanation of symbols

	Manufacturer
	CE-sign of a notified body (TÜV Rheinland)
	Product type BF
	Disposal notes
	Product period (MM/YY)
	Read the instruction manual
	Keep dry

Rev. 25/07/2012/GB

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