

GE Healthcare

TONOPORT V

Ambulatory Blood Pressure System

Firmware Version 2.1

Operator's Manual

2001589-085 ENG Revision F



Note

The information in this manual only applies to TONOPORT V, firmware version 2.1. It does not apply to earlier firmware versions.

Due to continuing product innovation, specifications in this manual are subject to change without notice.

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Revision History

This manual is subject to the GE Healthcare change order service. The revision code, a letter that follows the document part number, changes with every update of the manual.

Part No./Revision	Date	Comment
2001589-085 Revision A	2009-05	Initial release
2001589-085 Revision B	2010-04	General Information: modifications in 3rd paragraph Section 1.3: additional information concerning the ingress of liquids Chapter 2: four symbols added Chapter 3: additional information concerning alternative charger
2001589-085 Revision C	2011-10-31	CardioSys was removed globally Chapters 1.1, 5 and 7: interface restrictions for CASE/CardioSoft were added Chapter 2: relevant battery charger symbols were added Chapter 7: CardioSoft version 6.7 for Windows 7 and reference to the "CASE-CS" folder were added Chapter 9: measuring range for mean pressure was corrected to '50 to 250 mmHg'
2001589-085 Revision D	2014-01-31	Changes on pages 4, 5, 11, 12, 23, and 24.
2001589-085 Revision E	2015-05-07	Changes on pages 8, 17, and 27.
2001589-085 Revision F	2016-07-12	Changes on pages 4, 11, and 28.

General Information

- The product **TONOPORT V** bears the CE marking **CE-0482** (notified body MEDCERT GmbH) indicating its compliance with the provisions of the Council Directive 93/42/EEC about medical devices (including amendment 2007/47/EC) and fulfills the essential requirements of Annex I of this directive. It has an internal power source and is an MDD class IIa device. The device fulfills the requirements of the Directive 2011/65/EU of the European Parliament and of the Council.
- It has a type BF applied part.
- The product fulfills the requirements of the standard EN/IEC 60601-1 "Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance" as well as the electromagnetic immunity requirements of the standard EN/IEC 60601-1-2 "Medical electrical equipment – Collateral standard: Electromagnetic compatibility – Requirements and tests" and applicable amendments.
- The radio-interference emitted by this product is within the limits specified in CISPR11/EN 55011, class B.
- The CE marking covers only the accessories listed in the "Order Information" chapter.
- This manual is an integral part of the equipment. It should be available to the equipment operator at all times. Close observance of the information given in the manual is a prerequisite for proper equipment performance and correct operation and ensures patient and operator safety. **Please note that information pertinent to several chapters is given only once. Therefore, carefully read the manual once in its entirety.**
- The symbol  means: Consult accompanying documents. It indicates points which are of particular importance in the operation of the equipment.

- This manual reflects the equipment specifications and applicable safety standards valid at the time of printing. All rights are reserved for devices, circuits, techniques, software programs, and names appearing in this manual.
- On request GE Healthcare will provide a detailed Service Manual.
- The safety information given in this manual is classified as follows:

Danger

indicates an imminent hazard. If not avoided, the hazard will result in death or serious injury.

Warning

indicates a hazard. If not avoided, the hazard can result in death or serious injury.

Caution

indicates a potential hazard. If not avoided, the hazard may result in minor injury and/or product/property damage.

- To ensure patient safety and interference-free operation and to guarantee the specified measuring accuracy, we recommend only original equipment accessories as available through GE Healthcare distribution. The user is responsible for the application of accessories from other manufacturers.



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The country of manufacture appears on the device label.

1 Application, Safety Information

1.1 Application

Intended Use

TONOPORT V is a small-size, patient-borne blood pressure monitor for ambulatory, non-invasive measurement of the patient's blood pressure. If the blood pressure cuffs listed in chapter 10 "Order Information" fit the patient, it can be used on adults, children, and small children. TONOPORT V is **not** suitable for blood pressure measurements in neonates. Also it is **not** suitable for use in intensive-care medicine.

For periods of up to 30 hours, TONOPORT V records the patient's blood pressure at selectable intervals and saves the results. There is a choice of three different measurement protocols.

Using TONOPORT V with CASE™ / CardioSoft

TONOPORT V can be operated in conjunction with CASE™ (version 5.15 or later) or with the analysis program CardioSoft (version 4.14 or later) that is included with TONOPORT V. If the USB port is used (CardioSoft only), it is necessary to install the appropriate driver first (see "Software Installation" on page 23). With these systems, individual measurement protocols can be created and the stored data can be reviewed on-screen in tabular and graphic form. With V6.5 and subsequent versions, the patient ID used by the analysis program can be stored in TONOPORT V to allow the collected data to be downloaded without selecting the patient first (refer to the respective Operator Manuals; you will find the CardioSoft manual on the CardioSoft CD).

Biocompatibility

The parts of the equipment described in this manual, including all accessories, that come in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards if used as intended. If you have questions in this matter, please contact GE Healthcare or its representatives.

Oscillometric Measuring Method

The blood pressure is measured by the oscillometric method. The criteria for this method are the pressure pulsations superimposed with every systole on the air pressure in the cuff.

The blood pressure cuff is wrapped around the upper arm and inflated to a pressure which must be clearly above the expected systolic pressure. A pressure transducer measures the cuff pressure as well as the superimposed pressure pulsations. During blood pressure measurements the cuff must be level with the heart. If this is not ensured, the hydrostatic pressure of the liquid column in the blood vessels will lead to incorrect results.

- When the patient is sitting or standing during measurements, the cuff is automatically at the correct level.

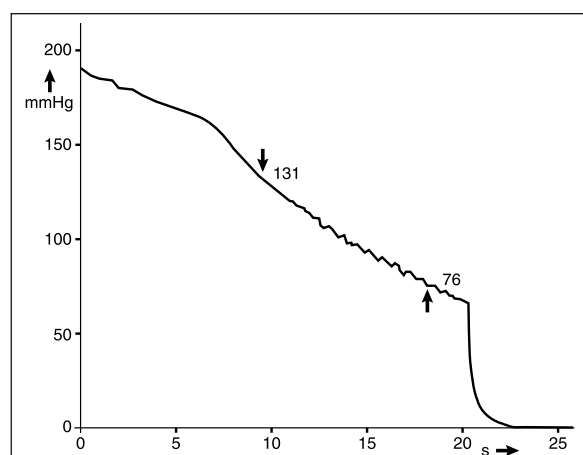


Fig. 1-1 Waveform representing the pressure decrease in the cuff during a measurement: systolic pressure at 131 mmHg, diastolic pressure at 76 mmHg

1.2 Functional Description

The TONOPORT V monitor accommodates the blood pressure measuring system and a microprocessor for system control and data processing. The monitor is powered by two AA size batteries (either rechargeable NiMH batteries or alkaline batteries).

1.3 Safety Information

Danger

Risk to persons —

- *The equipment is not designed for use in areas where an explosion hazard may occur. Explosion hazards may result from the use of flammable anesthetic mixtures with air or with oxygen, nitrous oxide, skin cleansing agents or disinfectants.*

Warning

Risk to persons —

- *Equipment may be connected to other equipment or to parts of systems only when it has been made certain that there is no danger to the patient, the operator, or the environment as a result. In those instances where there is any element of doubt concerning the safety of connected equipment, the user must contact the manufacturers concerned or other informed experts as to whether there is any possible danger to the patient, the operator, or the environment as a result of the proposed combination of equipment. Compliance with the standard IEC 60601-1 must always be ensured.*
- *TONOPORT V may be connected to CASE™ or to a PC with the CardioSoft program. While connected to any of these devices, TONOPORT V must be disconnected from the patient.*
- *Chemicals required for the maintenance of the equipment, for instance, must under all circumstances be prepared, stored, and kept at hand in their specific containers. Failure to observe this instruction may have severe consequences for the patient.*
- *The equipment has no protection against the ingress of liquids. Liquids must not enter the equipment. Equipment into which liquids have entered must be inspected by a service technician before use.*
- *Before cleaning, TONOPORT V must be disconnected from other equipment (CASE™, PC).*
- *Dispose of the packaging material, observing the applicable waste-control regulations. Keep the packaging material out of children's reach.*

Warning***Incorrect measurements —***

- *Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that external equipment operated in the vicinity of TONOPORT V complies with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems, etc. are possible sources of interference as they may emit higher levels of electromagnetic radiation.*

Caution***Equipment damage, risk to persons —***

- *Before connecting the battery charger to the power line, check that the voltage ratings on the nameplate match those of your local power line.*
- *The battery charger is not a medical device. It must not be used in the patient environment.*
- *Before using the equipment, the operator is required to ascertain that it is in correct working order and operating condition.*
- *The operator must be trained in the use of the equipment.*
- *Only persons who are trained in the use of medical technical equipment and are capable of applying it properly are authorized to apply such equipment.*
- *There are no user-replaceable components inside the equipment. Do not open. For service or repair, please contact your local, authorized dealer (<http://gehealthcare.com>).*

2 Controls and Indicators

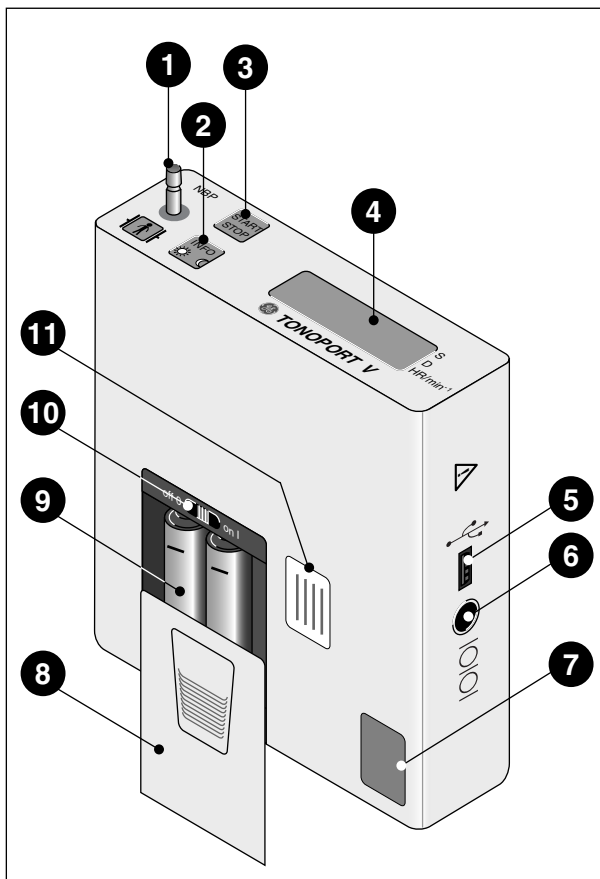





Fig. 2-1 TONOPORT V controls and indicators

Functions of the Button

Button 	Message on display	Function
Push once	H 1	clear memory
Push twice	H 2	set date and time
Push 3 times	H 3	select the measurement protocol
Push 4 times	H 4	activate calibration mode
Push 5 times	H 5	display firmware version
Push 6 times	H 6	select energy source
Push 7 times	H 7	enable/disable audio signal
Push 8 times	H 8	toggle pressure unit between mmHg and kPa

- 1 Connection for blood pressure cuff
- 2 Button  : push to display the most recent parameter readings. Readings appear in the following order:
 - systolic value "S" (unit mmHg or kPa shown on the display)
 - diastolic value "D" (unit mmHg or kPa shown on the display)
 - pulse rate "HR" (unit min^{-1})
 The same button is used
 - to toggle between the day phase and the night phase chapter 4, section "Toggle Manually Between Day and Night Phase") and
 - to program the BP monitor (chapter 3 "Setup")
- 3 Button  : push to start and stop a measurement, and to confirm entries
- 4 Liquid crystal display (LCD)
- 5 Port for connection to PC (USB)
- 6 Port for connection to PC (RS232)
- 7 Calibration mark
- 8 Lid covering battery compartment
- 9 (Rechargeable) batteries
- 10 ON/OFF switch
- 11 Nameplate

Explanation of Signs and Symbols

Symbols used on the equipment and on the packaging



Caution, consult accompanying documents



This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.



Type BF applied part (defibrillation-proof)



Catalogue number



Serial number



CE marking



CE marked per the Medical Device Directive 93/42/EEC of the European Union. The notified body is MEDCERT GmbH.



Gossudarstvenny Standart Russia (GOST)

Rx Only

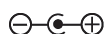
In the USA, the product is only for use by or on the order of a physician, or persons licensed by U.S. law.



USB port, connection to PC



Serial port, connection to PC



Polarity of the DC input (charger only)



Approval mark for use of the equipment in a vehicle (charger only, xxx-xx xxxx alphanumeric characters)



Class II equipment



For indoor use only



For indoor use only



Manufacturer's identification



Date of manufacture.
The number found under this symbol is the date of manufacture in the YYYY-MM format.



Calibration mark, valid in Germany only (see section "Technical Inspections of the Measuring System" in chapter 8)

Symbols used on the display



blinks with each detected oscillation; is continuously lit when the monitor contains data



blinks when the batteries are almost depleted; is continuously displayed when batteries are discharged and no more BP measurements can be taken



day phase selected



night phase selected

Further relevant symbols used on the battery charger

TR15RA120

100-240V 0.4A

47-63Hz

12V 1.1A

Power supply type designation and ratings



UL-certified product



Approval mark for Japan



Pollution control symbol according to the Chinese standard SJ/T11363-2006

3 Setup

Some Basic Facts on Battery Power

TONOPORT V is either powered by two rechargeable Nickel Metal Hydride batteries (NiMH) or by two alkaline batteries. The device must be set to the power source used (see section "Insert Batteries" below). The device also contains a Lithium cell that powers the clock. The Lithium cell can only be replaced by a service technician.

The capacity of two fully charged or new batteries is sufficient for a minimum of 30 hours of operation or for 200 measurements.

The capacity of rechargeable batteries decreases with age. If the capacity of fully charged batteries is considerably less than 24 hours, the batteries must be replaced.

Caution

Equipment damage —

- Only use the original rechargeable, size AA Nickel Metal Hydride batteries (from manufacturers such as Sanyo, Panasonic, Energizer, Duracell, Varta, or GP) with a capacity ≥ 1500 mAh or size AA high-rate discharge alkaline batteries (such as Panasonic Evoia, Energizer Ultimate, Duracell Ultra, Duracell Power Pix, or Varta maxtech).
- Charge the NiMH batteries to capacity before using them for the first time.
- Recharge the NiMH batteries immediately after use and do not leave batteries uncharged.
- Use only the original charging unit to recharge the NiMH batteries.
- Do not attempt to recharge the alkaline batteries.
- If the TONOPORT V will not be used for one month or more, remove the (rechargeable) batteries from the device.
- Batteries must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of the batteries.

Insert Batteries

Note

Switch TONOPORT V off before inserting the batteries. To do so, slide the ON/OFF switch (10, Fig. 2-1) to the left while looking at the display.

- Hold TONOPORT V as shown in Fig. 3-1 and slide the lid of the battery compartment open (approx. 1 cm).

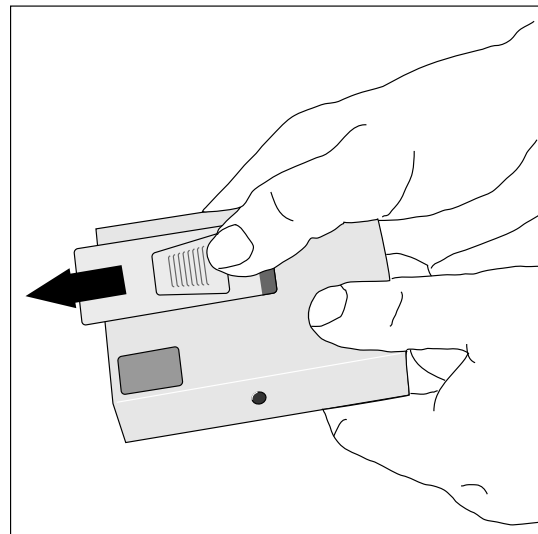







Fig. 3-1 Opening the battery compartment

It is not possible to open the lid more than about 1 cm which is just enough to reach the ON/OFF switch. To replace batteries, you must take off the lid (pull upward).

- Place the two batteries in the compartment as indicated by the symbols.

Select Energy Source

- Turn on the BP monitor. The switch is located inside the battery compartment. Slide the switch to the right, while looking at the display.
- Wait for the time to be displayed.
- Push  six times: the display shows "H 6".
- Push  : the display will show "AAAA" when the BP monitor is set up for rechargeable NiMH batteries (as shipped) and "bbbb" when it is set up for alkaline batteries.
- Confirm the displayed information with  or change the selection with  and confirm the new selection with .
- Next the BP monitor will briefly display the capacity of the inserted batteries. "A 100", for instance, means that the rechargeable batteries have a capacity of 100%, i.e., they are fully charged. "b 50" means that

the alkaline batteries have a capacity of only 50%, i.e., they are half depleted.

- Place the lid on the battery compartment and close.

Note

The energy source needs to be selected only when the BP monitor is put into service for the first time or when you change from NiMH to alkaline batteries and vice versa.

Charge NiMH Batteries

Caution

Equipment damage, risk to patients —

- *The charger is not a medical device. It must not be used in the patient environment.*
- *The contact surface of the NiMH batteries and of the charger must always be kept clean.*
- *The charger is to be used indoors only and must be protected against oil, grease, aggressive detergents and solvents to prevent damage.*
- *If the charger is damaged in any way, e.g. after a drop or when the mains pins are bent, the local authorized dealer must be contacted immediately.*
- *High temperatures affect the charging process. Ideally, the room temperature should not exceed 40 °C (104 °F).*
- *After quick charging, please wait for some minutes before another quick charge. Otherwise the temperature sensors will not function correctly.*

If TONOPORT V is powered by rechargeable batteries (4 of them are shipped with the equipment), they should be recharged immediately after use (24 hours). Use only the original charger supplied. It consists of an AC power adapter and the charging unit itself.

- Check that the voltage ratings on the nameplate of the charging unit match those of your local power line.

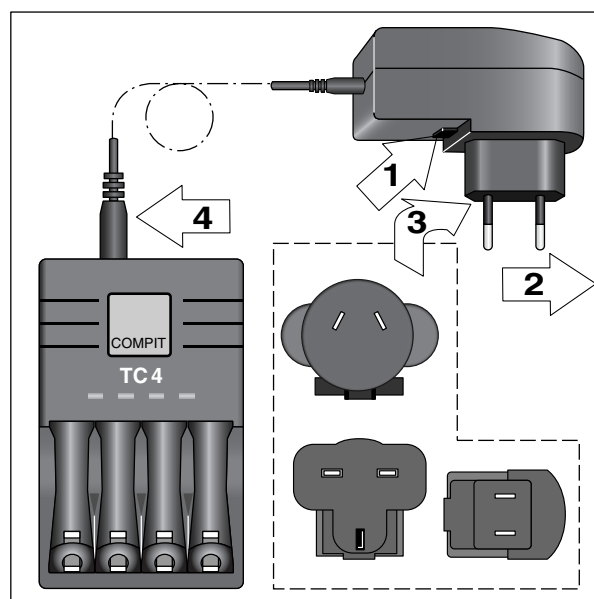


Fig. 3-2 Exchanging the connector, connecting the charger

- If necessary, replace the connector to match the wall outlet type:
 - push the button below the connector and hold it depressed (1, Fig. 3-2)
 - remove the connector and insert the suitable type of connector 2, 3
 - ensure that the new connector locks into place.
- Connect the cable of the AC power adapter to the charging unit 4 and plug the AC power adapter into the wall outlet.
- Insert the two batteries into the charging unit, observing the correct polarity.

Two different charger models are available:

- COMPIT TC4
- VARTA

Charge Batteries with the COMPIT TC4 Charger

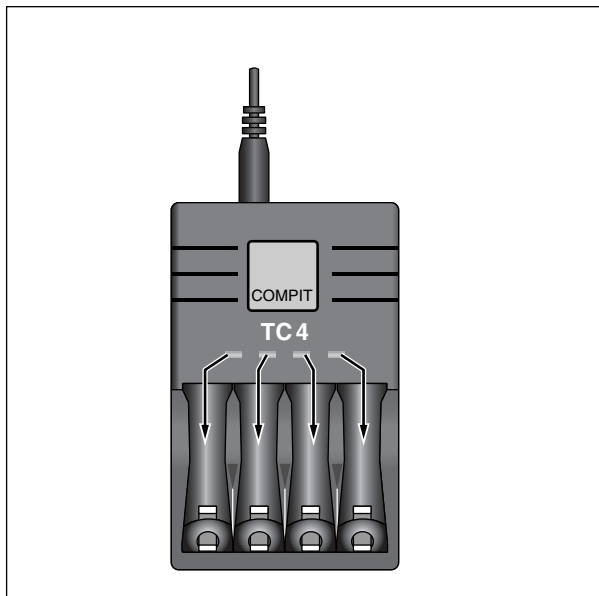


Fig. 3-3 Red LEDs on charger

The batteries take up to 3 hours to recharge. Each of the red LEDs corresponds to one of the charger compartments (Fig. 3-3). During the charge cycle, the corresponding red LED blinks at a slow rate (approximately once per second). Note: If the red LED does not light up, the battery may be inserted the wrong way round. When the battery is charged, the LED is solid red. The charging unit now trickle-charges the battery to compensate for self-discharging.

The battery temperature is monitored in the charger. When the temperature is too high, the LED is solid red and the charger switches to trickle-charging.

If the battery is correctly inserted and the red LED does not light up, the charger has identified a battery problem. The charging current to the compartment concerned will be cut off. Remove the battery and discard, observing the applicable waste-disposal regulations.

Charge Batteries with the VARTA Charger



Fig. 3-4 Battery symbols and bars in the charger display

Insert 4 or 2 batteries. To charge only 2 batteries, insert them in the two compartments on the right or on the left. The batteries take up to 3 hours to recharge. Once the batteries are inserted, battery symbols will appear in the charger display where each symbol corresponds to one of the charger compartments (Fig. 3-4). During the charge cycle, the corresponding bar in the battery symbols blinks. Note: If the battery symbols and bar do not light up, only one battery may be inserted or the batteries are inserted the wrong way round. When the batteries are charged, the bars are permanently illuminated. The charging unit now trickle-charges the battery to compensate for self-discharging.

The battery temperature is monitored in the charger. When the temperature is too high, the bar in the battery symbol is permanently illuminated and the charger switches to trickle-charging.

If the batteries are correctly inserted and the displayed battery symbols show no bars, the charger has identified a battery problem. The charging current to the compartment concerned will be cut off. Remove the battery and discard, observing the applicable waste-disposal regulations.

Performance Check

When turned on, TONOPORT V runs a self-test that includes all symbols and segments on the LCD (Fig. 3-5). Then it checks the batteries and indicates the remaining capacity. "A 100", for instance, means that the rechargeable batteries have a capacity of 100%, i.e., they are fully charged. "b 50" means that the alkaline batteries have a capacity of only 50%, i.e., they are half depleted.

The minimum battery capacity for a 24-hour measurement is 90%.

If the capacity is below 90%, new or fully charged batteries must be inserted.

BP monitors that have passed the self-test and completed the battery test will indicate the following information:

- the time of day
- the measuring phase (day ☀ / night ☾)
- whether or not data are stored in the BP monitor (**M**) (Fig. 3-6).

The BP monitor will also emit an audio signal, if enabled.



Fig. 3-5 Test display on LCD



Fig. 3-6 Example: display after successful self-test
(**M**= BP data in memory,
☀ measuring phase: day)

Before using TONOPORT V on a patient





1. clear the memory
2. check date and time and correct, if required
3. select a measurement protocol
4. enable or disable the audio signal.

Note

When using TONOPORT V in conjunction with CASE™ / CardioSoft, it is recommended to perform the first three steps at the PC.

Clear the Memory









The symbol **M** on the display indicates that memory contains BP data. If these data still need to be analyzed, refer to chapter 5 "Data Output" for details on data evaluation. If you do not need the data any more, delete it as follows:

- Briefly switch TONOPORT V off and on again and wait for the time to be displayed.
- Push  : the display indicates "H 1".
- Push  : the display indicates "LLLL".
- To delete the data, push  again: the display indicates "0000", followed by the time (if you do not wish to clear the memory, turn off the BP monitor instead of pushing ).






Time and Date

Usually the BP monitors are set to the correct time and date before delivery. Therefore, the time only needs to be corrected to change between Standard Time and Daylight Saving Time.

Setting Date and Time

- Briefly switch TONOPORT V off and on again and wait for the time to be displayed.
- Push  twice: the display indicates "H 2".
- Push  : the display indicates the year, e.g. "2009".
- If the indicated year is correct, confirm it with  or correct it with  and confirm with .
 - The display indicates the month, e.g. "03".
- If the indicated month is correct, confirm it with  or correct it with  and confirm with .
- In the same manner, correct day, hour and minute.
- In the end, the time of day will be displayed again.

Selecting the Pressure Unit

- Briefly switch TONOPORT V off and on again and wait for the time to be displayed.
- Push  eight times: the display indicates "H 8".
- Push  : the display indicates "mmHg" or "kPa".
- Confirm the pressure unit with  or select the other unit with , then confirm with .






Measurement Protocols

There is a choice of three different measurement protocols:






Protocol	Day Phase	Night Phase
	(7 a.m. to 10 p.m.)	(10 p.m. to 7 a.m.)
P1	every 15 minutes	every 30 minutes
P2	every 20 minutes	every 40 minutes
P3	every 30 minutes	every 60 minutes

Max. inflation pressure: day phase 250 mmHg
night phase 220 mmHg

Select a Measurement Protocol

- Briefly switch TONOPORT V off and on again and wait for the time to be displayed.
 - Push  three times: the display indicates "H 3".
 - Push  : the display indicates "LLLL" (Selecting a protocol automatically clears the memory. If you do not wish to clear the memory, turn the BP monitor off.)
 - Push  : the display indicates "P1" (protocol 1).
 - Using , select protocol 2 or 3
- OR
- Confirm the displayed protocol with .

Enable or Disable the Audio Signal

- Briefly switch TONOPORT V off and on again and wait for the time to be displayed.
- Push  seven times: the display indicates "H 7".
- Push  : the display indicates "0000" when the audio signal is turned off, and "1111" when it is turned on.
- Either confirm the setting with  or press  to select the alternate setting and confirm with .

4 Application

Symbols used on the cuff



Refer to Operator Manual.



Follow the instructions in the Operator Manual.



Cuff suitable for adult patients of the indicated height (see man in box). Adult-sized cuffs are available as standard, small, large and extra large.



BP cuff suitable for the indicated arm circumference.



BP cuff width.



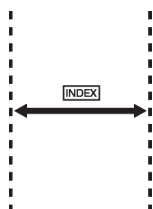
When the cuff is applied, this label must face the skin.



When the cuff is applied, these two arrows must be located over the brachial or femoral artery.



This line identifies the end of the cuff which must be situated within the range identified by the INDEX label when the cuff is closed.



The end of the cuff must be situated within this range when the cuff is closed.



Latex-free BP cuff.



CE marking, cuff fulfills EU directives.

Cleaning the Cuffs

- Use a moist cloth to wipe the cuffs clean if they are only slightly soiled.
- Clean cuffs that are heavily contaminated by washing them with soapy water or a suitable cleaning agent that contains a disinfectant (do not machine-wash). Ensure that no liquid penetrates into the cuff bladder or the pressure tubing (for this reason, remove the bladder from the cuff before cleaning).
- After cleaning, rinse the cuff thoroughly with water and let it dry at room temperature for about 15 hours.
- The cuffs can be disinfected with isopropyl alcohol 70%, ethanol 70%, Microzid, Buraton liquid, Sporicidin or Cidex. After disinfection, rinse the cuff thoroughly with tap water and air-dry.

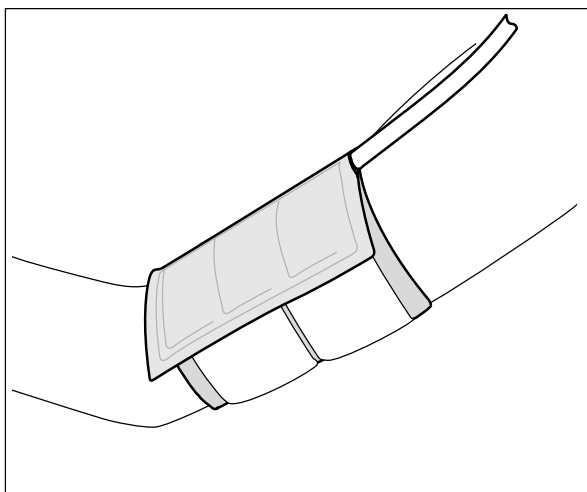


Fig. 4-1 Applying the cuff

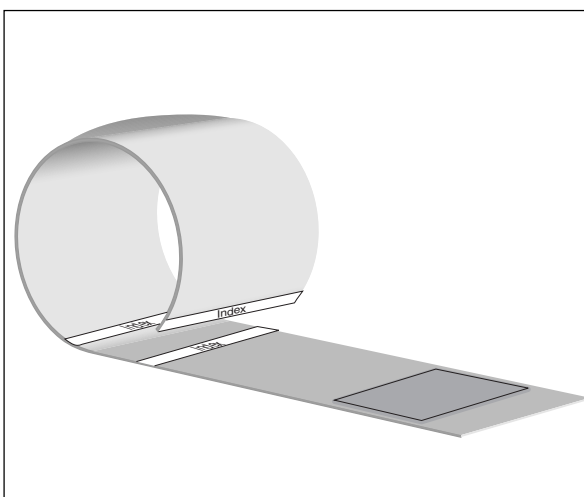


Fig. 4-2 Applying the cuff

Applying the Cuff

Warning

Risk to persons —

Disconnect TONOPORT V from other equipment (CASE™, PC) before connecting it to the patient.

- Always insert two fully charged NiMH batteries or two new alkaline batteries, before starting a measurement.
- Check that the memory has been cleared (see “Clear the Memory” on page 15).
- Select the appropriate cuff size (see cuff label). **When the cuff is too small the BP values will be overrated, when it is too big, the measured values will be too low.**




Caution

Incorrect measurements —

- **Use only the cuffs listed in chapter 10 "Order Information".**
- **Replace cuffs on a regular basis. Damaged Velcro fasteners may cause incorrect readings.**


- Place the cuff on that arm of the patient that is used less frequently during normal daily activities. On adults it should be placed about 2 fingers' breadth above the bend of the elbow; on children, a little closer. Bending the arm must not change the cuff level. Verify that
 - the cuff tubing points up toward the shoulder (Fig. 4-1)
 - the side with the **Patient** label is on the skin
 - the arrow is located above the brachial or femoral artery
 - the dashed white line at the end of the cuff is located between the two dashed **Index** lines when you close the cuff (if this is not the case, select another cuff size, Fig. 4-2)
 - the cuff fits snugly around the arm, but does not compress the blood vessels.

Initiate a Trial Measurement

- Turn on TONOPORT V and place it in the carrying pouch. There is an aperture in the pouch to accommodate the cuff connection tube.
- Attach the pouch to the patient (shoulder strap, belt). For reasons of hygiene, it is not advised to carry the pouch on the bare skin.
- Guide the pressure tubing around the patient's neck as a strain relief and connect it to the blood pressure cuff port on the TONOPORT V (1, Fig. 2-1). Advise the patient to avoid kinking the tubing during the measurement.
- Check that the display indicates the time of day. If the memory contains data from a previous procedure, the letter "M" will appear on the display when you turn on the device. If you still try to initiate a measurement, the message "LLLL" prompts you to clear the memory. Push  twice to delete the data. If you do not wish to delete the data, turn off the device instead of pushing .
- **To avoid erroneous measurements, ensure that the patient does not move during the trial measurement. The patient may stand or sit.**
- Push  to initiate the first measurement.

Within a few seconds, the device starts inflating the cuff. When the inflation pressure has been reached, the cuff will gradually be deflated. The changing cuff pressure is indicated on the display and the letter "M" appears with each detected oscillation. At the end of the measurement the measured data appears in the following order



- the systolic reading (S in mmHg or kPa)
- the diastolic reading (D in mmHg or kPa)
- the pulse rate (HR/min⁻¹).

If an error code, such as "E 29" (insufficient number of oscillations detected) is displayed after the measurement, tighten the cuff a little and push  again (see also chapter 6 "Error Codes").

If the trial measurement has been successfully completed, the device is ready for automatic measurements.

Patient Information



Advise your patient

- **not to move while a measurement is being taken to avoid motion artifacts that may lead to erroneous readings and to keep the cuff inflation time as short as possible**
- to place TONOPORT V on the night stand while in bed
- how to switch the device manually from the day to the night phase (see page 19)
- that events considered important should be noted down in a diary and that intermediate measurements can be initiated with 
- that the measurement can be stopped at any time with  (the cuff will be deflated)
- not to open the battery compartment
- about the audio signal and its meaning.

Warning

Risk to persons —

Instruct your patient

- *to terminate the measurement with , whenever the cuff is not deflated within about 2 minutes,*
- *to remove the cuff if it is not deflated after activation of the  button. This could be due to kinked tubing. The cuff must be reapplied as described earlier before additional measurements can be taken.*

General Information on Ambulatory BP Measurement

These are the buttons on TONOPORT V used during an ambulatory blood pressure measurement:



starts and stops a measurement



displays the most recent measurement results or the most recent error message, toggles between day and night phase (see next section)

For the first measurement, the cuff is inflated to a pressure of 160 mmHg (initial pressure). For subsequent measurements, the device inflates the cuff to a pressure which is 15 mmHg above the systolic value of the previous measurement (minimum inflation pressure: 120 mmHg).

If the measuring value is above the inflation pressure, the device will increase the cuff pressure another 50 mmHg.

A manual measurement can be taken at any time between the automatic measurements. Manual measurements are identified with the "+" symbol in the tabular BP data.


The device will repeat a measurement after 2 minutes, if unsuccessful. An error code referring to failed measurements is generated only after three consecutive unsuccessful measurements.

Error codes E02 (battery depleted), E06 (inflation time over) and E08 (200 measurements taken) do not lead to a second measurement. The next measurement after error code E06 takes place at the selected interval.

After error codes E02 and E08, the device enters the power-save mode to prevent over-discharging of the rechargeable batteries. This mode can only be terminated by turning the device off and on again.

Toggle Manually Between Day and Night Phase

In the three measurement protocols the day phase lasts from 7 a.m. to 10 p.m. and the night phase from 10 p.m. to 7 a.m. On the display the two phases are represented by the symbols ☀ (day) and ☾ (night).

Patients whose day and night phases are different from these predefined periods can push the  button twice to change from one phase to the other.

Note

If the measurement protocol was created with CASE™ / CardioSoft and only 1 BP period has been specified, switching from one phase to the other will leave the measurement intervals unchanged. They will always be the same. The information "day phase" and "night phase" is only used to identify the measurements.

Audio Signal

If enabled (see page 16), the audio signal will be emitted in the following situations:

- shortly after TONOPORT V was switched on
- just before TONOPORT V starts inflating the cuff (during the day phase only)
- after TONOPORT V has detected an erroneous measurement

5 Data Output

The measurement data are output via CASE™ / CardioSoft.

Warning

Risk to persons —

While connected to the patient, TONOPORT V must be disconnected from other equipment (CASE™, PC).

Note

If the USB port is used (CardioSoft only), it is necessary to install the appropriate driver first (see “Software Installation” on page 23).

CASE™ must always be connected to the serial port.

- Put the PC-based system into operation (see CASE™ or CardioSoft Operator Manual).
- Turn off TONOPORT V.
- Connect TONOPORT V to the PC system:
 - via cable 2001589-040, if the USB port of TONOPORT V is used (**a** Fig. 5-1)
 - via cable 2001589-011, if the serial port of TONOPORT V is used (**b** Fig. 5-1)
- Turn on TONOPORT V and wait for the time to be displayed on TONOPORT V.

For more information about data output, please refer to the Operator Manual of CASE™ or CardioSoft.

When you have finished downloading data to CASE™ / CardioSoft and do not intend to continue working with this system, disconnect TONOPORT V and turn it off.

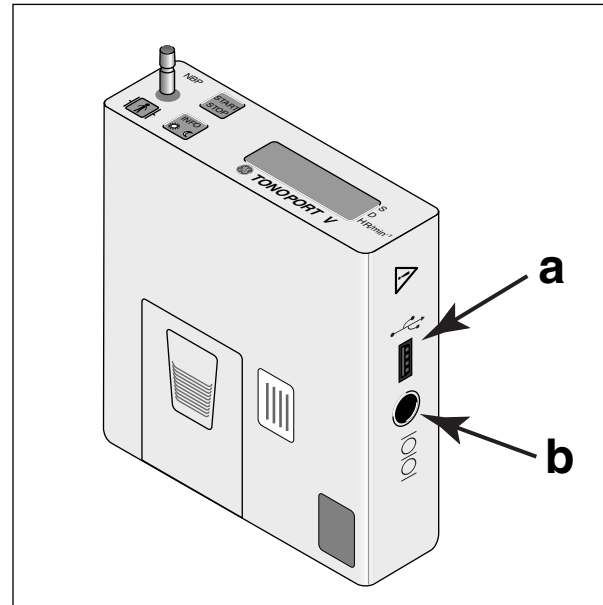


Fig. 5-1 Connections for PC cable

a USB port

b RS232 port

6 Error Codes

- E 02** Batteries depleted. Code appears when the battery capacity is insufficient for new BP measurements. The device differentiates between two states: the memory has just been cleared (i.e., the battery test is performed with a higher drain to ensure that fresh batteries will be inserted at the beginning of the measurement) or measurements have already been taken.
- E 03** Measurement time over. Code is displayed after a measurement duration of 180 seconds.
- E 06** Inflation time over. The maximum inflation time of 130 seconds has elapsed. This condition indicates a leak in the cuff or tubing, or a defective connection to the blood pressure cuff.
- E 07** This code appears
- when the device could not determine a systolic value although the cuff pressure was already increased twice
 - when the current cuff pressure would exceed the selected maximum pressure.
- E 08** 200 pressure measurements taken; storage capacity exhausted.
- E 14** Diastolic reading below 40 mmHg. Code appears when the cuff pressure has dropped to 40 mmHg and no diastolic pressure could be identified (TONOPORT V does not measure diastolic pressures below 40 mmHg).
- E 15** Motion artifact during diastole detection.
- E 17** Internal hardware error. Please contact your local, authorized dealer (<http://gehealthcare.com>).
- E 18** Systolic reading outside measuring range.
- E 19** Diastolic reading outside measuring range. (Codes **E 18** and **E 19** are displayed when the systolic and diastolic values are outside the range in which oscillations were detected.)
- E 21** Difference between systolic and diastolic pressure too small (10 mmHg or less).
- E 22** Motion artifact during systole detection.
- E 24** No systole detected in the provided time frame.
- E 26** Systolic reading below measuring range.
- E 27** Systolic reading above measuring range.
- E 29** Insufficient number of oscillations detected: For a correct measurement, the system must detect a minimum of 8 oscillations. Tighten the cuff so that one finger, but not two, can be inserted between the patient's arm and the cuff. At the same time the device switches to a deflation rate of 4 mmHg/s. When it detects more than 13 oscillations later on, the rate changes to 6 mmHg/s.

7 Software Installation

Install CardioSoft and the USB driver on your PC only if you are familiar with the Windows operating system.

CardioSoft from version 6.73 SP2 and the USB driver run only under these operating systems: Windows 8.1 Pro and Enterprise 64-bit as well as Windows 7 Professional 32-bit, 64-bit.

CardioSoft version 6.7 (except 6.73 SP2) and the USB driver run only under these operating systems: Windows 7 Professional 32-bit, 64-bit, and Windows XP Professional 32-bit with Service Pack 3.

CardioSoft version 6.6 and the USB driver run only under these operating systems: Windows XP Professional, Windows Vista Home Premium 32-bit, and Windows Vista Business 32-bit.

CardioSoft pre version 6.6 and the USB driver run under these operating systems: Windows 2000, Windows XP Professional, Windows Vista Home Premium 32-bit, and Windows Vista Business 32-bit.

CardioSoft (Standalone Workstation)

You will need administrator privileges for installation of the USB driver.

1. Turn on the PC and the monitor. Exit ALL programs.
2. Insert the CardioSoft CD in the CD ROM drive. If the CD drive does not automatically start up, start "setup.exe" (on the CardioSoft CD, "Disk1" or "CASE-CS" folder) via the Windows Explorer.
3. Follow the displayed prompts.
4. Confirm the two proposed directories with *Next*.
5. Enter the serial number (see CD-ROM).
CardioSoft will now be installed on your computer.
6. Restart Windows.

USB Driver

You will need administrator privileges for installation of the USB driver.

1. Turn on the PC and the monitor. Exit ALL programs.
2. Insert the CD with the USB drivers in the CD ROM drive. If the CD drive does not automatically start up, start "setup.exe" (on the USB driver CD, "Disk1" folder) via the Windows Explorer.
3. Follow the displayed prompts. Select *Allow* if the system informs you that you are using an unidentified program.
4. Click *Finish* to complete the first part of the USB driver installation procedure.
5. Turn on TONOPORT V and connect it to the PC, using the USB connection cable.
Windows will automatically detect TONOPORT V (TUSB3410).
6. Follow any additional prompts that may be displayed.
7. When Windows indicates that the drivers were successfully installed and the new hardware can be used, remove the USB driver CD from the CD-ROM drive.

Note

If you will be using the serial port of TONOPORT V (Fig. 5-1, b) installation is now complete.

To be able to use the USB port of TONOPORT V (Fig. 5-1, a), you will have to install the USB driver and check the communication as described below.

USB Port Verification

For verification of the USB port, turn on TONOPORT V and connect its USB port to the PC.

1. Start the Device Manager of the operating system.
2. Double-click *Ports (COM and LPT)* to view all ports.

If CardioSoft version 6.72 or higher is used or if a USB serial port (TUSB3410 Device) between COM1 and COM4 has been selected, it is not necessary to choose another port. Note down the selection, because the same port must be set in CardioSoft, and close all windows to return to the Windows desktop.

If a USB serial port greater than COM4 has been selected one of the ports COM1 through COM4 must be disabled at the PC so that it can be assigned to the USB port.

3. Select one of the ports COM1 through COM4 that is not needed for other devices and disable it (right-click > *Disable*). Confirm the message that the device will not be functional any longer.
4. Right-click *USB - Serial Port (COM X)* and click *Properties*.
5. Click *Port Settings > Advanced* and at *COM Port Number* select the port that you disabled earlier. Select *Yes*, if a message appears that this COM port is already used by another device. The selected port must also be set in CardioSoft.
6. Select *OK* where needed and/or close all windows to save the settings.
7. Disconnect the USB cable and restart Windows.

8 Cleaning, Maintenance, Disposal

8.1 Cleaning, Disinfection

Equipment Surface

Warning

Shock hazard —
Disconnect TONOPORT V from the PC before cleaning.

- Turn off TONOPORT V.
- Wipe the device down with a soft, lint-free cloth, using a mild cleaning solution or dish liquid in a low concentration. Many cleaning agents and disinfectants commonly used in hospitals are suitable. Do not let liquid enter the device.

Caution

Equipment damage —
Do not disinfect the device surface with phenol-based disinfectants or peroxide compounds.

Warning

Shock hazard, equipment damage —
Equipment into which liquids have entered must be inspected by a service technician before use.

Cuffs

For cuff cleaning information, see “Cleaning the Cuffs” on page 17.

Cables

- Disconnect cables from the device before cleaning.
- Use a cloth moistened with soapy water to wipe the cables clean. Do not immerse cables in liquid.

8.2 Maintenance

Checks before each use

- Before each use visually check the device and the cables for signs of mechanical damage.

If you detect damages or impaired functions which may result in a hazard to the patient or the operator, the device must be repaired before it can be used again.

Technical Safety Inspections

For safety, the devices require regular maintenance. To ensure functional and operational safety of TONOPORT V, Technical Safety Inspections should be carried out on an annual basis.

These checks should be performed by persons with adequate training and experience.

The checks can be carried out by GE Healthcare within the framework of a service agreement. Please contact your local, authorized dealer for details.

The nature and scope of these checks are explained in the corresponding sections of the Service Manual.

On request GE Healthcare will provide a detailed Service Manual.

The device does not require any other maintenance.

Technical Inspections of the Measuring System

The non-invasive pressure measurement system of TONOPORT V should be inspected every two years.

These checks should be performed by persons with adequate training and experience.

The checks can be carried out by GE Healthcare within the framework of a service agreement. Please contact your local, authorized dealer for details.

The nature and scope of these checks are explained in the corresponding sections of the service manual.

On request GE Healthcare will provide a detailed Service Manual.





Disposal of the Product






The product described in this operator manual must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Calibration Mode

(e.g. to check the pneumatic system for leaks)

- Connect a rubber bulb between pressure tubing and cuff, using a T-adapter.
- Roll up cuff tight.
- Switch off device and switch it on again after a few seconds.
- Wait for time to be displayed.
- Push  four times: the display indicates "H 4".
- Push  : the display indicates an internal value that must be between 25 and 100. If the displayed value is outside this range, TONOPORT V must be returned for repair.
- Push  again: the display indicates "0" (the display now indicates the pressure in mmHg).
- Generate a test pressure of 200 mmHg and measure the pressure decrease after waiting at least 30 seconds. (Pressure decreases between 3 and 5 mmHg are typical; a pressure decrease > 6 mmHg indicates a leak and the system needs to be repaired.)
- Push  to exit the calibration mode.

View Firmware Version

- Turn on the device and wait for the time to be displayed.
- Push  five times: the display indicates "H 5".
- Push  : the firmware version is indicated, e.g.
 - "21:00" = firmware version 2.1
- Push  to end the display.

9 Technical Specifications

Measuring Range

- systolic pressure: 60 to 260 mmHg
(8.0 to 34.6 kPa)
- diastolic pressure: 40 to 220 mmHg
(5.3 to 29.3 kPa)
- mean pressure: 50 to 250 mmHg
(6.7 to 33.3 kPa)
- pulse rate (HR): 35 to 240 min⁻¹

Measurement Accuracy (determined in a clinical study)

- systematic measurement deviation
-0.7 mmHg (systolic)
-0.8 mmHg (diastolic)
- empirical standard deviation
4.6 mmHg (systolic)
4.4 mmHg (diastolic)

Acquisition Period

- up to 30 hours or 200 measurements

Interfaces

- USB (1.1 or 2.0)
- RS232

Battery

- 2 AA size rechargeable NiMH batteries, 1.2 V,
≥1500 mAh or
- 2 AA size alkaline batteries

Battery Charge Time

- 2 to 3 hours

Maximum Cuff Pressure

- 300 mmHg

Measuring Method

- oscillometric

Battery Charger

- protection class II, IP20
- 100 to 240 VAC 50/60 Hz, 0.5 A

Environment

Operation

- temperature between +10 and +40 °C
- relative humidity between 15 and 85 %, no condensation
- atmospheric pressure between 700 hPa and 1060 hPa
- altitude (relative to sea level) -400 to 2800 meters

Transport and Storage

- temperature between -20 and + 70 °C
- relative humidity between 10 and 90 %, no condensation
- atmospheric pressure between 500 hPa and 1060 hPa
- altitude (relative to sea level) -400 to 4500 meters

Dimensions and Weight

- height 27 mm
- width 80 mm
- depth 100 mm
- weight 199 g, incl. batteries

Protection Class

- IP 20

10 Order Information

TONOPORT V Ambulatory Blood Pressure System

- TONOPORT V recording unit
- Connection cable TONOPORT V to PC (USB)
- Connection cable TONOPORT V to PC (RS232)
- Battery charging unit
- Rechargeable NiMH batteries (4, size AA)
- Carrying pouch
- Belt for carrying pouch
- Blood pressure cuff for adults, standard, width 13 cm, for circumference between 24 and 32 cm, Rectus connector
- TONOPORT V Operator Manual
- CardioSoft CD
- USB driver CD

Accessories

- | | |
|-------------|--|
| 2001589-041 | Battery charging unit |
| 2001589-014 | Rechargeable NiMH battery (device requires 2) |
| 737 000 08 | Alkaline battery, 1.5 V (device requires 2) |
| 2001589-015 | Carrying pouch |
| 2001589-016 | Belt for carrying pouch |
| 2001589-040 | Connection cable TONOPORT V to PC (USB), length approx. 1.5 meters |
| 2001589-011 | Connection cable TONOPORT V to PC (RS232), length approx. 1.2 meters |
| 2001589-212 | Blood pressure cuff for adults, standard, width 13 cm, for circumference between 24 and 32 cm, Rectus connector |
| 2001589-211 | Blood pressure cuff for adults, small, width 9 cm, for circumference between 17 and 26 cm, Rectus connector |
| 2001589-213 | Blood pressure cuff for adults, large, width 15 cm, for circumference between 32 and 42 cm, Rectus connector |
| 2001589-214 | Blood pressure cuff for adults, extra large, width 15 cm, for circumference between 38 and 46 cm, Rectus connector |
| 2001589-093 | USB driver CD |

11 Appendix - Electromagnetic Compatibility (EMC)

Changes or modification to this system not expressly approved by GE Healthcare could cause EMC issues with this or other equipment. This system is designed and tested to comply with applicable regulation regarding EMC. It needs to be installed and put into service according to the EMC information stated as follows.

Warning


Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

Warning

The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
TONOPORT V is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that TONOPORT V is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions to EN 55011/ CISPR 11	Group 1	TONOPORT V uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. TONOPORT V is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions to EN 55011/ CISPR 11	Class B	
Harmonic emissions to EN 61000-3-2/IEC 61000-3-2	not applicable	
Voltage fluctuations/flicker emissions to EN 61000-3-3/IEC 61000-3-3	not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
TONOPORT V is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that TONOPORT V is used in such an environment.			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) to EN 61000-4-2/IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst to EN 61000-4-4/IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	not applicable not applicable	Mains power should be that of a typical commercial or hospital environment.
Surge to EN 61000-4-5/IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	not applicable not applicable	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines to EN 61000-4-11/IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	not applicable not applicable not applicable not applicable	Mains power should be that of a typical commercial or hospital environment. If the user of TONOPORT V requires continued operation during power mains interruptions, it is recommended that TONOPORT V be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field to EN 61000-4-8/IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
TONOPORT V is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that TONOPORT V is used in such an environment.			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
<p>Conducted RF to EN 61000-4-6/IEC 61000-4-6</p> <p>Radiated RF to EN 61000-4-3/IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of TONOPORT V, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.33 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol</p> 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

- a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which TONOPORT V is used exceeds the applicable RF compliance level above, TONOPORT V should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.
- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communication equipment and TONOPORT V

TONOPORT V is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of TONOPORT V system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and TONOPORT V as recommended below, according to the maximum output power of the communications equipment

Rated Maximum Output Power of Transmitter [W]	Separation Distance According to Frequency of Transmitter [m]		
	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all instances. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Compliant Cables and Accessories

Warning

The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

The list below shows the accessories that have been tested and found EMC compliant for use with TONOPORT V.

Note

Any supplied accessories that would not affect electromagnetic compatibility (EMC) are not included.

2001589-011 Connection cable TONOPORT V to PC (RS232), length of 1.2 meters

2001589-040 Connection cable TONOPORT V to PC (USB), length of 1.5 meters

Für Ihre Notizen

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CE-0482



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