MEDEL SENSE
TYPE GCE602

CE 0123

ENGLISH

Contents

Included in delivery

- Blood pressure monitor
- Upper arm cuff
- 4 x 1.5 V LR6 AA batteries
- Storage bag
- Instructions for use

Dear customer,

Thank you for choosing one of our products. Our name stands for high-quality, thoroughly tested products for applications in the areas of weight, blood pressure, body temperature, pulse, electrostimulation, beauty and air. Please read these instructions for use carefully and keep them for later use, be sure to make them accessible to other users and observe the information they contain.

With kind regards,
Your Medel International team

1. Getting to know your device

Check that the device packaging has not been tampered with and make sure that all contents are present. Before use, ensure that there is no visible damage to the device or accessories and that all packaging material has been removed. If you have any doubts, do not use the device and contact your retailer or the specified Customer Services address.

INTENDED USE

The Medel Sense automatic Blood Pressure Monitor is indicated for home use for the non-invasive measurement of diastolic and systolic blood pressures and pulse rate

of adults by means of an inflatable cuff which is wrapped around the upper arm.
INTENDED USER
Adult population with upper arm size 22-42cm.
The patient is the intended operator, except in case of patients that require special assistance.

2. Important notes

⚠ Signs and symbols

The following symbols are used in these instructions for use, on the packaging and on the type plate for the device and the accessories:

	Attention
	Note Note on important information
	Observe the instructions for use
	Application part, type BF
	Direct current

	Disposal in accordance with the Waste Electrical and Electronic Equipment EC Directive – WEEE
	Dispose of packaging in an environmentally friendly manner
	Manufacturer
	Permissible storage and transport temperature and humidity
	Permissible operating temperature and humidity
IP21	Protected against solid foreign objects 12.5 mm in diameter and larger, and against vertically falling drops of water
SN	Serial number : lot number / serial number
CE 0123	The CE labelling certifies that the product complies with the essential requirements of Directive 93/42/EEC on medical devices.
EC REP	Authorised Representative in the European Community.

⚠ Notes on use

- In order to ensure comparable values, always measure your blood pressure at the same time of day.
- Do not take a measurement within 30 minutes of eating, drinking, smoking or exercising.
- Before the initial blood pressure measurement, make sure always to rest for about 5 minutes.
- Furthermore, if you want to take several measurements in succession, make sure always to wait for at least 1 minute between the individual measurements.
- Repeat the measurement if you are unsure of the measured value.
- The measured values taken by you are for your information only – they are no substitute for a medical examination. Discuss the measured values with your doctor and never base any medical decisions on them (e.g. medicines and their administration).
- Using the blood pressure monitor outside your home environment or whilst on the move (e.g. whilst travelling in a car, ambulance or helicopter, or whilst undertaking physical activity such as playing sport) can influence the measurement accuracy and cause incorrect measurements.
- Do not use the blood pressure monitor on newborns or patients with pre-eclampsia. We recommend consulting a doctor before using the blood pressure monitor during pregnancy.
- Cardiovascular diseases may lead to incorrect measurements or have a detrimental effect on measurement accuracy. The same also applies to very low blood pressure, diabetes, circulatory disorders and arrhythmias as well as chills or shaking.
- This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who is responsible for their safety or are instructed by such a person in how to use the device. Supervise children around the device to ensure they do not play with it.
- The blood pressure monitor must not be used in connection with a high-frequency surgical unit.
- Only use the device on people who have the specified upper arm measurement for the device.
- Please note that when inflating, the functions of the limb in question may be impaired.
- During the blood pressure measurement, the blood circulation must not be stopped for an unnecessarily long time. If the device malfunctions remove the cuff from the arm.

- Avoid any mechanical restriction, compression or bending of the cuff line.
- Do not allow sustained pressure in the cuff or frequent measurements. The resulting restriction of the blood flow may cause injury.
- Make sure that the cuff is not placed on an arm in which the arteries or veins are undergoing medical treatment, e.g. intravascular access or intravascular or therapy, or an arteriovenous (AV) shunt.
- Do not use the cuff on people who have undergone a mastectomy.
- Do not place the cuff over wounds as this may cause further injury.
- Place the cuff on your upper arm only. Do not place the cuff on other parts of the body.
- You can either use the blood pressure monitor with batteries or with a mains adapter. For mains operation, the device must be set up so that it can be disconnected by the user at any time. As soon as the batteries are empty or the mains adapter is disconnected from the power supply, the blood pressure monitor loses the date and time.
- To conserve the batteries, the blood pressure monitor switches off automatically if you do not press any buttons for 30 seconds.
- The device is only intended for the purpose described in these instructions for use. The manufacturer is not liable for damage resulting from improper or careless use.

⚠ Instructions for storage and maintenance

- The blood pressure monitor is made from precision and electronic components. The accuracy of the measured values and service life of the device depend on its careful handling:
  – Protect the device from impacts, humidity, dirt, marked temperature fluctuations and direct sunlight.
  – Do not drop the device.
  – Do not use the device in the vicinity of strong electromagnetic fields and keep it away from radio systems or mobile telephones.
  – Only use the cuff included with the delivery or original replacement parts. Otherwise incorrect measured values will be recorded.
- We recommend that the batteries be removed if the device will not be used for a prolonged period of time.

⚠ Notes on handling batteries

- If your skin or eyes come into contact with battery fluid, rinse the affected areas with water and seek medical assistance.

- ⚠ **Choking hazard!** Small children may swallow and choke on batteries. Store the batteries out of the reach of small children.
- Observe the plus (+) and minus (-) polarity signs.
- If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.
- Protect batteries from excessive heat.
- ⚠ **Risk of explosion!** Never throw batteries into a fire.
- Do not charge or short-circuit batteries.
- If the device is not to be used for a relatively long period, take the batteries out of the battery compartment.
- Use identical or equivalent battery types only.
- Always replace all batteries at the same time.
- Do not use rechargeable batteries.
- Do not disassemble, split or crush the batteries.

ⓘ Instructions for repairs and disposal

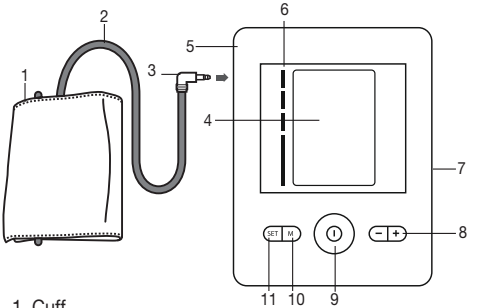
- Batteries do not belong in household waste. Please dispose of empty batteries at the collection points intended for this purpose.
- Do not open the device. Failure to comply will result in voiding of the warranty.
- Do not repair or adjust the device yourself. Proper operation can no longer be guaranteed in this case.
- Repairs must only be carried out by Customer Services or authorised suppliers. Before making a claim, please check the batteries first and replace them if necessary.
- Please dispose of the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment).

If you have any questions, please contact the local authorities responsible for waste disposal.

⚠ Notes on electromagnetic compatibility

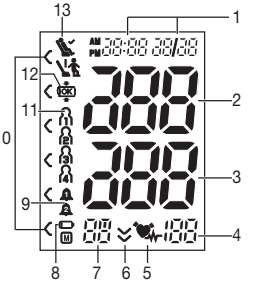
- The device is suitable for use in all environments listed in these instructions for use, including domestic environments.
- The use of the device may be limited in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the display/device.
- Avoid using this device directly next to other devices or stacked on top of other devices, as this could lead to faulty operation. If, however, it is necessary to use the device in the manner stated, this device as well as the other devices must be monitored to ensure they are working properly.
- The use of accessories other than those specified or provided by the manufacturer of this device can lead to an increase in electromagnetic emissions or a decrease in the device's electromagnetic immunity; this can result in faulty operation.
- Failure to comply with the above can impair the performance of the device.

3. Device description



1. Cuff
2. Cuff line
3. Cuff connector
4. Display
5. Connection for cuff connector
6. Risk indicator
7. Connection for mains adapter
8. Function buttons **-/+**
9. **START/STOP**button ⏻
10. Memory button **M**
11. Setting button **SET**

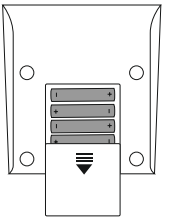
Information on the display:



1. Time and date
2. Systolic pressure
3. Diastolic pressure
4. Calculated pulse value
5. Cardiac arrhythmia symbol, pulse symbol
6. Release air
7. Memory display: average value (A), morning (AM), evening (PM), memory space number
8. Battery replacement symbol
9. Alarm function
10. Risk indicator
11. User memory
12. Cuff position control
13. Resting indicator display

4. Preparing the measurement

Inserting the batteries



- Open the battery compartment lid.
- Insert four 1.5V AA (alkaline type LR6) batteries. Make sure that the batteries are inserted the correct way round.
  Do not use rechargeable batteries.
- Close the battery compartment lid again carefully.
- All display elements are briefly displayed, 24 h flashes in the display. Now set the date and time as described below.

If the low battery indicator is permanently displayed, you can no longer perform any measurements and must replace the batteries. Once the batteries have been removed from the device, the time must be set again.

Battery disposal

- The empty, completely flat batteries must be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries.
- The codes below are printed on batteries containing harmful substances:
  Pb = Battery contains lead,
  Cd = Battery contains cadmium,
  Hg = Battery contains mercury

Setting the hour format, date and time

It is essential to set the date and time. Otherwise, you will not be able to save your measured values correctly with a date and time and access them again later.

There are two different ways to access the menu from which you can adjust the settings:

- Before initial use and after each time you replace the battery:
  When inserting batteries into the device, you will be taken to the relevant menu automatically.
- If the batteries have already been inserted:
  Press and hold the settings button **SET** on the device when **switched off** for approx. 5 seconds.

To set the date and time, proceed as follows:

- Select 12h or 24h mode using the function buttons -/+. Press **SET** to confirm. The year display will start to flash. Set the year with the function buttons -/+ and confirm with **SET**.
- Set the month, day, hour and minute and confirm each with the setting button **SET**.
- The blood pressure monitor switches itself off automatically.

Set alarm

You can set 2 different alarm times to remind yourself to take the measurement. To set the alarm, proceed as follows:

- Press and hold the function buttons - and + simultaneously for 5 seconds.
- Alarm 1 1 is shown in the display, „on“ or „off“ flashes at the same time. With the function buttons -/+, choose whether alarm 1 should be activated („on“ flashes) or deactivated („off“ flashes) and confirm with the setting button SET.
- If alarm 1 1 is deactivated („off“), you automatically switch to setting alarm 2 2.
- If alarm 1 1 is activated, the hours flash on the display. Select the desired hour using the function buttons -/+ and confirm with SET. The minutes flash on the display. Select the desired minute using the function buttons -/+ and confirm with SET.
- Alarm 2 2 is shown in the display, „on“ or „off“ flashes at the same time. To set, proceed as for alarm 1 1. The blood pressure monitor switches itself off automatically.

Operation with the mains adapter

You can also operate this device with a mains adapter. When doing so, there must not be any batteries in the battery compartment.

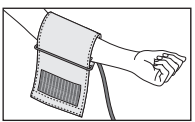
- To prevent possible damage to the device, the blood pressure monitor must only be used with the mains adapter described here.
- Insert the mains adapter into the connection provided for this purpose on the blood pressure monitor. The mains adapter must only be connected to the mains voltage that is specified on the type plate.
- Then insert the mains plug of the mains adapter into the mains socket.
- After using the blood pressure monitor, unplug the mains adapter from the mains socket first and then disconnect it from the blood pressure monitor. As soon as you unplug the mains adapter, the blood pressure monitor loses the date and time setting but the saved measurements are retained.

5. Measuring blood pressure

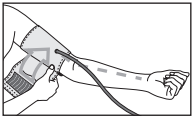
Ensure the device is at room temperature before measuring. The measurement can be performed on the left or right wrist.

Attaching the cuff

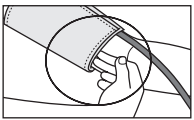
Place the cuff onto the bare upper arm. The circulation of the arm must not be hindered by tight clothing or similar.



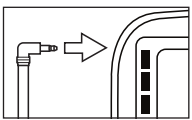
The cuff must be placed on the upper arm so that the bottom edge is positioned 2 – 3 cm above the elbow and over the artery. The line should point to the centre of the palm.



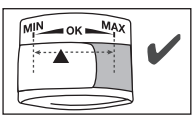
Now tighten the free end of the cuff, but make sure that it is not too tight around the arm and close the hook-and-loop fastener. The cuff should be fastened so that two fingers can fit under the cuff.



Now insert the cuff line into the connection for the cuff connector.



This cuff is suitable for you if the index mark (▼) is within the OK range after fitting the cuff on the upper arm.

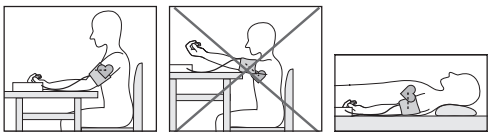


ⓘ If the measurement is performed on the right upper arm, the line should be located on the inside of your elbow. Ensure that your arm is not pressing on the line.

Blood pressure may vary between the right and left arm, which may mean that the measured blood pressure values are different. Always perform the measurement on the same arm.
If the values between the two arms are significantly different, please consult your doctor to determine which arm should be used for the measurement.

Important: The unit may only be operated with the original cuff. The cuff is suitable for an arm circumference of 22 to 42 cm.

Adopting the correct posture



- Before the initial blood pressure measurement, make sure always to rest for about 5 minutes. Otherwise deviations can occur.
- Furthermore, if you want to take several measurements in succession, make sure always to wait for at least 1 minute between the individual measurements.
- You can take the measurement while sitting or lying. Always make sure that the cuff is at heart level.

- To carry out a blood pressure measurement, make sure you are sitting comfortably with your arms and back leaning on something. Do not cross your legs. Place your feet flat on the ground.
- To avoid falsifying the measurement, it is important to remain still during the measurement and not to speak.

Performing the blood pressure measurement

- As described above, attach the cuff and adopt the posture in which you want to perform the measurement.
- Start the blood pressure monitor with the **START/STOP** button ⏻. After the full-screen display, the respective alarm symbols are displayed if alarm 1 / 2 is activated.
- The cuff automatically inflates. The cuff's air pressure is slowly released. If you already recognise a tendency for high blood pressure, you should reinflate the cuff and increase the cuff's pressure again. As soon as a pulse is found, the pulse symbol ♥ will be displayed.
- The cuff position control symbol OK is displayed throughout the entire measurement. If the cuff is applied too tightly or too loosely, then and "Er 3" are displayed. In such cases, the measurement is cancelled after approx. 5 seconds and the device switches itself off. Apply the cuff correctly and take a new measurement.
- The systolic pressure, diastolic pressure and pulse rate measurements are displayed. A symbol is displayed to indicate whether you were sufficiently relaxed during the blood pressure measurement (= sufficiently at rest; = not at rest). Observe the chapter on interpreting results/measuring the resting indicator in these instructions for use.
- You can cancel the measurement at any time by pressing the **START/STOP** button ⏻.
- E_ appears if the measurement has not been performed properly. Observe the chapter on error messages/troubleshooting in these instructions for use and repeat the measurement.
- Now select the desired user memory by pressing the memory button **M**. If you do not select a user memory, the measurement is stored in the most recently used user memory. The relevant 1, 2, 3 or 4 symbol appears on the display.
- To switch off, press the **START/STOP** button ⏻. If you forget to turn off the device, it will switch itself off automatically after approx. 3 minutes.

Wait for at least 1 minute before taking another measurement.

6. Evaluating results

Cardiac arrhythmia:

This device can identify potential disruptions of the heart rhythm when measuring and if necessary, indicates this

after the measurement with the symbol . This can be an indicator for arrhythmia. Arrhythmia is an illness in which the heart rhythm is abnormal because of flaws in the bioelectrical system that regulates the heartbeat. The symptoms (skipped or premature heart beats, pulse being slow or too fast) can be caused by factors such as heart disease, age, physical make-up, excess stimulants, stress or lack of sleep. Arrhythmia can only be determined through an examination by your doctor. If the symbol is shown on the display after the measurement has been taken, repeat the measurement. Please ensure that you rest for 5 minutes beforehand and do not speak or move during the measurement. If the symbol appears frequently, please consult your doctor. Self-diagnosis and treatment based on the measurements can be dangerous. Always follow your GP's instructions.

Risk indicator:

The measurements can be classified and evaluated in accordance with the following table.
However, these standard values serve only as a general guideline, as the individual blood pressure varies in different people and different age groups etc.
It is important to consult your doctor regularly for advice. Your doctor will tell you your individual values for normal blood pressure as well as the value above which your blood pressure is classified as dangerous.

The bar chart on the display and the scale on the unit show which category the recorded blood pressure values fall into. If the values of systole and diastole fall into two different categories (e.g. systole in the High normal category and diastole in the Normal category), the graphical classification on the device always shows the higher category; for the example given this would be High normal.

Blood pressure value category	**Systole** (in mmHg)	**Diastole** (in mmHg)	**Action**
Setting 3: severe hypertension	≥180	≥110	seek medical attention
Setting 2: moderate hypertension	160–179	100–109	seek medical attention
Setting 1: mild hypertension	140–159	90–99	regular monitoring by doctor
High normal	130–139	85–89	regular monitoring by doctor
Normal	120–129	80–84	self-monitoring
Optimal	<120	<80	self-monitoring

Source: WHO, 1999 (World Health Organization)

Measuring the resting indicator (using the HSD diagnosis)
The most frequent error made when measuring blood pressure is taking the measurement when not at rest (haemodynamic stability), which means that both the systolic and the diastolic blood pressures are distorted. While measuring the blood pressure, the device automatically determines whether you are at rest or not. If there is no indication that your circulatory system is not sufficiently at rest, the symbol (haemodynamic stability) is displayed and the measurement can be recorded as a reliable resting blood pressure value.

Haemodynamic stability
Measurement of the systolic and diastolic pressure is increased when the circulatory system is sufficiently at rest and is a very reliable indicator of resting blood pressure. However, if there is an indication that the circulatory system is not sufficiently at rest (haemodynamic instability), the symbol is displayed. In this case, the measurement should be repeated after a period of physical and mental rest. The blood pressure measurement must be taken when the patient is physically and mentally rested, as it will be the basis for diagnosing the blood pressure level and regulating the patient's medical treatment.

Lack of haemodynamic stability
It is very probable that the systolic and diastolic blood pressures have not been measured whilst the patient is at rest and the resting blood pressure measurement has therefore been distorted. Repeat the measurement after a rest and relaxation period of at least five minutes. Go to a sufficiently quiet and comfortable spot and remain there calmly; close your eyes, breathe deeply and evenly and try to relax. If the next measurement also shows insufficient stability, you can repeat the measurement after another resting period. If the measurements continue to show some instability, identify these blood pressure measurements as having been taken when the circulatory system had not been sufficiently rested. In this case, nervousness or inner anxiety may be the cause and this cannot be cured by brief periods of rest. Existing cardiac arrhythmias may also prevent a stable blood pressure measurement. A lack of resting blood pressure can have various causes, such as physical or mental strain or distraction, speaking or experiencing cardiac arrhythmias during the measurement. In an overwhelming number of cases, the HSD diagnosis will give a very good guide as to whether the circulatory system is rested when taking the measurement. Certain patients suffering from cardiac arrhythmia or chronic mental conditions can remain haemodynamically unstable in the long-term, something which

persists even after repeated periods of rest. The accuracy of the resting blood pressure results is reduced in these users. Like any medical measurement method, the precision of the HSD diagnosis is limited and can lead to incorrect results in some cases. The blood pressure measurements taken when the circulatory system was at rest represent particularly reliable results.

7. Saving, displaying and deleting measured values

The results of every successful measurement are stored together with the date and time. If there are more than 30 measurements, the oldest measurements are lost.

- Press the memory button **M**. Select the desired user memory (1 ... 4) by pressing the memory button **M** again.
- If you press the function button **+**, the average value A of all the stored measured values in the user memory will be displayed. If you press the function button **+** again, the average value of the morning measurements for the last 7 days will be displayed (morning: 5 a.m. – 9 a.m., display AM). If you press the function button **+** again, the average value of the evening measurements for the last 7 days will be displayed (evening: 6 p.m. – 8 p.m., display PM). If you continue to press the function button **+**, the most recent individual measured values are displayed in turn with the date and time.
- To switch off, press the **START/STOP** button ⏻.
- If you forget to switch off the device, it will switch itself off automatically after 30 seconds.
- If you want to delete the whole memory for a specific user, press the memory button **M**. Press and hold down the memory button **M** and the setting button **SET** simultaneously for 5 seconds.

8. Error messages/troubleshooting

In the event of errors, the error message E_ appears on the screen.

Error messages may appear if:

- It was not possible to correctly record the pulse: E 1 ;
- No measurement could be taken: E 2 ;
- The cuff is fastened too tightly or loosely: E 3 ;
- Errors occur during the measurement: E 4 ;
- The pump pressure is higher than 300 mmHg: E 5 ;
- There is a system error. If this error message appears, please contact Customer Services: E 6 .
- The batteries are almost empty: 🪫.

In the above cases, you must repeat the measurement. Make sure that the cuff tube is properly inserted and that you do not move or talk.

Re-insert the batteries if necessary, or else replace them.

9. Cleaning and storing the device and cuff

- Clean the device and cuff carefully using a slightly damp cloth only.
- Do not use any cleaning agents or solvents.
- Under no circumstances hold the de

vice and cuff under water, as this can cause liquid to enter and damage the device and cuff.

- If you store the device and cuff, do not place heavy objects on the device and cuff. Remove the batteries. The cuff line should not be bent sharply.

10. Technical specifications

Type / Model	GCE602 / Medel SENSE
Measurement method	Oscillometric, non-invasive blood pressure measurement on the upper arm
Measurement range	Cuff pressure 0-300 mmHg, Systolic 50-280 mmHg, Diastolic 30-200 mmHg, Pulse 40-199 beats/minute
Display accuracy	Systolic ±3 mmHg, Diastolic ±3 mmHg, Pulse ±5% of the value shown
Measurement inaccuracy	Max. permissible standard deviation according to clinical testing: Systolic 8 mmHg / Diastolic 8 mmHg
Memory	4 x 30 memory spaces
Dimensions	L 134 mm x W 103 mm x H 60 mm
Weight	Approximately 367 g (without batteries, with cuff)
Cuff size	22 to 42 cm
Permissible operating conditions	+10°C to +40°C, 10 to 85% relative humidity (non-condensing), 800-1050 hPa ambient pressure
Permissible storage conditions	-20°C to +55°C, 10 to 90% relative humidity, 800-1050 hPa ambient pressure
Power supply	4 x 1.5V ⎓ AA batteries
Battery life	For approx. 300 measurements, depending on levels of blood pressure and pump pressure
Classification	Internal supply, IP21, no AP or APG, continuous operation, application part type BF

The serial number is located on the device or in the battery compartment.
Technical information is subject to change without notification to allow for updates.

- This device complies with European Standard EN60601-1-2 (In accordance with CISPR 11, IEC61000-3-2, IEC61000-3-3, IEC61000-4-2, IEC61000-4-3, IEC61000-4-4, IEC61000-4-5, IEC61000-4-6, IEC61000-4-7, IEC61000-4-8, IEC61000-4-11, EN55024) and is subject to particular precautions with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit.
- The device complies with the EU Medical Devices Directive 93/42/EEC, the German Medical Devices Act (Medizinproduktgesetz) and IEC80601-2-30 (Medical electrical equipment – Part 2 – 30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers).
- The accuracy of this blood pressure monitor has been carefully checked and developed with regard to a long useful life. If using the device for commercial medical purposes, it must be regularly tested for accuracy by appropriate means. Precise instructions for checking accuracy may be requested from the service address.

11. Mains adapter (not included)

Model no.	LXCP12-006060BEH
Input	100–240V, 50–60 Hz, 0.5A max
Output	6V DC, 600mA, only in connection with Medel blood pressure monitor.
Supplier	Shenzhen longxc power supply co., ltd
Protection	This device is double insulated and protected against short circuit and overload by a primary thermal fuse. Make sure to take the batteries out of the compartment before using the mains adapter.
	Polarity of the the DC voltage connection
	Double insulated/equipment class 2
Enclosures and Protective Covers	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test). The operator shall not contact the patient and the output plug of AC mains adapter simultaneously.

12. Warranty/service

The device is guaranteed for 5 years from the date of purchase against any defectsoriginating in materials or workmanship.

•The warranty consists of free replacement of defective components at the origin.

•The warranty does not cover accessories supplied and parts subject to normal wear and tear.

•The shipping costs of the appliance are borne by the user.

•The warranty shall lapse if the appliance has been tampered with, if the defect is caused by improper use or if the damage is not attributable to the manufacturer (accidental fall, improper transport, etc.).

•The warranty does not imply any compensation for damages, either direct or indirect, of any kind, to people or property during the period in which the product cannot be used.

•The warranty is valid from the date of purchase of the product certified by the receipt or the purchase invoice.

Assistance

+39 02 83451193