Finometer® Model-2

User's Guide

Finometer® Midi User's Guide

This document is for information purposes only

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Suggested reading order

The suggested reading order for this User's Guide is:

- first turn to the next pages with warnings and cautions.
- next, try out the quick start at section 1.3 [Quickstart] which describes every step to perform a finger blood pressure measurement for the first time. Soon thereafter, wrapping a finger cuff will become routine, and starting a measurement is a one button operation.

If you find anything missing in this User's Guide please contact Us at Finapres Medical Systems B.V., see page 9 [Customer support], as we may be able to provide the missing information.

Picture of Finometer® Model-2

The Finometer® Model-2 components

Each Finometer® Model-2 device (commercially known as Finometer® Midi) consists of the units listed below:

- **Main unit:** A box holding the principal electronic and pneumatic components, the embedded computer, the front panel control buttons, and the display. A three-pronged grounded power cord is included.
- **Frontend Unit:** A box to be worn on the back of the hand or the wrist and containing connectors for the finger cuff and the Height Correction Unit.
- **Finger cuff:** One M-cuff (beige, medium) and one S-cuff (white, small) is part of the standard package. Finger cuffs are also available in one other sizes: blue, L-size, large.
- **Height Correction Unit (HCU):** A device to automatically correct for hydrostatic height changes when the measured hand moves away from heart level. It allows free hand movement during measurements with the device.
- **Serial interface cable (RS232):** A cable to connect the main unit to a PC or laptop with a RS232 (COM) port for on-line recording and remote control of the device, using the Beatscope® Easy software.
- **USB/RS232 converter:** A Converter to connect between the Serial interface cable and a PC or laptop with a USB port.
- **Finometer® Model-2 User's Guide:** The document you are presently reading.
- **Finger Pressure Reference Guide:** A document containing background information on finger arterial pressure measurement. The guides are available on CD-ROM as PDF files in printable format and in interactive screen display format. Use Acrobat Reader version 6 or later for viewing. Further copies are available from Finapres Medical Systems B.V.

- **BeatScope® Easy software:** A Microsoft Windows based software program running on a PC offering a remote monitor screen, recording functions and remote control of the most important Finometer® Model-2 device functions. The BeatScope® Easy software program presents and records waveforms and beat-to-beat derived data, measured with Finometer® Model-2. The program CDROM is part of the standard package.

Optional accessories:

- **Finger cuff:** Sizes: S, M, L.
- **Analog I/O unit:** Five BNC connectors for four-channels analog signal output and one-channel analog signal input.
- **ECG-module:** A three lead ECG module providing an analog ECG signal which is sampled and stored simultaneously with the blood pressure waveform.
- **BeatScope®:** The optional BeatScope® software allows online monitoring, control, storage and offline review of the complete data including cardiac parameters.

Packaging:

The Finometer® Model-2 configuration is packed in a specially developed carton box with spacers to avoid damage during transport. If the package arrives with external damage please notify Finapres Medical Systems B.V.

Upon unpacking a quick inspection of proper functioning of the Finometer® Model-2 device is obtained by following the instructions in section 1.3 [Quickstart]. Please contact Finapres Medical Systems B.V. immediately in case of malfunction.

Cautions in using Finometer® Model-2

- Direct finger arterial pressure is not within the ANSI/AAMI SP10 standard. Inverse filtering and level correction improve bias and precision and are automatically applied in the default configuration, but systolic precision is still below that required for blood pressure diagnostics.
- Finometer® Model-2 should not be used without interruption for periods longer than four (4) hours on a single finger in awake subjects.
- The only mode of measuring blood pressure levels in compliance with the recommendations of the ANSI/AAMI SP10 standard is when the device is used with the return-to-flow method of calibration, as available in Finometer® Model-1 only.

When to use Finometer® Model-2

The Finometer® Model-2 is a non-invasive instrument to measure blood pressure in the finger of a human subject. Since it is non-invasive, application is associated with little risk.

The Finometer® Model-2 is intended to be used when there is a need for a non-invasive hemodynamic monitor. The Finometer® Model-2 provides a non-invasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow as well as in various hemodynamic parameters derived from these pressure and flow signals. The device does not report any diagnosis but provides numerical values. It is the physician's responsibility to make proper judgments based on these numbers.

The non-invasively blood pressure waveform is measured by using the Finapres method of Peñáz/Wesseling. Cardiovascular parameters include cardiac output and total peripheral resistance based on the Modelflow method of Wesseling.

The Finometer® Model-2 is intended to be installed and operated by a qualified physician or operator. Pressure measurements are validated for subjects above 18 years of age.

The device, equivalent to the Finapres device, is not equipped with the return-to-flow method of calibration and does not allow for the

measurement of accurate absolute blood pressure data, but provides optimal trending of blood pressure data.

Modelflow built-in calibration is useful from 18 years on. Cardiac output measured with this device under the Modelflow model requires a calibration with thermal dilution.

The physiological parameters provided by the device have clinical significance only if determined by a physician and should not be used as the sole means for a subject's diagnosis.

The data provided by the device can be further processed by the included PC-based BeatScope® software.

When not to use Finometer® Model-2

When 100% availability of arterial pressure is required in critically ill subjects since treatment depends on it, and other means are available, Finometer® Model-2 is not the preferred choice. Still, in two studies we found that the overall percentage availability of Finapres in the operating room during coronary artery bypass grafting (Wesseling3) and of Portapres in 24 hour ambulatory recordings (Imholz2) was equal to that of the intra-arterial lines. The finger is a distal measuring site and smooth muscle in the arteries and arterioles of the circulation of hand and finger can come to full contraction. An extreme example of this is Raynaud's phenomenon. Measures have been built into Finometer® Model-2 to alert the user to such conditions developing. When full contraction does occur finger pressure measurement is no longer possible, and cannot be restored quickly.

Avoiding injury to subjects and personnel

- (USA) Federal law restricts this device to sale by or on the order of a physician. This device is intended for use by trained health care professionals.
- The physiological parameters provided by this device have clinical significance only if determined by a physician and should not be used as the sole means for determining a subjects diagnosis.

- Explosion hazard exists when operated in the presence of flammable gases and liquids.
- Protection against the ingress of liquids is limited. Do not apply electrical power to the device when liquids did enter, as this may cause internal short circuits and unpredictable external electrical currents.
- Always use a grounded 3-wire electrical cable and connector to plug into the power line.
- Selecting a proper sized cuff and the correct placement of a cuff on a finger are critical for success.
- Do not wrap finger cuffs around a toe or the wrist of an infant.
- Accuracy of measurement on a toe has not been established. An inflated finger cuff applied to the wrist causes congestion of blood in the distal circulation of the hand, which may become painful and restricts distal oxygenation.
- The zero adjustment of all pressure transducers built-in is automatic, except for the pressure transducer of the Height Correction Unit for which nulling has to be performed manually (see section 5.1). It is the responsibility of the operator to periodically check the zeros and sensitivities of the transducers. Finometer® Model-2 devices leave our premises with carefully calibrated transducers. Immediately after transport, and at any time that the instrument is dropped or otherwise damaged, the zeros and calibrations should be rechecked. These checks are quick and easy to perform (see section 8.4).
- For safe and reliable operation and optimal accuracy only use Finapres Medical Systems B.V. cuffs and only use software approved by Finapres Medical Systems B.V.
- Externally generated analog signals coming from other devices, such as respiratory signal and ECG can be connected to the Finometer® Model-2 for recording. Furthermore, personal computing equipment can be interfaced to the digital I/O port of the Finometer® Model-2 for obtaining signals and data, and for remote control. Connected equipment has to meet the IEC specifications (IEC 601 for electro medical devices or IEC 950 for data processing devices). The configuration has to meet the IEC system standard (IEC 601-1-1). He who connects such additional devices is responsible for adherence to the IEC 601-1-1 standard.
- Complete specifications of Finometer® Model-2 are listed in Chapter 9, Specifications.

Customer support

The Finometer® Model-2 device is manufactured by Finapres Medical Systems B.V.

The Finometer® Model-2 device and its accessories are constructed of high quality materials and great care has been taken in its manufacture. We stand behind our product and will do whatever is in our power to have you as a satisfied customer and Finometer® Model-2 user.

If the product fails to function properly, or when assistance, or service, or recalibration is needed, please contact our After Sales department:

Finapres Medical Systems B.V.
Paasheuvelweg 34a
NL-1105 BJ AMSTERDAM ZO
The Netherlands

Phone : + 31 20 609 0974
Fax : + 31 20 609 0677
E-mail : support@finapres.com

If accessories for the Finometer® Model-2 device are needed, such as extra cuffs, please contact our Sales department.

Phone : + 31 20 697 2228
Fax : + 31 20 609 0677
E-mail : sales@finapres.com

The Finometer® Model-2 device contains no field serviceable parts.

Servicing of any component of this device, therefore, is to be performed by Finapres Medical Systems B.V. only. Unauthorized repairs or modifications may violate the conformity of the Finometer® Model-2 device with the requirements in the Medical Device Directive 93/42/EEC set forth by Finapres Medical Systems B.V.

Warranty

The Finometer® Model-2 device and its accessories are constructed of high quality materials and great care has been taken in its manufacture.

The Finometer® Model-2 device is guaranteed by Finapres Medical Systems B.V. for a period of one year after the date of shipment. During this period of guarantee Finapres Medical Systems B.V. will, without charge for labor or parts, repair or replace the defective parts.

The guarantee does not include the following:

1. Finger cuffs. Finger cuffs, however, are reusable items which can often be used for several years, provided that the cuffs are handled with care.
2. Transport costs and insurance of the shipment of the device to Finapres Medical Systems B.V.
3. Defects caused by repairs by unauthorized personnel, or the use of accessories not obtained from, or approved by Finapres Medical Systems B.V.
4. Periodic check-ups, upon request of the user.
5. Damage through misapplication, misuse, or failure to follow the instruction in this User's Guide or in other accompanying documents.
6. Accidents that affected Finometer® Model-2 or its accessories.

Every Finometer® Model-2 unit has an identification label with a specific identification string. The string contains the serial number of the Finometer® Model-2 system, e.g. 060605020.

Disclaimer

DISCLAIMER OF WARRANTIES AND LIMITATIONS

FINAPRES MEDICAL SYSTEMS B.V. MAKES NO WARRANTY OR REPRESENTATION, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE FINOMETER® MODEL-2 DEVICE, ITS QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE. THE EQUIPMENT IS PROVIDED AS IS, NO ORAL OR WRITTEN INFORMATION OR ADVICE GIVEN BY EITHER PARTY OR ITS EMPLOYEES SHALL CREATE A WARRANTY OR MAKE ANY MODIFICATION, EXTENSION OR ADDITION TO THE WARRANTY

FINAPRES MEDICAL SYSTEMS B.V. SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS AND DAMAGES FOR PERSONAL INJURY OR PROPERTY DAMAGE, ARISING FROM OR IN CONNECTION WITH THE LICENSED RIGHTS OR ITS USE WHATSOEVER.

IN NO CASE SHALL FINAPRES MEDICAL SYSTEMS B.V.'S LIABILITY EXCEED THE PURCHASE PRICE FOR THE DEVICE.

Information in this document is subject to change without notice and does not represent a commitment on the part of Finapres Medical Systems B.V.

The BeatScope® Easy software is furnished under a license agreement. The software may be used only in accordance with that agreement.

Table of Contents

1 Introduction

This introduction represents a general description of Finometer® Model-2 in terms of methods used, with literature references, features, available derived parameters from the blood pressure waveform and bias and precision of the principal blood pressure parameters.

1.1 What is Finometer® Model-2?

Finometer® Model-2 is an instrument to monitor finger arterial pressure continuously. Finometer® Model-2 is the successor of the well-known Finapres (TNO and Ohmeda models) and provides the measurement of blood pressure in a finger based on the arterial volume-clamp method of the Czech physiologist Peñáz, and the Physiocal - physiological calibration - criteria for the proper unloading of the finger arteries of Wesseling. Hydrostatic pressure changes due to relatively slow movement of the hand are compensated by a so-called Height Correction Unit.

Finometer® Model-2 is a novel stationary device for measuring continuous non-invasive blood pressure and fits in between Portapres (ambulatory Finapres) and Finometer® Model-1 (refined version of Finapres with AAMI SP10 accuracy and precision.)

Finometer® Model-2 provides the analog blood pressure waveform in the same way as Finapres and can be connected to a remote PC to store the full finger pressure waveform and beat-to-beat derived parameters on the PC by using the BeatScope® Easy software.

1.2 Related publications

This User's Guide is written for the operator of the Finometer® Model-2 device. It contains installation and operating instructions, and routine maintenance procedures. Other documents relevant for a Finometer® Model-2 user are:

- **Finger Pressure Reference Guide**
  The reference guide contains background information about the device, the measurement principles, hints and pitfalls in a finger blood pressure measurement and a bibliography of finger arterial pressure measurements.

- **BeatScope® Easy User's Guide**
  Guide to the PC based BeatScope® Easy recording software package.

Figure 1.1 The Frontend Unit and ECG cable connectors

1.3 Quickstart

This chapter describes step by step how to make a first measurement with Finometer® Model-2 and how to sample an external signal during a finger pressure measurement.

Before you start a first measurement please read the "Warnings, cautions and protective measures" in chapter 2. Then do the following:

- Connect the power cable at the rear of the Finometer.
- Plug the power cable into a grounded AC power outlet.
- Switch Finometer on, the switch is at the rear. The Starting message will appear on the LCD display.
- Observe the error message that may show up on the LCD display on Finometer® Model-2 when the Frontend Unit is not yet connected.
- Take the Finometer Frontend Unit and cable (see Figure 1.2) and insert the Frontend Unit connector straight into the receptacle at the Finometer® Model-2 front left, (see Figure 1.1 The Frontend Unit and ECG cable connectors). The red dot should point upwards. The connector must go in straight and smoothly and must be seated firmly and with a click. By pulling smoothly at the cable try to pull the connector out. This should fail.
- Install BeatScope® Easy onto your laptop or PC.
- Connect the PC to Finometer® Model-2 via the serial I/O port, using the RS232 cable.
- Run the BeatScope® Easy software.

Your system is set up. It is time to turn to your subject.

Figure 1.2 The Frontend Unit and cable with medium size finger cuff attached

1.4 A first Finometer® Model-2 measurement

Next, attach to your subject the following sensor systems: the finger cuff and the Height Correction Unit:

- Strap the Frontend Unit to a subject's hand or wrist. The Frontend Unit cable should run away from the fingers and along the arm towards the shoulders.
- Select a properly sized finger cuff (see Figure 6.1).
- Wrap the cuff as shown in Figure 6-2 Applying the finger cuff. Note that finger cuffs have a conical form. Gently try to remove the finger cuff by pulling. This should fail.
-
    - Connect the Height Correction Unit, (see Figure 3.5).
    - Insert its electrical connector at the rear end of the Frontend Unit in the telephone chassis part.
    - Null the Height Correction Unit, Follow the instructions of paragraph 5.1 Height Correction Unit nulling procedure.
    - Position and attach both Height Correction Unit sensors as described in paragraph 3.4. Attach the Height Correction Unit at the finger cuff and the pillbox at heart level.
- Press START once to start a measurement. Observe the blood pressure waveform and trending on the PC screen.
- Continue the measurement for some minutes and move the hand gently in height. If the Height Correction Unit was connected and properly nulled you should observe no substantial effect. If not connected a substantial level shift should be seen in the curve displayed.
- Press STOP once to stop the measurement. You have just successfully completed your first measurement with Finometer® Model-2.

When the measurements are completed, switch off the power using the power on/off switch on the back panel of the Finometer® Model-2.

2 Safety information

2.1 Warnings, subject safety

- The data produced by Finometer® Model-2 or the accompanying software is intended as an adjunct in subject assessment and should not be used as a sole means for determining a subject's diagnosis.
- Finometer® Model-2 is a finger blood pressure monitor. Never use the finger cuffs on other parts of the body.
- Finometer® Model-2 can only be used in persons aged over 18 years.
- To maintain designed operator and subject safety only use accessories such as finger cuffs provided by Finapres Medical Systems B.V.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Finometer® Model-2 is class B equipment according to EN 60601-1. Use the Finometer® Model-2 only with a properly grounded AC receptacle.
- To maintain designed operator and subject safety, peripheral equipment that is connected to Finometer® Model-2 or one of its components, shall comply with the relevant standards.

2.2 Cautions

- MRI compatibility: To prevent damage to the device, do not use Finometer® Model-2 during Magnetic Resonance Imaging (MRI) scanning. The cuff pressure control valve inside the frontend unit is electromagnetically driven and cannot operate within the strong magnetic field.
- To prevent possible damage to the keys do not use sharp or hard objects to press the keys, only use fingertips.
- Never clean the device or one of its components by submersing it into a liquid. Follow the cleaning instructions in this User's Guide.

- No serviceable parts are inside the device. Any modification to any component of this device is to be performed by Finapres Medical Systems B.V. only. **Unauthorized repairs will void the warranty and possibly the CE-mark and other requirements.**
- Don't apply air pressure to the finger cuff unless it is wrapped around a finger or any other solid object.
- Don't try to repair defective finger cuffs. This will substantially affect measurement accuracy.
- Don't bend finger cuffs outwards to a flat shape. This will damage the finger cuff.
- Read and have a thorough understanding of the Finometer® Model-2 documentation.

2.3 Precautions

- To obtain accurate finger blood pressure determinations, movement of the hand and fingers should be minimized. Keep the hand at heart level when the Height Correction Unit is not available.
- Finger blood pressure accuracy depends on the application and proper size of the finger cuffs. Always verify that you are using the proper cuff size (see Figure 6.1).
- To avoid hydrostatic effect on the finger blood pressure determination, make sure that the Height Correction Unit is active and properly nulled (see Figure 5.1 Checking the Height Correction Unit nulling) and check that the reference ending of the Height Correction Unit is at heart level and that the transducer ending is at finger cuff level.

2.4 Symbols and icons

Symbol	Description
SN	Serial number
	Read Instructions For Use (IFU)
	Type B Equipment
	Type CF equipment, defibrillator proof
	Class II equipment
CE0344	Indicates compliance with the Medical Device Directive 93/42/EEC
	Year of Manufacture
	Inside use
	Manufacturer
	Equipotentiality
	Waste electrical and electronic equipment (WEEE)

2.5 Protective measures

Cuff pressures on the finger up to 300 mmHg are practically painless and do no harm unless applied for long periods. Finometer® Model-2 electrical circuits do not touch the skin and are not in contact with body fluids. The following measures are taken for the safety and comfort of the subject monitored and the convenience of the operator.

Electrical

- Low cuff LED current (<30 mA), voltage (<1.8 V) and power dissipation (<50 mW) prevent undue heating or skin irritation, or electrical hazard.
- An electrical short circuit in the cuff or the instrument cuts off cuff pressure within 1 second.
- An interrupted Frontend Unit cable or cuff cable cuts off pressure within 1 second.
- All analog signal outputs are fully short circuit proof.
- A self test of vital instrumental functions and parameters is performed every second.

Cuff pressure

- Air pressure to the Frontend Unit is regulated to 380 mmHg (500 hPa).
- Pressure is limited to 380 mmHg.
- A watchdog timer cuts off cuff pressure in case of internal computer malfunction.
- A cuff pressure greater than 250 mmHg sustained for 2.5 seconds cuts off cuff pressure.
- During the start procedure cuff pressure is limited to a maximum of 295 mmHg lasting less than 2 seconds.

General

- If cuff pressure oscillates when measuring finger pressure, although this presents no hazard or discomfort to the subject, software takes action to remove the oscillation.
- When fully contracted finger arteries are detected during the start procedure, allowing no pressure monitoring, Finometer® Model-2 issues a warning display.
- Increases in the contraction state of the finger arteries to such a degree that a correct measurement is dubious are flagged by showing question marks (?) in the display. Before this situation actually occurs the operator is alerted of full contraction being near, by exclamation marks (!) in the display, and warnings in the data files generated by the accompanying BeatScope® Easy software.

3 System description

3.1 Checklist of Finometer® Model-2 configuration units

A standard Finometer® Model-2 device consists of a number of separate units listed below. The device is contained in a carton box with separate accessory boxes. This section shortly describes the standard and optional items of the Finometer® Model-2 system. For a system overview, see Figure 3.1 Finometer® Model-2 system overview.

Figure 3.1 Finometer® Model-2 system overview

Standard Finometer® Model-2 device:

- **Main unit:**
  The central units of Finometer® Model-2 are contained in the main unit housing. The main unit comprises a computer board and electronics for the servo-controlled finger cuff pressure. The air circuitry comprising a compressor and pressure control devices is also part of the main unit.
- **Frontend Unit:**
  A small box to be worn on the wrist accompanying finger cuff connectors.
- **AC power cord:**
  Country dependent type (see table on page 87).
- **Finger cuff:**
  One M-cuff (beige, medium) and one S-cuff (white, small) is part of the standard package. Finger cuffs are also available in one other sizes: blue, L-size, large.
- **Height Correction Unit:**
  A device to automatically correct for hydrostatic height changes when the measured hand moves away from heart level. It allows free hand movement during measurements with the device.
- **Serial interface cable (RS232):**
  To connect the main unit to a PC or laptop with a RS232 (COM) port for on-line recording and remote control of the device, using the Beatscope® Easy software.
- **USB/RS232 converter:**
  A converter to connect between the Serial interface cable and a PC or laptop with a USB port, which have no RS232 (COM) port available.
- **BeatScope® Easy software (CDrom):**
  A program to monitor and record Finometer® Model-2 measurements on a PC and to view pressure waveform files.

Optional Finometer® Model-2 accessories:

- **Analog I/O unit:**
  A separate box with five BNC connectors providing four analog outputs and one analog input.
- **ECG-module:**
  A standard 3-lead ECG providing an analog ECG signal as input to Finometer® Model-2.

Standard documentation:

- **Finometer® Model-2 User's Guide:**
  The operator's guide of Finometer® Model-2.
- **BeatScope® Easy User's Guide:**
  The BeatScope® Easy software operator's guide.
- **Finger Pressure Reference Guide:**
  Background information about the measurement of finger arterial pressure.

Optional documentation:

- **ECG operations manual:**
  The operator's guide of the accessory ECG-module.

3.2 Main Unit

The central units of Finometer® Model-2 are contained in the main unit housing (see Figure 3.2). The main unit comprises a computer board and electronics for the servo-controlled finger cuff pressure. The air circuitry comprising of a compressor and pressure control devices is also part of the main unit.

Figure 3.2 The Finometer® Model-2 Main Unit

3.3 Frontend Unit

The Frontend Unit (Figure 3.3 Finometer® Model-2 Frontend Unit) contains an air pressure control valve, a pressure transducer, electronics for the infrared plethysmograph in the finger cuff, and electronics for the Height Correction Unit.
The Frontend Unit is connected to the Main Unit with the Frontend Unit connector. The cable and air tubing run in parallel in the sheet of the Frontend Unit cable assembly. The air connection of the Frontend Unit to the controlled pressure source in the Main Unit is integrated in the Frontend Unit connector. The Height Correction Unit is connected to the back of the Frontend Unit. The finger cuffs are connected to a cuff connector and an air outlet positioned on the frontal side of the Frontend Unit.

Figure 3.3 Finometer® Model-2 Frontend Unit

3.4 The Height Correction Unit (HCU)

The Height Correction Unit (see Figure 3.5) consists of a liquid filled tube connected at one end to a pressure transducer, called the HCU transducer. This transducer has to be positioned at finger cuff level. The tube ending comprises a circular container which has a small very compliant plastic bag inside. This reference point has to be positioned at heart level (see Figure 3.4). The Height Correction Unit connector connects the unit to the Frontend Unit.

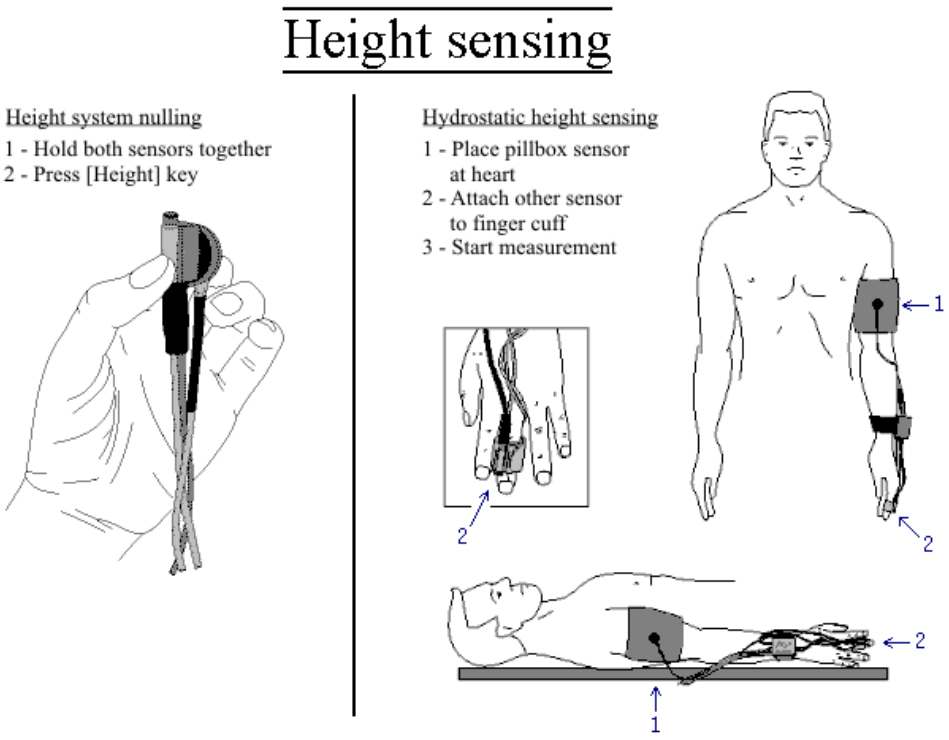


Figure 3.4 Height Correction Unit nulling and placement

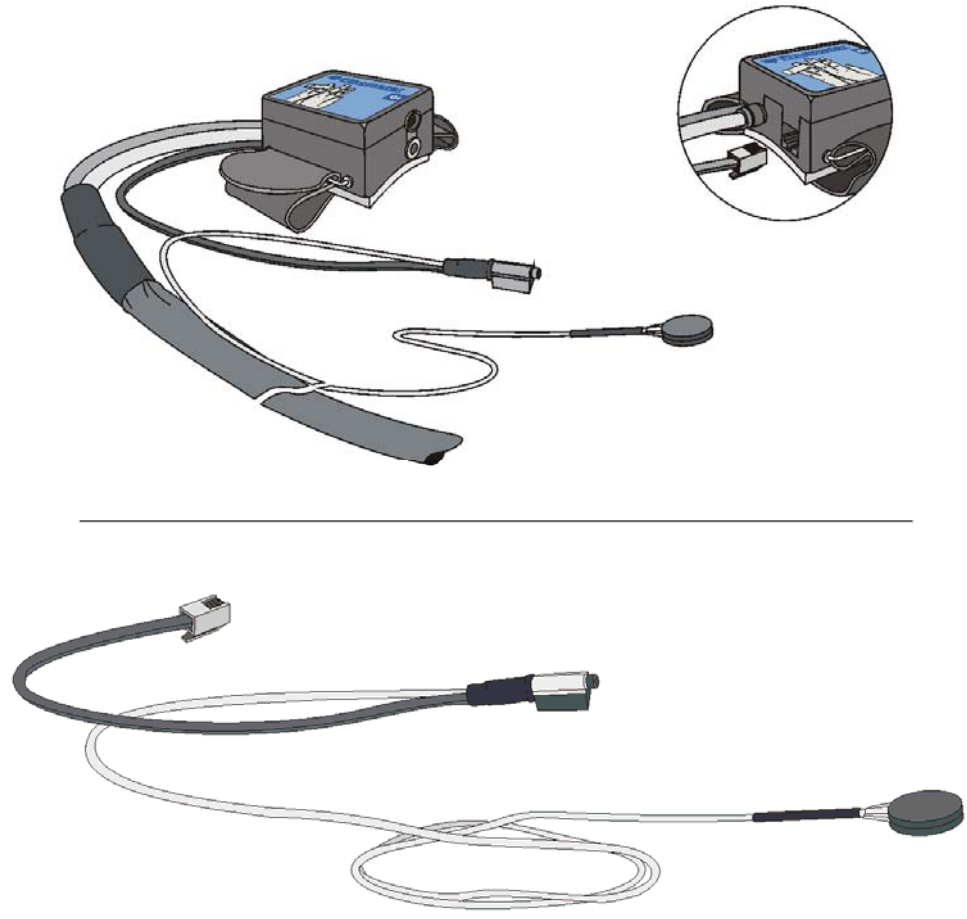


Figure 3.5 Finometer® Model-2 Frontend Unit (top) with rear mounted telephone receptacle to receive the Height Correction Unit electrical connector and, separately, the Height Correction Unit (bottom). The pillbox is the reference sensor to be attached to the subject at heart level.

3.5 The (optional) 3-lead ECG module

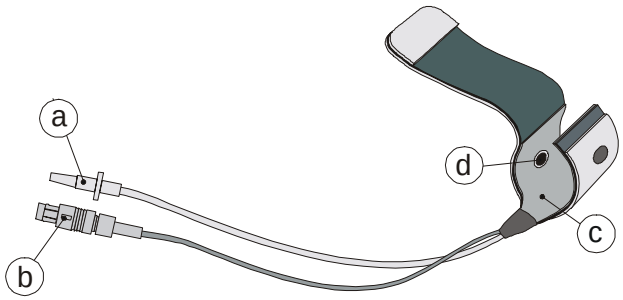
The ECG module is intended to provide an analog single channel ECG signal. The analog ECG circuitry is contained in a small module to be worn by the subject. The module has three built in leads with clip endings. The unit is powered from the Finometer® Model-2 when it is connected to the main unit via the USB-Lemo cable.

The ECG module conforms to the relevant standards and regulations.

Figure 3.6 Finometer® Model-2 ECG module

3.6 Finger cuff

A finger cuff (Figure 3.7 Finger cuff) consists of an air bladder and several layers of plastic, rubber material and Velcro adhesive. The cuff contains the electronic components (LED and photodiode) of an infrared photo-plethysmograph. A cuff cable connector and an air hose connector connect the finger cuff to the Frontend Unit. The cuffs are available in three sizes: **S**mall (white), **M**edium (beige) and **L**arge (blue).



a: Air hose connector
b: Cuff cable connector
c: Air bladder
d: Infrared photo-plethysmograph

Figure 3.7 Finger cuff

3.7 Finometer® Model-2 Control

Finometer® Model-2 can be controlled by means of a four key keypad, located on the front panel (Figure 3.8 Finometer® Model-2 control through Keypad and LCD). User interaction is through a 2x16 character LCD display. Use the keypad to control the Main Unit and to start and stop a measurement cycle.

Figure 3.8 Finometer® Model-2 control through Keypad and LCD

A: 2x16 character LCD display
B: Key pad with four keys
C: Connector for the optional ECG module
D: Connector for the Frontend Unit

On-line monitoring, recording and control of Finometer® Model-2 is also possible by using the BeatScope® Easy PC-software that comes with the device.

3.8 Connecting the Frontend Unit

To connect the Frontend Unit:

1. Apply the Frontend Unit to the subject's wrist and fasten the strap so, that it cannot twist. It is recommended to use the non-dominant arm.
2. Guide the Frontend Unit cable along the arm and fasten the arm straps.
3. Connect the Frontend Unit connector to the Main Unit (connector marked [Front end], see Figure 3.8, marked with D).

3.9 Connecting the Height Correction Unit

In addition to the above steps 1 through 3:

4. Fix the reference ending of the Height Correction Unit to the subjects arm at heart level near the body. The Height Correction Unit transducer should be fixed to the finger cuff. For more detailed information about height level compensation see the Finger Pressure Reference Guide.

3.10 Connecting the ECG (optional)

To connect the optional ECG module:

1. Connect the ECG module (section 3.5) to the main unit Lemo connector marked ECG (connector marked [ECG], see Figure 3.8 marked with C).
2. Read the ECG Manual for further instructions on how to use the ECG.

When the ECG module is connected to the Finometer® Model-2, the combination complies with the IEC 60601-1-1 for electro medical equipment.

3.11 Connecting to a PC

To perform online monitoring and remote control of Finometer® Model-2 the main unit has to be connected to a PC. Connect the PC serial port to the 9-pin D-type Finometer® Model-2 serial connector, marked RS232, using the serial interface cable that is part of the standard package.

To maintain designed operator and subject safety, the user should verify that peripheral equipment that is connected to Finometer® Model-2 or one of its components complies with the relevant standards. After connecting peripheral equipment the total configuration should comply with IEC 60601-1-1 for electro medical equipment.

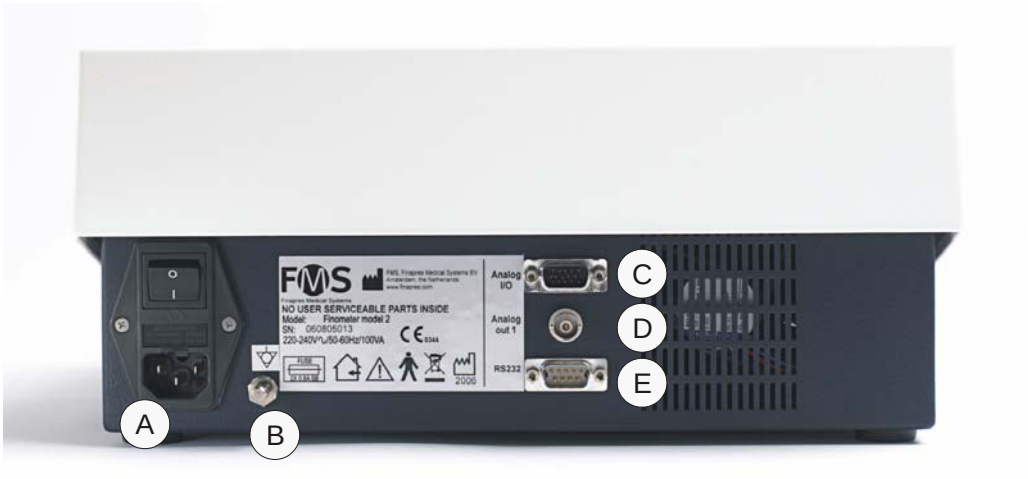


Figure 3.9 Finometer® Model-2 back side

A: AC power connector
B: Potential equalisation connector
C: Analog I/O
D: BNC output
E: RS232

4 Using the control keypad

4.1 Control keys

The keypad of the Main Unit has four keys. These keys have a main function and a secondary function which depends on the mode Finometer® Model-2 is in.

Key name	Main function	Secondary function
START/STOP	• Start a measurement • Stop, return to Ready Mode	ENTER
PHYSIOCAL	• Switch on/off Physiocal (physiological calibrations) when in Run mode (while performing a measurement)	(PRESSURE UP, during Steady Pressure Calibration see 8.4)
MARKER	• Event marker key when in Run mode	(NEXT CONFIGURATION ITEM, when the configuration menu was entered see 5.4)
HEIGHT	• Perform Height Correction Unit nulling procedure when in Ready mode • Check runtime information when in Run mode	(PRESSURE DOWN, during Steady Pressure Calibration see 8.4)
MARKER & PHYSIOCAL	• Go into the configuration menu, only active in ready mode (see 5.4)	

Table 4.1 Finometer® Model-2 control key functions

4.2 Finometer® Model-2 modes

Finometer® Model-2 can be in one of the following modes: Startup (boot) mode, Connect Frontend mode, Ready mode, Run mode, or Error mode. The information displayed on the LCD display and the function of the keys depend on the mode Finometer® Model-2 is in.

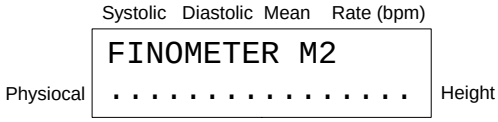
When Finometer® Model-2 is powered, with the Frontend Unit connected, the device will startup and enter into Ready mode. In Ready mode Finometer® Model-2 is ready to start a finger blood pressure measurement. Finometer® Model-2 is in Connect Frontend mode when the Frontend Unit is not yet connected to Finometer® Model-2.

If a measurement is started Finometer® Model-2 switches to Run mode. This mode is continued until the measurement is stopped, either via the keypad STOP, or via a remote PC STOP, or when an error condition is detected. If an error is detected Finometer® Model-2 switches to Error mode. Finometer® Model-2 will stop the measurement and alert the user by 3 beeps (if the buzzer is on, see 5.4.3) and a message on the LCD related to the error condition.

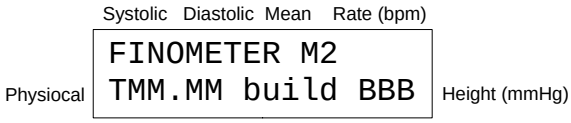
The following sections help you understanding the information displayed in the different modes.

4.2.1 Startup mode

When the Finometer® Model-2 is powered, it will start the internal program after performing several initializations and hardware function checks. During startup the LCD display will show the following information:



After being initialized the following information on the LCD display indicates that the device is up and running:

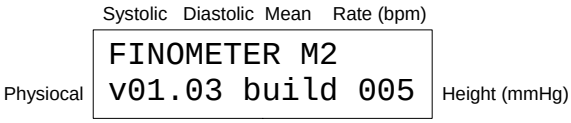


Identifier	Description	Possible values
T	Version type	v = production release b = beta release a = alpha release
M	Major or minor version number	0 – 9 per digit
B	Build number	0 – 9 per digit

Example version number : Version type = v
Major version number = 1
Minor version number = 3
Build number = 5,

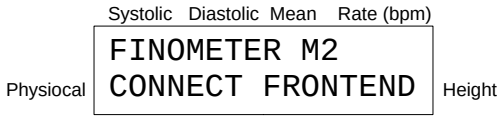
has the following format : v01.03 build 005

The display will show the following during the startup mode:



4.2.2 Connect Frontend mode

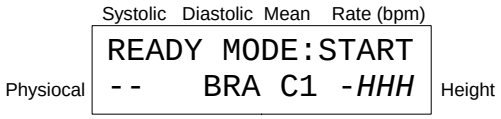
When the Frontend Unit has not yet been connected, the display will read, e.g.:



This display shows the message that the Frontend Unit is not connected to the main unit. After connecting the Frontend Unit, Finometer® Model-2 automatically switches to Ready mode.

4.2.3 Ready mode

After powering up Finometer® Model-2 with the Frontend Unit connected, the control unit should display e.g.:



The following table describes the Ready mode display.

Item	Description	Options
'BRA'	Beat-to-beat blood pressure data derived from reconstructed brachial artery pressure	'FIN' Beat-to-beat blood pressure data derived from finger pressure
'C1'	Finger cuff connection C1	
-HHH	Height correction value in mmHg. A negative sign means that the Height Correction Unit transducer (at the finger) is below heart level; positive above.	• value in range -128 to +128 [mmHg]. • 'NC' if not connected. • 'NZ' if not properly nulled (zeroed).

Table 4.**2** Ready mode display description

The choice between BRA (reconstructed brachial artery pressure) or FIN (finger artery pressure) as the basis for the beat-to-beat blood pressure data is made from the BeatScope® Easy PC program.

4.2.4 Run mode

In Run mode, when Finometer® Model-2 measures finger blood pressure, a typical display looks like, e.g.:

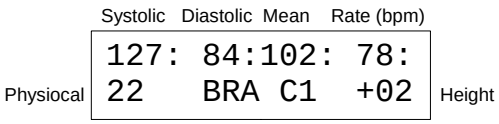


Table 4.3 Run mode display description, shows the descriptions of these items and their options. Note that in Run mode, the labels around the LCD display on the Main Unit correspond with the nearest displayed beat values.

Item	Description	Options
127	Systolic finger pressure	To be used for trending only
84	Diastolic finger pressure	To be used for trending only
102	Mean finger pressure	To be used for trending only
78	Pulse rate [bpm]	-
22	Number of beats to the next Physiocal	• number in range 1..70. • 'OFF' blinking when Physiocal is switched off.
BRA	Selected pressure reconstruction	• BRA, reconstructed brachial artery pressure waveform. • FIN finger blood pressure.
C1	selected finger cuff	• 'c1' (C1).
+02	Current height correction value [mmHg]	• value in range –128 to +128 [mmHg]. • 'NC' if not connected. • 'NZ' if not properly nulled.

Table 4.3 Run mode display description

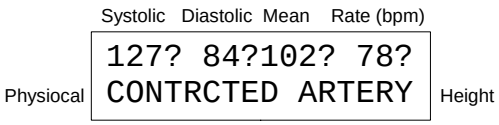
CAUTION:
The precision of systolic pressure measured with the Finometer® Model-2 does not meet the requirements of the ANSI/AAMI SP10 standard. For this reason the beat-to-beat values of Systolic, Diastolic and Mean pressure should be used for trending only.

The code ':' between the beat values has a special meaning, and can also be '!' or '?' (see Table 4.4 Codes between the values of beat-to-beat BP and HR).

Code	Description
:	Normal situation, good quality recording.
?	Beat values may have become dubious, full arterial contraction is close.
!	Beat values are dubious due to arterial contraction.

Table 4.4 Codes between the values of beat-to-beat BP and HR

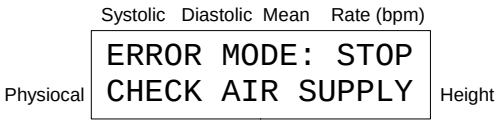
In Run mode when full arterial contraction is close, a typical display looks like, e.g.:



4.2.5 Error mode

In Error mode Finometer® Model-2 has detected an error condition. Recovery is through intervention of the operator.

A typical error message looks like:



This message indicates that an error occurred in the air supply (e.g. pump unit, Frontend Unit air hose or finger cuff air hose). The measurement is stopped permanently. Press the STOP key to confirm that the message has been noticed. After pressing the START/STOP key, Finometer® Model-2 switches to Ready mode.

5 Configuring the device

Consider the following options and settings before starting a measurement:

- Height Correction Unit nulling (if connected).
- Using the analog I/O unit (if provided).
- Using on-line PC monitoring and recording with BeatScope® Easy.

5.1 Height Correction Unit nulling procedure

The Height Correction Unit nulling should always be checked before starting a measurement. If necessary a Height Correction Unit nulling procedure needs to be performed. During a Height Correction Unit nulling procedure the offset of the Height Correction Unit is determined when the Height Correction Unit transducer and the reference point (Figure 5.1 Checking the Height Correction Unit nulling) are at the same level. This offset is stored in volatile memory and will therefore be no longer available when Finometer® Model-2 is powered off. The same holds true when the Height Correction Unit is disconnected and later reconnected.

Check the Height Correction Unit before use on the presence of an air column near the circular housing at the end of the tube. The presence of a small air bubble (< 0.5 cm) is no problem.

The presence of a large air bubble (> 0.5 cm) points towards a possible leakage of the fluid from the closed Height Correction Unit as may be visible from remnants of the liquid, most likely on the circular housing.

Don't use the Height Correction Unit if this is the case, but contact Finapres Medical Systems B.V. , for replacement or repair of the Height Correction Unit (see page 9).

5.1.1 Checking Height Correction Unit nulling

To check the current Height Correction Unit nulling:

1. Keep the Height Correction Unit transducer and reference point of the Height Correction Unit at the same level (Figure 5.1 Checking the Height Correction Unit nulling).

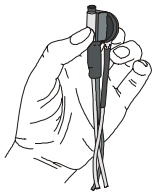


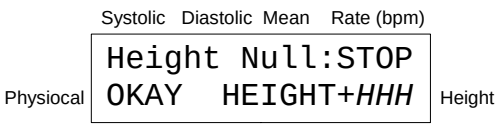
Figure 5.1 Checking the Height Correction Unit nulling

2. Check the height value that is displayed in Ready mode on the LCD display. This value should be '00'. Perform a Height Correction Unit nulling procedure if this value is not '00'.

5.1.2 Performing a Height Correction Unit nulling procedure

To perform a Height Correction Unit nulling procedure:

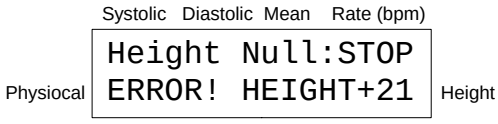
1. The Finometer® Model-2 should be in Ready mode.
2. Keep the Height Correction Unit transducer and reference point of the Height Correction Unit at the same level (Figure 5.1 Checking the Height Correction Unit nulling).
3. Press the HEIGHT key to start the procedure.
   After about a second the following message should be displayed:



4. The height value will be updated continuously.
5. Press the START/STOP key to return to Ready mode.

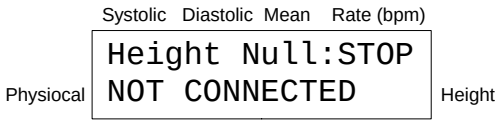
Troubleshooting

- When the offset of the Height Correction Unit transducer is more than 15 mmHg, the lower line during height-nulling reads e.g.:



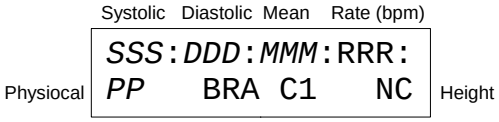
  This message is accompanied by three beeps of the buzzer (if the buzzer is on, see 5.4.3). Check that both ends of the Height Correction Unit are indeed at the same level. If not repeat steps 3 and 4 above.
  The height value displayed here is the offset of the Height Correction Unit transducer. If the error persists, contact Finapres Medical Systems B.V. and report the offset.

- When the Height Correction Unit is not connected while performing the nulling procedure, the display will change to:



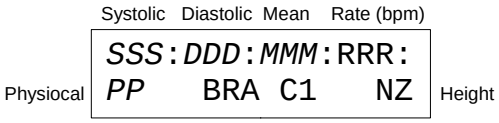
  When this message is displayed, connect the connector of the Height Correction Unit to the Frontend Unit.

Note 1: If the Height Correction Unit has been nulled, the measured finger blood pressure and derived beat-to-beat data will be corrected for hydrostatic height differences. Disconnection of the Height Correction Unit will result in measurements not corrected for hydrostatic height.
Then, the lower line in the display shows the string 'NC' instead of the height value, e.g.:



In this case the hand needs to be kept at heart level during the entire measurement.

Note 2: If the Height Correction Unit nulling was unsuccessful, the measured finger blood pressure and derived beat-to-beat data will not be corrected for hydrostatic height differences. In this situation the string 'NZ' (not zeroed) is displayed instead of the height value, e.g.:



If this is the case the hand needs to be kept at heart level during the entire measurement.

5.2 Using the analog I/O cable

If one wants to connect a stripchart recorder or a real-time data acquisition system to Finometer® Model-2, one can use the analog outputs. The BNC connector on the rear of the device provides the analog finger blood pressure (Figure 3.9 Finometer® Model-2 back side). Other signals can be selected by using BeatScope® Easy.

An analog I/O cable with five BNC connectors is available to provide additional analog output signals as well as one external signal input.

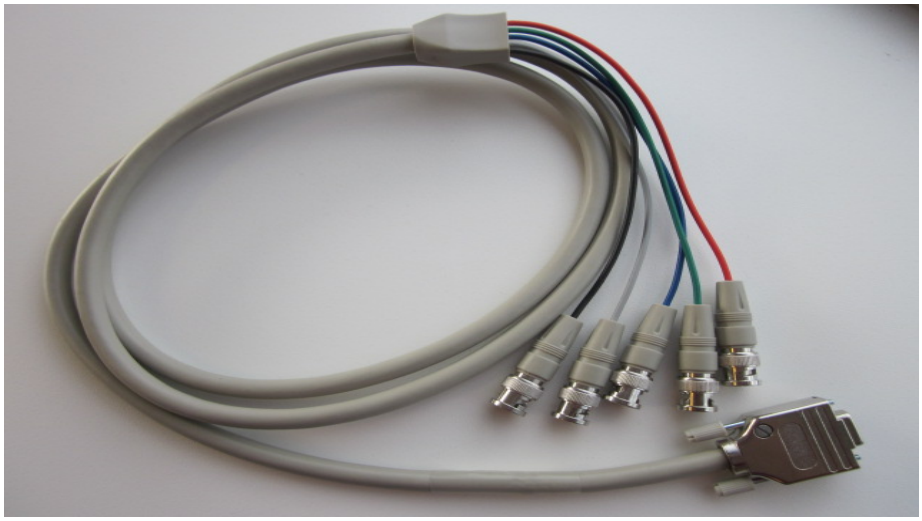


Figure 5.2 Finometer® Model-2 analog I/O unit

Attach the connector of the analog I/O cable to the corresponding connector on the rear side of the main unit, indicated with the label 'Analog I/O' (Figure 3.9 Finometer® Model-2 back side).

Warning
To maintain designed operator and subject safety, peripheral equipment that is connected to Finometer® Model-2 or one of its components must comply with the relevant standards.

5.2.1 Definition of output signals

The following outputs are available by default:

Output Nr.	Signal	Description
1	finger	Finometer® Model-2 Finger waveform is the raw continuous finger pressure signal.
2	reBAP	Finometer® Model-2 reBAP waveform is the reconstructed brachial artery pressure signal.
3	ECG input at the front	Finometer® Model-2 ECG is the analog ECG signal which is available when the optional ECG module (section 3.5) is connected to the ECG input at the front (see Figure 1.1), or any other external signal applied to this input.
4	Plethysmogram	Representing the volume pulsations of the finger arteries as seen by the finger cuff plethysmograph.

See Chapter 9 for further specifications, calibration and offset.

Note1: With BeatScope® Easy v02.10build004 it is possible to select different signals for these 4 analog outputs. For each channel a choice can be made from the following signals / parameters: Finger pressure; Height; Calibration (Square Wave), Marker*; Finap (Filtered Finger Pressure); reBAP (reconstructed brachial artery pressure); SYS (Systolic pressure), DIA (Diastolic pressure); MAP (Mean arterial pressure) and HR (Heart Rate). See BeatScope® Easy manual for further information.

*) When the MARKER key is pressed on the Finometer® Model-2 keypad, the MARKER output channel will generate a voltage of 2V as long as the key is pressed. When a marker is set with Beat-Scope® Easy, the MARKER output will generate a voltage of 1V.

Note2: In BeatScope® Easy v01.02build002 the default output 4 is the Marker signal. This can be changed to Plethysmogram or to the signal provided on the external input.

5.2.2 Analog signal input

One BNC connector is available on the I/O unit, to input an external signal into the Finometer® Model-2. This signal must range between -5V and + 5V and will be sampled and stored simultaneously with the blood pressure waveform samples.

5.3 Calibration options

5.3.1 Analog output calibration

Finometer® Model-2 generates a calibration pattern on its analog outputs to calibrate a stripchart recorder or other recording system. With this signal the dynamic response, polarity and sensitivity of subsequent (external) recording channels can be calibrated and tested.

The calibration signal is available when the Finometer® Model-2 is in Ready Mode. The calibration signal is available only for output 1, 2 and 4 of the I/O unit, when Finometer® Model-2 is used stand-alone.

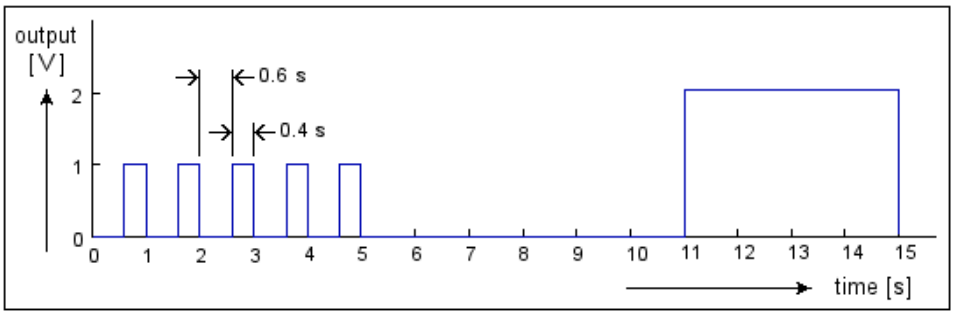


Figure 5.3 Calibration signal specification

Other calibration options can be found in the configuration option menu see 5.4.1 and 5.4.2.

Note: In ready mode, output channel 3 of the I/O box will generate the applied signal of the ECG input at the front of Finometer® Model-2.

5.4 Configuration option menu

The "Configuration Option Menu" can be activated by pressing the MARKER and PHYSIOCAL key simultaneously while the system is in ready mode. The first available procedure is the steady pressure check. When the MARKER key is pressed, the "Configuration Option Menu" procedure will show the next option, being the "Pressure waveform calibration output". Hereafter the "Beeper", "Serial protocol" and finally the "Software version" options can be chosen, respectively. When the MARKER key is pressed again, the circular "Configuration Option Menu" will start again with the steady pressure check.

When the START/STOP key is pressed at any time, the chosen settings are saved and the system goes back into Ready mode. Saved means that the configuration parameters for beeper and serial protocol are stored on the internal storage as defaults, remaining valid when the device is switched on again after power off.

5.4.1 Steady pressure calibration check

When the steady pressure check is started (see Table 4.1 Finometer® Model-2 control key functions, how to enter this mode) the following will be displayed:

Systolic Diastolic Mean Rate (bpm)

Physiocal

```
STEADY  PRESSURE
G:NNN M:NNN mmHg
```

Height

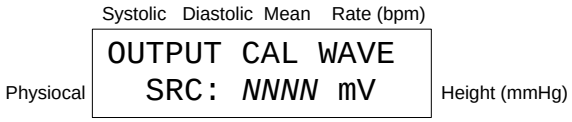
"G" stands for generated pressure, "M" stands for measured pressure. "NNN" can be any numerical value between 0 and 250 in units of

mmHg. The presented generated pressure value will be applied to the air outlet of the Frontend Unit.
The generated pressure output starts at 0 mmHg. Each time PHYSIOCAL is pressed, the pressure will go up with 50 mmHg. Each time the HEIGHT key is pressed, the pressure will go down with 50 mmHg. A step will go in sub steps of 0,25 mmHg each sample time (=5 ms for 200Hz). So it takes 1 second to move 50 mmHg during a step. This is repeated endlessly until the START/STOP key is pressed.
When the START/STOP key is pressed at any time, during the steady pressure check, the system will go back into ready mode and the configuration is saved.
When the MARKER key is pressed, the "Configuration option menu" will show the next configuration item, being the waveform calibration output.

5.4.2 Waveform calibration output

The pressure wave calibration signal is a single, exactly repeating finger artery pulsation, recorded in a young adult subject. Its systolic pressure is 1295 mV (129.5 mmHg), diastolic is 710 mV (71 mmHg), pulse interval is 930 ms (exact) and calibrated heart rate is (60 x 1000 / 930) = 64.5 BPM. For Finometer® Model-2, 1000 mV has to correspond to 100 mmHg. Thus S/D is 129.5/71 mmHg.

When the pressure waveform calibration is started (see Table 4.1, Finometer Model-2 control key functions how to enter this mode) the following will be displayed:



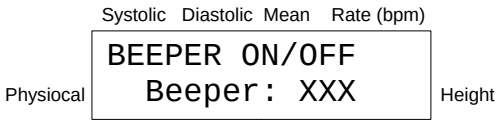
SRC: indicates the source voltage. The defined pressure wave form will appear on the analog BNC output and on output channel 1,2 and 4 of the I/O box.

When the START/STOP key is pressed at any time during the pressure waveform calibration, the system will go back into Ready mode and the configuration is saved.

When the MARKER key is pressed, the configuration option menu will show the next configuration item, being the beeper configuration.

5.4.3 Beeper configuration

When the beeper configuration is started (see Table 4.1, Finometer Model-2 control key functions, how to enter this mode) the following will be displayed:

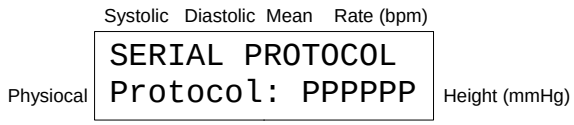


Where "XXX" can be: "on" or "off".
Default the beeper is on. Each time PHYSIOCAL or HEIGHT is pressed, the beeper toggles between on or off. Also the display will change to the actual setting.
When the START/STOP key is pressed at any time during the beeper configuration, the system will go back into Ready mode and the configuration is saved.

When the MARKER key is pressed, the "Configuration option menu" will show the next configuration item, being the serial protocol configuration.

5.4.4 Serial protocol

When the serial protocol configuration is started (see Table 4.1, Finometer Model-2 control key functions how to enter this mode) the following will be displayed:



Where "PPPPPP" can be : FMS or OHMEDA

By default the FMS protocol is selected. Each time PHYSIOCAL or HEIGHT is pressed, the protocol toggles between FMS or OHMEDA.
When a protocol is selected and a measurement is started the serial port will use the selected protocol.

Note : BeatScope® Easy uses the FMS protocol.

The pressure reconstruction level depends on the chosen serial protocol. The following table shows which pressure reconstruction level is selected automatically when a specific serial protocol is chosen in the configuration menu and when the setting is loaded from disk during system boot.

Serial protocol	Pressure reconstruction level after system boot
FMS	BRA
OHMEDA	FIN

When the system is running and the serial protocol is changed from OHMEDA back to FMS, the pressure reconstruction level will stay at the finger level indicated by FIN.

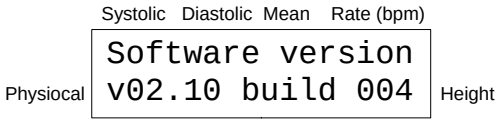
When the START/STOP key is pressed at any time during the serial protocol configuration, the system will go back into ready mode and the configuration is saved.

When the MARKER key is pressed, the configuration menu will show the next configuration item, being the software version display option.

5.4.5 Software version

When the software version display option is started (see Table 4.1,

Finometer Model-2 control key functions how to enter this mode) the following will be displayed:



See paragraph 4.2.1 for an explanation of the format of the software version.
The display will be frozen until the next option in the menu is chosen or until the menu is left.
When the START/STOP key is pressed at any time during the software version display option, the system will go back into Ready mode and the configuration is saved.

When the MARKER key is pressed, the "Configuration option menu" will show the first configuration item again, being the steady pressure calibration check.

5.5 PC monitoring and recording with BeatScope® Easy

It is possible to monitor and record the pressure waveform and trend of the beat-to-beat derived parameters in real-time, when Finometer® Model-2 is connected to a PC through the serial line or through a USB to serial converter to connect to the device's serial port, e.g. the FTDI US232-R-100 cable. Install the correct driver to connect to COM1 or COM2. See also: Installation Guide USB/RS232 converter.
The BeatScope® Easy software provides this monitoring and recording capability in addition to control the most important functions of the Finometer® Model-2 device from PC.

To monitor and record the pressure waveform and beat-to-beat data in real-time:

1. Connect a serial cable from the main unit serial port connector - indicated with the 'RS-232' label - to an unused serial port on a PC.
2. Run BeatScope® Easy.

3. Configure BeatScope® Easy if necessary (e.g. correct serial port number).

During an online recording with BeatScope® Easy the pressure waveform is displayed in one panel and trends of systolic, diastolic, mean pressure and heart rate are shown in a second panel. Cardiac output is shown in a third panel.
With BeatScope® Easy it is possible to configure a user specific set in panels, presented waveforms and trends. The choice for FIN (finger pressure) or BRA (reconstructed brachial artery pressure) as the basis for the derived beat-to-beat blood pressure data is made from the BeatScope® Easy PC program before starting up a measurement.
It is also possible to configure a wide range of settings for the analog I/O of Finometer® Model-2.

Note: The optional ECG can be displayed on the PC screen simultaneously with the blood pressure waveform.

6 Performing a measurement

6.1 Using finger cuffs

Proper finger cuff application is critical to the success of the Finometer® Model-2 finger arterial pressure measurement. Therefore, read the following sections about finger cuff selection, cuff handling and cuff application with special attention!

6.1.1 Finger cuff selection

There are 3 different finger cuff sizes (see Table 6.1 Finger cuff selection): small (S), medium (M) and large (L). Every size has its own color. The finger cuff should be applied to the middle phalanx of a finger. We have had best experience with the middle or ring finger, but the index finger can be used equally well in most cases.
The preformed conical finger cuff is not designed for application to the thumb. You may only apply the finger cuff to the thumb when it is impossible to measure finger arterial pressure on any finger.

Select the proper finger cuff size by using the table below. When in doubt, use the smaller size finger cuff.

Finger circumference * [mm]	Finger cuff size	Finger cuff color
45 - 55	S (small)	White
55 - 65	M (medium)	Beige
65 – 75	L (large)	Blue

* measured at the center of the middle phalanx of the finger

Table 6.1 Finger cuff selection

To obtain a good transmission of pressure from the airbladder to the underlying tissues both sides of the airbladder should just make contact (see Figure 6.1).

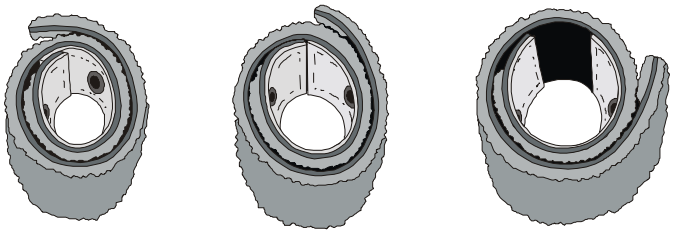


Figure 6.1 Cuff size selection

6.1.2 Warnings on cuff handling

Take into account the following notes to prevent finger cuff damage:

Don't remove the finger cuff from a finger before stopping the measurement or before disconnecting the air hose from the Frontend Unit. The finger cuff may be damaged even though Finometer® Model-2 automatically takes pressure away when the finger cuff unwraps.

- Don't apply air pressure to a finger cuff, when it is not wrapped around a finger or any other solid object! This may damage the finger cuff.
- Don't bend finger cuffs outwards to a flat shape since this may damage the bonding and the electrical shielding. Finger cuffs are preformed around a conical mandrel during manufacturing.
- Do not try to repair defective finger cuffs with e.g. adhesive tape, this will substantially affect measurement accuracy.

6.1.3 Cuff application

To wrap the finger cuff around the finger:

1. Bend the finger cuff open just enough to see the LED and photocell.
2. Place the finger in the cuff such that the LED and photocell are symmetrically placed on each side of the finger's soft parts in the center of the middle phalanx (Figure 6-2). The cuff cable and

airhose are now at the back of the hand and should point towards the Frontend Unit.

3. Make sure the finger cuff is placed in the middle between the two knuckles, touching each knuckle (Figure 6-2).

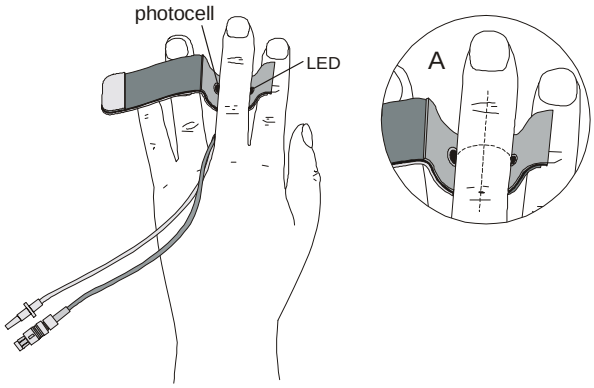


Figure 6-2 Applying the finger cuff

4. Wrap the finger cuff tightly for best performance. The finger cuffs are designed in such a way that correct wrapping is almost natural. Check that it is not easy to rotate the finger cuff after application. A common mistake is to wrap the finger cuff not tight enough.
5. Guide the cuff cable and air hose between the fingers to the back of the hand and connect them to the Frontend Unit which is worn on the wrist (see Figure 6.3).

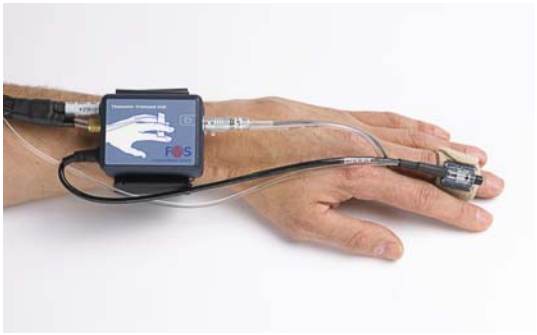


Figure 6.3 Connecting the finger cuff to the Frontend Unit

Height Correction Unit:

The next step is to apply the Height Correction Unit transducer to the finger cuff (see Figure 6.3). Perform the Height Correction Unit nulling procedure (see section 5.1.2) before mounting the unit to the subject.

6.2 Checklist

Before starting a measurement consider the following questions:
- Is the finger cuff connected properly? (see section 6.1)
- Is the Height Correction Unit properly nulled and connected? (see section 5.1)

6.3 Starting a measurement

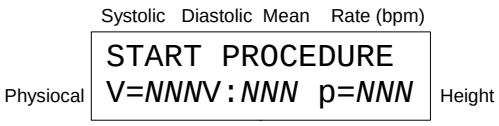
Important notice!
With Finometer® Model-2 measuring cuff pressure, a slight pulsation in the cuffed finger is felt synchronous with the heart beat. Arrhythmia's can often be sensed also. At regular intervals a physiological calibration, Physiocal, is performed. During a Physiocal, cuff pressure is held constant and no pulsation can be felt for two or more beats. The subject should be told that these missed beats are not caused by his/her heart beating irregularly, but are purely instrumental.

To start a blood pressure measurement press the START/STOP key, while in Ready mode.

6.3.1 Startup messages

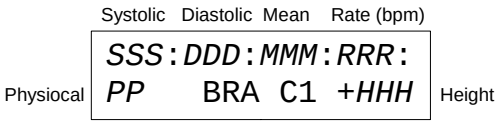
The following steps are successively performed at start-up:

- A staircase pressure sequence is performed. The finger plethysmogram is observed at different pressure levels and the correct set-point is determined. The display changes to:



showing the current DC level (V=NNN) and pulsatile AC (V:NNN) components of the plethysmogram in arbitrary, but compatible units(N=0…9), and cuff pressure (p=NNN) in mmHg for each pressure level during the pressure staircase procedure.

- After performing the pressure staircase at start-up, Finometer® Model-2 starts displaying beat-to-beat values in Run mode, e.g.:



where the labels on the front panel around the display correspond with the nearest displayed beat-to-beat values.
See section 6.7 for more information about the beat-to-beat display during Run mode.

6.4 Measurement options

This section describes the available functions while in Run mode.

6.4.1 Switching Physiocal ON/OFF

During Run mode the pressure waveform is interrupted for two or more beats at intervals determined by the software to observe the plethysmogram and the physiological state of the finger. This Physiocal procedure can be switched off and on by pressing the PHYSIOCAL key. Refer to the Finger Pressure Reference Guide for more detailed information about this option.
Physiocal status information is given on the lower line of the display, e.g.:

	Systolic	Diastolic	Mean	Rate (bpm)	
	SSS:	*DDD*:	*MMM*:	*RRR*:	
Physiocal	22	BRA	C1	+02	Height

where '22' is the number of beats to the next Physiocal. With Physiocal switched off, the number of beats change to a blinking 'OFF':

	Systolic	Diastolic	Mean	Rate (bpm)	
	SSS:	*DDD*:	*MMM*:	*RRR*:	
Physiocal	OFF	BRA	C1	+02	Height

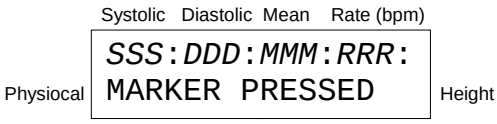
Physiocal should normally be "ON" to follow any changes in finger physiology. It is advised not to measure longer than 5 to 10 min, with the Physiocal function switched "OFF", because some pressure drift may result, if finger physiology is not stable in this period. When Physiocal is switched off for more than 2 minutes, 2 beeps will be generated by the buzzer (if the buzzer is on, see 5.4.3). These beeps will be kept generated every 2 minutes until Physiocal is switched on again.

6.4.2 Marking events

To generate an event marker press the MARKER button on the main unit (see Figure 6.4). After pressing the MARKER button, it will become available on output channel 4 of the I/O unit.

Figure 6.4 The 4 keys keypad

Upon pressing the MARKER button the LCD display changes to:

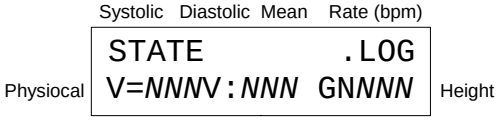


Note: It is recommended to use a logbook during a measurement to note the time and the reason for pressing the MARKER key. Only usable in combination with the Analog I/O unit and/or BeatScope® Easy.

Note: When BeatScope® Easy is used to set a marker, it is possible to enter a corresponding note immediately.

6.4.3 Checking run time information

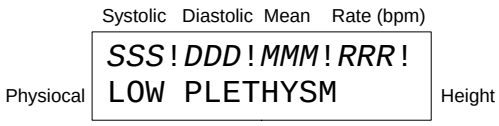
During a measurement the status of the plethysmograph and cuff pressure controller can be checked by pressing the HEIGHT key. The display will show the following, for a small period of time:



The top line shows the state of the internal servo system. The upper right corner shows information on the internal status of Finometer® Model-2, not relevant to the user. The lower line shows the DC (V=NNN) and pulsatile (V:NNN) components of the plethysmogram observed during the last Physiocal and the gain (GN*NNN*) of the servo controller in arbitrary units.

6.5 Run time messages

Run time messages occur during Run mode. These messages refer to the contraction state of the finger arteries. Below is an example of a run time message during a measurement:



The run time messages are defined in the following table (Table 6.2 Run time messages).

Message	Description
CONTRCTED ARTERY	No plethysmogram is observed, probably due to cold hands: • Warm the hand and the arm proximal of the cuff. • Try another finger.
LOW PLETHYSM	Pulsatile component (V:) of plethysmogram is too small: • Warm the hand and the arm proximal of the cuff. • Try another finger.

Table 6.2 Run time messages

6.6 Stopping a measurement

Upon completion of the measurement, it is stopped as follows:

1. Press the START/STOP key to stop the measurement.
2. Disconnect the cuff air hoses from the Frontend Unit to protect the finger cuffs from accidental inflation.
3. Unwrap and remove the finger cuffs and take the Frontend Unit away from the subject.

6.7 Data on a PC

To start a Finometer® Model-2 recording on a PC:

1. Connect the serial cable between main unit and a serial port in the PC.
2. Run the BeatScope® Easy PC software.
3. Refer to the BeatScope® Easy User's Guide for further information.
4. Make sure that the FMS serial protocol is configured, see 5.4.4.

6.7.1 Ohmeda protocol

The Ohmeda serial protocol can be used for PC software that was used with the Ohmeda Finapres. For this the OHMEDA protocol must be configured, see 5.4.4.

6.7.2 Ohmeda protocol and HyperTerminal

The Ohmeda protocol is an one way protocol. This means that when this protocol is selected it will output data on the serial port during a measurement.
The Windows application called HyperTerminal can be used to present or capture this data.
The output parameters are as follows:

Data output format

All data coming from the Finometer® Model-2 are ASCII code characters.
In RUN mode the numeric data comes as a string:

psssdddmmmrrriiii±hh<CR>

p is a preamble representing the status of the data measurements as described in Table 4.4.
The preamble is one of the following 3 characters ":" or "?" or "!"

:	normal situation, good quality recording
?	beat values may have become dubious, full arterial contraction is close.
!	beat values are dubious due to arterial contraction

sss	are three characters for systolic pressure value in mmHg.
ddd	are three characters for diastolic pressure value in mmHg.
mmm	are three characters for mean pressure value in mmHg.
rrr	are three characters for pulse rate value in beats/minute.
iiii	are four characters for pulse interval in milliseconds with a resolution of 5 milliseconds.
±hh	is the sign character and two value digits for the measured height signal in mmHg. This output is only available if the Height Correction Unit is connected and nulled.

An example of a normal (:) output string with HEIGHT CORRECTION UNIT connected and nulled is

:126 86102 77780-12<CR>

Meaning	Systolic	= 126
	Diastolic	= 86
	Mean	= 102
	Rate	= 77
	Interval	= 780
	Height	= -12

An example of a normal (:) output string with no Height Correction Unit connected is

:126 86102 77780<CR>

Meaning	Systolic	= 126
	Diastolic	= 86
	Mean	= 102
	Rate	= 77
	Interval	= 780

In a period of Physiocal no pressure data is available but rate, IBI and height are valid. The pressure values are replaced by the product sign * (hex 2A). A string with zeroed height will show up as:

:********* 77780-12<CR>

Data transmission is done whith the following settings:

Baud rate	:	9600
Data bits	:	8
Stop bit	:	1
Parity	:	no parity

7 Error messages and troubleshooting

7.1 Audible indicators

The Finometer® Model-2 main unit has a buzzer that generates beeps to indicate its status (if the buzzer is on, see 5.4.3). The next sections describe the meaning of these beeps.

7.1.1 Key beeps

Beeps	Indicating that …
1x	• A valid key or key combination is pressed.
2x	• A key or key combination is pressed which is not valid in the current mode of Finometer® Model-2, e.g. a MARKER key when Finometer® Model-2 is in Ready mode. • Physiocal is off for more than 2 minutes, every 2 minutes.

Table 7.1 Finometer® Model-2 key beeps

7.1.2 Error beeps

Beeps	Indicating that…
3x	• An error condition has been detected.

Table 7.2 Finometer® Model-2 error beeps

7.2 Error messages

When Finometer® Model-2 detects an error, an error message is displayed. Often such an error is caused by a simple mistake of the operator (e.g. cuff cable not connected). However, other errors may be caused by a serious hardware problem in the device, requiring a system check by Finapres Medical Systems B.V.
The following 4 sections describe what error messages may occur and what actions has to be taken.

7.2.1 Plethysmogram, finger cuff error messages

Error message	Action
FINGER TOO THIN	The infrared level transmitted through the finger is too high. This may occur on very thin, near bloodless fingers: • Retry. • Try a smaller finger cuff. • If this fails wrap some thin cloth around the finger and replace the cuff. Use darker cloth when necessary.
NO PLETHYSMOGRAM	During the start-up procedure (staircase pressure pattern) no significant plethysmogram was detected, usually caused by contracted arteries. • Retry. • Try another finger. • Warm the hand.

7.2.2 Air pressure, finger cuff error messages

Error message	Marker message	Action
CHECK AIR SUPPLY		The pump system fails to generate enough pressure or flow: • Check if the finger cuff air hose is inserted in the Frontend Unit. • Check the air hose between the Frontend Unit and main unit. • Check for leaks or kinks. If the error persists, have the device checked by Finapres Medical Systems B.V.
UNACCEPTABLE P/V	64001	A pressure and/or plethysmogram error has occurred. Pressure has been below 10 mmHg, or above 250 mmHg for 2.5s, or the plethysmogram was not sufficiently small during the measurement: • Retry. • Check if the finger cuff is wrapped tight enough around the finger. • cf. 'CHECK AIR SUPPLY' and 'CONNECT CUFF CABL' errors.
PRESSURE LOW	64000	Mean pressure is too low. Mean pressure has been below 10 mmHg for 2.5s, or too low when trying to perform a Physiocal.
PRESSURE TOO LOW	64003	Pressure is to low during a Physiocal, the pressure is measured being below 30 mmHg during Physiocal.
MEAN PRES HIGH	64002	Mean pressure is too high. Mean pressure has been above 250 mmHg for 2.5s
UNSTABLE PRES		During the pressure staircase procedure at start-up or during a physiocal, constant pressure levels were not stable enough: • Check if the finger cuff air hose is inserted in the Frontend Unit. • Retry. If the error persists, have the device checked by Finapres Medical Systems B.V.

7.2.3 Miscellaneous errors during a measurement

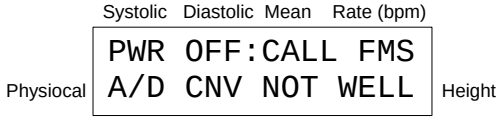
Error message	Action
MEASURED 12 HRS	Measured more then 12 hours on the same finger.
PREMATURE STOP	When operator presses the start/stop key during the start phase of the measurement.

7.2.4 Errors due to missing sub device

Error message	Description
RECONNECT HEIGHT	Height Correction Unit removed from Frontend Unit during measurement. Measurement will be stopped immediately.
RECONNECT FE	Frontend Unit not connected. When Frontend Unit is disconnected during measurement, the measurement will be stopped immediately.
CONNECT CUFF	The finger cuff cable is not connected to the Frontend Unit.

7.2.5 Fatal internal errors

When one of these errors is due, the system should be returned to Finapres Medical Systems B.V. for repair. The system informs the operator about this in the following way:



In this situation nothing else can be done then powering the system off. The error message will stay persistent on the display and an alarm signal is applied by generating three beeps every minute (if the buzzer is on, see 5.4.3), until the system is powered off.

See the following table for a description of possible fatal internal errors.

Error message	Description
A/D CNV NOT WELL	The signal ground voltage of the Analog/Digital converter is too high: • Power the device off and on. If the error persists, have the device checked by Finapres Medical Systems B.V.
PWR SUP NOT WELL	A short-circuit, zero offset or power supply unbalance developed: • Turn off the device immediately. • Retry power-on briefly without finger cuff. The error may also occur if you disconnect the Frontend Unit e.g. during a measurement: • Reconnect the Frontend Unit and power the unit off and on again. If the error persists, have the device checked by Finapres Medical Systems B.V.
INT GND FAULT	The zero offset of the pressure transducer is too large: • Power the device off and on a number of times. If the error persists, have the device checked by Finapres Medical Systems B.V.

8 Maintenance, storage and calibration

8.1 Maintenance

The Finometer® Model-2 device contains no field serviceable parts. It is recommended to send the unit to Finapres Medical Systems B.V. every two years for a general inspection and calibration check. An appointment for a service checkup can be made through customer support (see page 9).

8.2 Cleaning

The Finometer® Model-2 housing is made of materials that do not easily attract dust. If cleaning is needed follow the instructions below:

- Always first unplug the power cord.
- Wipe clean using a soft, slightly moistened cloth.
- Never apply liquid directly to the units of the device or its associated units, such as the Frontend Unit.
- Do not immerse the device.
- Never use alcohol, refined petrol, thinner, or other strong chemical agents that could damage the Finometer® Model-2 housing.
- Do not allow any water to enter the Finometer® Model-2 device or its units.
- For cleaning the finger cuffs we recommend to use Neodisher MediClean forte (www.drweigert.com). The finger cuffs (but not cable and air tube) can be immersed in this liquid without affecting the bonding of the cuff. Should liquid accidentally enter the finger cuff or air hose, then try to shake it out and allow enough time to dry.

Use the same cautions when cleaning the accessories such as the Height Correction Unit, finger cuffs or the I/O unit.

8.3 Storage

- Keep the Finometer® Model-2 device in a clean environment to protect it from dust and moisture.
- See chapter 9 for environmental storage conditions.

8.4 Pressure calibration check

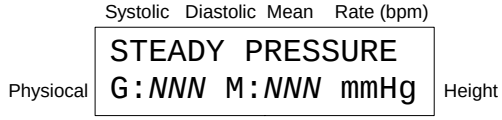
Pressure calibration should be checked at least once a year or when there is doubt about the validity of the finger cuff pressure readings.

To check the pressure calibration:

1. Connect the Finometer® Model-2 units as described in chapter 1.

2. Connect a calibrated precision manometer to air outlet C1 of the Frontend Unit.

3. Press the MARKER and PHYSIOCAL key simultaneously to enter the calibration check mode while the system is in Ready mode. The LCD display shows the following message:



4. Check zero level and then use the PHYSIOCAL key to increase the pressure in steps of 50 to 250 mmHg. Use HEIGHT key to decrease the pressure in steps of 50 to 0 mmHg. At each pressure level the precision manometer reading should be within 3 mmHg (1% full scale) of the selected pressure level. When no precision manometer is available, the check can be performed as follows:
   - Close the air outlet C1 of the Frontend Unit with a finger
   - Follow the pressure steps and selected pressure must be displayed in value NNN on the Display.

5. Press the START/STOP key to return to Ready mode.

If the indicated pressures are not within tolerance, contact Finapres Medical Systems B.V., [Customer support] to check the device.

9 Specifications

This device fulfills the provisions of the EC directive 93/42/EEC (Medical Device Directive) and the European Standards EN 60601-1; EN 60601-1-1, EN 60601-1-2.

Manufacturer: Finapres Medical Systems B.V.
Paasheuvelweg 34a
1105 BJ Amsterdam ZO
The Netherlands
Phone: + 31 20 609 0974
Fax: + 31 26 609 0677
E-mail: info@finapres.com

CE 0344

Important note: Specifications may be subject to change without notice.

9.1 Instrumental information

Item	Specification
Product category	Finometer® Model-2 finger blood pressure measuring device, with BeatScope® Easy PC-based software
Product type	Pressure- and hemodynamic trending
Measurement method	Arterial volume-clamp method of J. Peñáz and the Physiocal criteria of K.H. Wesseling
Cuff pressure	Max. 300 mmHg
Height sensing	Range $\pm$ 128 mmHg
Diastolic, systolic and mean pressure, pulse rate determination	See section 5.2.1
Blood pressure accuracy	1% of full scale (max. 3 mmHg), zeroing automatic
Data storage	Not applicable
Display	2x16 characters LCD
RS-232C connector	Serial port, 9-pin male, D-type
Analog pressure output connector	BNC-type
Analog signal I/O	1-input, 4 output, 15-pin male, D-type Range $\pm$ 5V max.
Finger cuff pump system	Pressure regulated at 350 mmHg Maximum pressure: 380 mmHg

9.2 Instrumental accuracy

Parameter	Accuracy
Finger cuff pressure	1% of full scale (max 3 mmHg) Automatic zeroing Typically <0.5 mmHg
Height correction	2% of full scale (max 3 mmHg), Zeroing manually
Pulse Rate (HR)	(Rate (BPM) / 60)%, thus 1% at 60 BPM
Inter Beat Interval	5 ms (peak, non-accumulating)

9.3 Analog signal outputs and signal inputs

9.3.1 Analog output signals

Label	Update frequency	Time delay	Offset	Scaling
Finometer® Model-2 finger pressure waveform	200 Hz	< 5ms	0	100 mmHg/V
Finometer® Model-2 reBAP waveform	200 Hz	1 s (This is a delayed signal, which is caused by a filtering and modeling process, The variable processing time is adjusted to 1s)	0	100 mmHg/V
Finometer® Model-2 ECG waveform	200 Hz	< 5ms	0	100 mmHg/V
Marker	200 Hz	< 5ms	0	2V signal as long as marker button is pressed 1V signal for an externally given marker (e.g. through BeatScope® Easy)

Table 9.1 Analog output signals

9.3.2 Analog input signals

Label	Update frequency	Resolution	Offset	Voltage range
Analog I/O cable Input	200 Hz	2.5 mV	<±5mV	-5 to + 5 V
ECG-input	200 Hz	2.5 mV	<±5mV	-5 to + 5 V

Table 9.2 Analog input signals

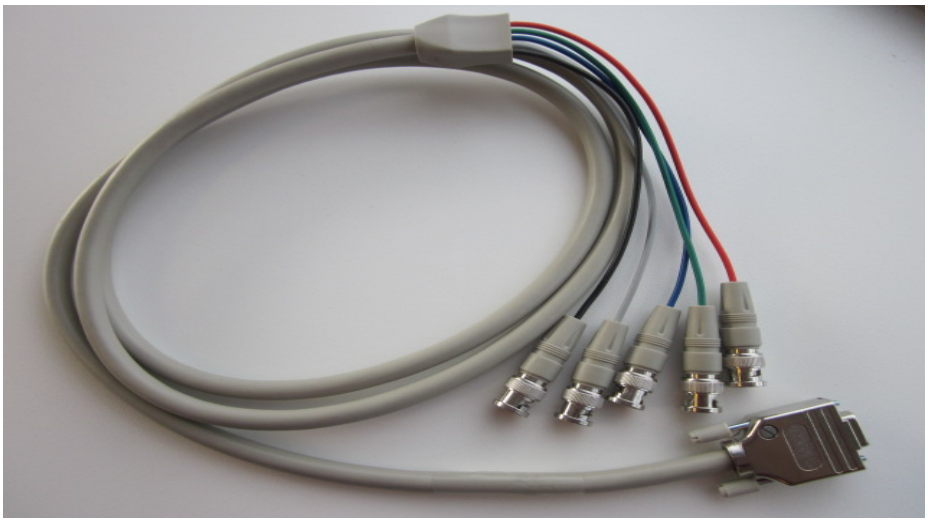


Figure 9.1 The analog input/output (I/O) cable

See section 9.3.3 for the color-coded input- and output channel connections.

9.3.3 Analog output connection

Item	Specification
Analog output range	0 to 4.0 V
Resolution	2.5 mV (all outputs)
Zero-offset	± 5 mV
Internal impedance	< 1Ω (all outputs)
Output current capability	2 mA (Short circuit proof)
15-pin HD-connector	Corresponding signal
Pin 1 Pin 2 Pin 3 Pin 4 Pin 5 Pin 6 Pin 7 Pin 8 Pin 9 Pin 10 Pin 11 Pin 12 Pin 13 Pin 14 Pin 15 Shield	NC (Not Connected) NC (Not Connected) NC (Not Connected) External input (Red) NC (Not Connected) Output 1 (Black) Output 2 (Gray) A-GND A-GND A-GND A-GND A-GND A-GND Output 3 (Blue) Output 4 (Green) Shield

9.4 Mechanical specifications

Item	Specification
Finometer® Model-2 Main unit Depth Width Height Weight	 350 mm 300 mm 100 / 160 mm (sloped surface) 8 kg
Frontend Unit Depth Width Height Weight	 65 mm 50 mm 30 mm 900 g (includes cable)
Analog I/O unit Depth Width Height Weight	 145 mm 90 mm 30 mm 280 g (includes cable)
Finger Cuff Size Weight	 S, M, L 18 – 23 g (depending on size)
Note: all specifications rounded upwards	

9.5 Electrical specifications

Item	Specification
Power requirements (optionally)	220 – 240 VAC, 50/60 Hz, 100 VA 100 – 120 VAC, 50/60 Hz, 100 VA
Main unit fuse 230V (optionally for 115 V)	IEC 127, 0.8 A slow blow IEC 127, 1.6 A slow blow
Power cord	IEC 320 to local mains plug (see Table 9.3 Power cord set)
Protection against electric shock (EN 60601-1)	Degree of protection: type B applied part. Type of protection: Class I equipment.
Protection against ingress of water and/or objects	IP20
Power dissipation	In main unit: < 100 W. In Frontend Unit: 1 W. In finger cuff: < 50 mW.
CMOS back-up battery	3.6 V non-rechargeable Lithium. One of the following types are used: Sonnenschein SL-389 / Tadiran TL5134. Sonnenschein SL-386 / Tadiran TL5135. Tadiran SL-889. Expected life time: 20 years.

The following power supply cords can be used for the countries specified in the table:

Object / part NO	Manufacturer / trademark	Type / model	Technical data	Standard	Mark(s) of conformity
Cord set (Europe)	Eurlectric	2pole, class I H05VV-F	Plug: 10/16 A,250V Cord: 3xmin 0,75 mm2 appliance Coupler: 10A,250V	IEC603 20 HD21	KEMA, VDE, (CENELEC)
Cord set (UK)	WELL SHIN	2pole, class I H05VV-F	Plug: 10A,250V Cord: 3xmin 0,75 mm2 appliance Coupler: 10A,250V	IEC 60320 C13	ASTA
Cord set (Europe)	Different Manufac-turers	2pole, class I H05VV-F	Plug: 10/16 A,250V Cord: 3xmin 0,75 mm2 appliance Coupler: 10A,250V	IEC603 20 HD21	CENELEC approved
Cord set * (USA,CAN)	Ta Hsing	2pole, class I SVT	Plug: 10A, 125V Cord: 3 x AWG 18 appliance Coupler: 10A, 125V	IEC603 20 C13	UL,CSA
Cord set * (USA,CAN)	Different Manufac-turers	2pole, class I SVT	Plug: 10A, 125V Cord: 3 x AWG 18 appliance Coupler: 10A, 125V	IEC603 20 C13	UL,CSA

Table 9.3 Power cord set

- For patient care equipment, where a "Hospital Grade" or "Hospital Only" MAINS PLUG exist for the particular electrical rating in question, the MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT with a protective earth connection shall comply with the requirements for a hospital grade attachment plug (mains plug) or the non-hazardous location locking type designated "Hospital Only" as specified in the Standard for Attachment Plugs and Receptacles UL 498.

9.6 Environmental specifications

Operation temperature	10°C to 40°C
Storage temperature	-20°C to 70°C
Humidity	5 to 90 % non-condensing
Ambient pressure	700 to 1100 hPa

Note: The device may not meet its performance specifications if stored or used outside the ranges specified above.

9.7 EMC / EMI declaration

This section describes the information regarding potential electromagnetic or other interference and advice regarding avoidance.

General information

The EMC conformity of the Finometer® Model-2 includes the use of the following external cables, transducers and accessories:

Cable / accessory	Description
Power cord	Country specific type
RS232 null modem cable	Up to 3m length
BNC cable	Up to 1 m length
Analog I/O connection box cable	Standard length 1 m
Frontend Unit connection cable	Standard length 2.75 m
ECG module connection cable	Standard length 2.75 m

The non-observance may result in increased emissions or decreased immunity of the Finometer® Model-2.

The Finometer® Model-2 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Finometer® Model-2 should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic emissions

The Finometer® Model-2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Finometer® Model-2 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Finometer® Model-2 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.
RF emissions CISPR 11	Class A	The Finometer® Model-2 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Information reference: electromagnetic emissions (IEC 60601-1-2:2001, table 201)

Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Finometer® Model-2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Finometer® Model-2 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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 IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines, not applicable for cables with length of < 3m and patient coupled cabling.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % *Ut* (>95 % dip in *Ut*) for 0,5 cycle 40 % *Ut* (60 % dip in *Ut*) for 5 cycle 70 % *Ut* (30 % dip in *Ut*) for 25 cycle < 5 % *Ut* (>95 % dip in *Ut*) for 5 sec	< 5 % *Ut* (>95 % dip in *Ut*) for 0,5 cycle 40 % *Ut* (60 % dip in *Ut*) for 5 cycle 70 % *Ut* (30 % dip in *Ut*) for 25 cycle < 5 % *Ut* (>95 % dip in *Ut*) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Finometer® Model-2 requires continued operation during power mains interruptions, it is recommended that the Finometer® Model-2 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: *Ut* is the a.c. mains voltage prior to application of the test level			

Information reference: electromagnetic emissions (IEC 60601-1-2:2001, table 202)

Guidance and manufacturer's declaration – electromagnetic immunity			
The Finometer® Model-2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Finometer® Model-2 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Finometer® Model-2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	d = 1,2 √P
Radiated RF IEC 61000-4-3	3 V/m 80 MHZ to 2,5 GHz	3 V/m	d = 1,2 √P 80 MHZ to 800 MHz d = 2,3 √P 800 MHz to 2,5 GHz 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 metres (m). 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[aa]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situation. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base station for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses 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 the Finometer® Model-2 is used exceeds the applicable RF compliance level above. The Finometer® Model-2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Finometer® Model-2. [aa] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Information reference: electromagnetic emissions (IEC 60601-1-2:2001, table 204)

Recommended separation distance between portable and mobile RF communications equipment and the Finometer® Model-2

The Finometer® Model-2 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Finometer® Model-2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Finometer® Model-2 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 = 1,2 √P	**80 MHz to 800 MHz** d = 1,2 √P	**800 MHz to 2,5 GHz** d = 2,3 √P
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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 separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situation. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Information reference: electromagnetic emissions (IEC 60601-1-2:2001, table 206)

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Note : see website (www.finapres.com) for additional references.

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