Non-Invasive Blood Pressure OEM board

NIBP Module MD

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Date:	2023-01-25	Date:	2023-01-25	Date:	2023-01-25
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Revision History of this Document

Dok.-Rev.	Date	Author	Remarks
1.0	02.09.13	L. Engel	Creation
1.1	26.06.14	T. Karczewski	Update chapter 5. Standards
1.2	03.07.14	T. Karczewski	Update of the whole document, name change from NIBP2020 to NIBP2020 UP
1.3	06.03.15	L. Engel	Chapter 1. General: updated with more details
1.4	29.06.15	L. Engel	Update Chapter 1. General; Chapter 2: picture with round pump added; Chapter 3: round pump added; Chapter 11: commands completed
2.0	24.09.15	L. Engel	New command 38 added; New command 57 added; New command 58 added; Chapter 16: Programmable tourniquet for Pulse Wave Analysis (PWA) added;
2.1	29.01.16	L. Engel	Chapter 3,7,11 and 16: updated
2.2	28.04.16	L. Engel	Chapter 12.3 Cuff Pressure Transmission updated
2.3	12.10.16	L. Engel	Leaving the programmable tourniquet mode before duration time has elapsed
2.4	24.01.17	L. Engel	Max. operating current, time required for BD measurement and heart rate accuracy updated
2.5	05.02.18	L. Engel	Chapter 3: Technical data more detailed Chapter 6.2: updated with more details
2.6	22.06.18	L. Engel	Method 3 added
2.7	03.12.18	L. Engel	Chapter 12.6: updated with two examples
2.8	28.10.20	U. Langenfeld	Basic formatting done, revision of the

			document, Update to FW 6.4 Chapter 1: Updated with more details Chapter 1.3: Added (SpO_2 Module) Chapter 3: Update more details, Update of Clinical Data Chapter 5: Update more details Chapter 6: Added (Cuffs) Chapter 7: IMT with Command 66 added (FW 6.4) Chapter 17: Added (SpO_2 Module)
2.9	30.04.21	U. Langenfeld	Commands added in Chapter 12
2.10	11.01.22	T. Fischer	Updated information about vital sign simulator testing in Chapter 3
2.11	2022-04-29	U. Langenfeld	Adding of NIBP2010 and NIBP2020 UP HW B FW 6.4, adding information about the SpO2 module and sensor, Address change
2.12	2023-01-25	U. Langenfeld	Sec 1 updated, Secs. 2.4, 7.5 to 7.7 added.

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CE 0482

Inhalt

1 General

This document is intended for professional technicians / engineers who integrate the module into a host system.

This document describes and defines specifications for the medical device NIBP OEM Blood Pressure Board (short: NIBP Module). The NIBP module can optionally be equipped with SpO_2 functionality.

The following variants are covered by this Technical description:

NIBP2010 HW C01 FW 3.44

NIBP2020 UP HW A1 FW 6.3a

NIBP2020 UP HW A1 FW 6.4, NIBP2020 UP HW A1+ FW 6.4,

NIBP2020 UP HW B FW 6.4, NIBP2020 UP HW B+ FW 6.4

1.1 Intended Purpose

A blood pressure measurement module, integrated as a subsystem in a host system, is intended to be used in combination with a suitable blood pressure cuff for the automatic non-invasive measurement of the blood pressure (single or repeated measurement of the systolic, diastolic and mean value), the heart rate and other vital or non-vital sign parameters of human beings in the clinical daily routine.

It is designed as a subsystem that must be integrated into a host system (f. e. patient monitor) which fulfils the essential requirements on safety for medical electric devices (EN 60601-1).

The intended patient groups are adults (age ≥ 12 years), children (3 years ≤ age < 12 years), infants (age ≤ 3 years) and neonates (age ≤ 28 days) whose arm circumference is between 3 cm and 54 cm. The NIBP modules are appropriate for dialysis patients and pregnant women (NIBP2020 UP).

The modules can be used if the physical state of the patient admits an automatic non-invasive blood pressure measurement. The preparation and the application of the resulting total system including the additional functionalities must be carried out by trained medical personnel. The modules do not make a diagnosis but provides the measurement data, which are the base for the physicians to make a diagnosis. Statements about the physical state of a patient should always be made in combination with other diagnoses. A module is used in combination with a cuff, therefore, the intended purpose of the cuffs must be considered, especially the described contraindications.

The NIBP module can be provided with a module and the respective sensor for the determination of the oxygen saturation in human beings (all age groups) by means of pulsoxymetry. Additionally, there is a tourniquet mode so that f. e. the host system can perform a pulse wave analysis to determine the arterial stiffness of adult patients. These measurements must be performed at rest and not at excessive activity. This mode should only be applied in adults, is not intended in intensive care and not intended for patients with arrhythmia or acute peripheral vascular disease.

The module can be reused on multiple patients.

1.2 Features of the NIBP Module

1.2.1 CE marking of the module

The NIBP module is a medical device (risk class IIa with regard to the MDR) and has undergone a conformity assessment procedure according to the MDR. Therefore, the module bears a CE mark with the number of the Notified Body and the EU Declaration of Conformity has been signed.

Therefore, if a manufacturer of a host system integrates the module into its host system, and conducts the conformity assessment procedure, he can refer to this fact. This means that the manufacturer of the host does **not need** to carry out the tests concerning the module. The manufacturer of the host needs only to test the host system after integration of the NIBP module. The manufacturer is responsible for the power supply of the module and for tests concerning the interactions of module and host. E.g. an EMC test of the entire system (module and host) must be carried out, the module was only EMC tested alone (without host).

This is a unique feature of the NIBP module.

1.2.2 Other features

- New additional Programmable tourniquet mode for Pulse Wave Analysis (PWA)
- Low noise emission, the generated noise has been reduced to a minimum
- New power down modus and resistant against artefacts
- The NIBP module operates very reliable and extremely patient-safe in the adult and neonatal mode: dual safety circuits for pumps, valves and pressure sensors.
- Additional supervisor system for more safety

- The accuracy and reproducibility of the measuring results is very good and has been demonstrated by extensive clinical tests according to ISO 81060-2 and the ESH-Protocol:
  - The uniformity of results in the neonatal mode is very high through calibration with arterial reference measurements (clinical trials in the Charité hospital Berlin)
  - For the deflation and the inflation mode, accuracy was proven through a studies with a large number of test persons with comparative measurements (85 test persons each with 6 readings parallel to sphygmomanometer evaluation)
- The long-life span of the valves and pumps employed has been achieved by using tried and tested parts.
- Artefacts are already recognized during the measuring sequence and effect a further validation of the readings.
- Automatic adjustment of the start pressure depending on data of a previous measurement, if a previous measurement is available.
- Automatic measuring mode, in which the repetition of measurements is controlled by a counter; the user can select between various times of repetition.
- Continuous mode, in which as many measurements as possible will be carried out within 5 minutes
- Determination of the heart rate from the oscillations transferred by the cuff
- Software compatible to NIBP2000 – modules

1.2.3 Additional Features of the NIBP2020 UP module

- Non-invasive blood pressure measurement by oscillometric measurement during deflation
- New additional measuring method possible: inflation measurement technology (IMT; blood pressure measurement already during inflation of the blood pressure cuff)
- Halving of the measuring time (patient involvement/contact) in IMT mode
- Inflation only up to an adjusted pressure level minimal above the systolic pressure
- Possible switch of the measuring method to known measuring during deflation
- High technical know-how allows the measurement of pregnant women and patients with weak oscillations (stiffened vessels) like dialysis patients
- Software compatible to NIBP2010 and NIBP2000 – modules

- Optional: Modules can also be supplied with an RS-232 interface instead of TTL (see chapter 3 “Interface to monitor”).

1.2.4 Features of the NIBP2020 UP with SpO_2 - Functionality

- The NIBP2020 UP-module with SpO_2 –functionality features pulse oximetry technology in a very small and low powered design.
- The board consists of a multilayer PCB with surface-mounted components with a total size of 80 mm × 60 mm × 33 mm (module with round pump).
- A new enhanced split-pulse-wave algorithm with fuzzy logic control technology is integrated and provides high quality and best results.
- The SpO_2 – module provides oxygen saturation, pulse rate, signal quality, pulse waveform and other output information via the serial digital interface.
- The SpO_2 - module operates on a split-pulse-wave algorithm. Additionally, plausibility calculations provide exact measurements.
- Depending on the application, three different response modes are available: sensitive, standard (default) and stable. The sensitive mode provides best accuracy with sensitive artefact rejection. To achieve very stable values, the stable mode is offered. During each mode, fast changes of oxygen saturation and pulse rates will be detected and transmitted.
- Every second current values of oxygen saturation and pulse rate will be transmitted for all response modes.
- The SpO_2 - measurement requires certain signal quality for high accuracy. Several criteria’s are implemented to detect the human pulse waveforms. Signals which do not meet these criteria, e.g. due to high motion artefacts, provide a low detection quality.
- For each measurement, quality information is transmitted to evaluate the measured oxygen saturation and pulse rate. The quality information data ranges from 1 % to 100 % and indicates the quality of the SpO_2- signal.

1.3 Serious Incidents

Any serious incident occurring in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2 Illustrations of the module

2.1 NIBP2010

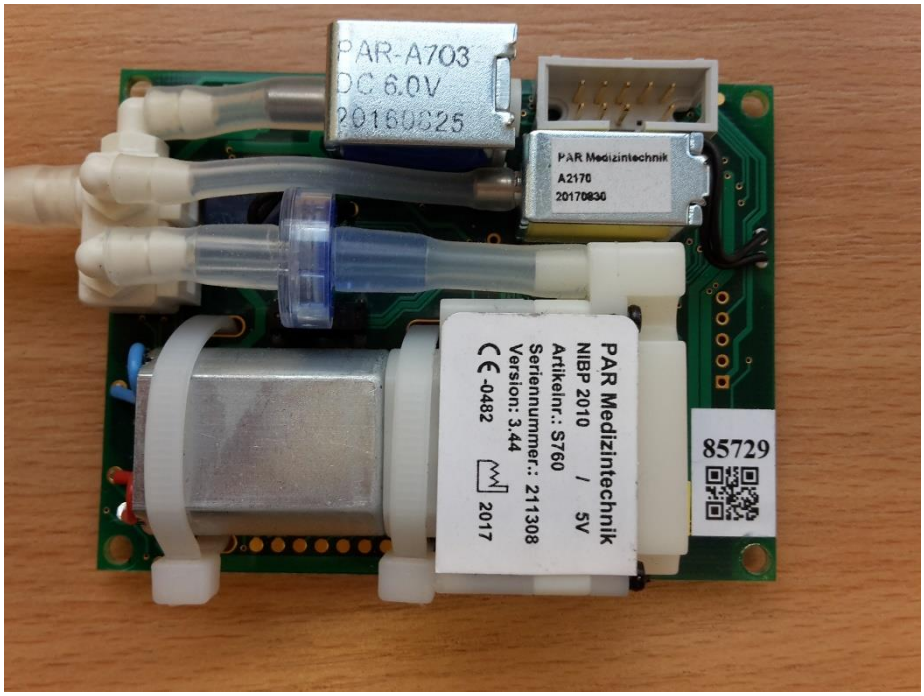


Figure 1: NIBP2010 module with flat pump

2.2 NIBP2020 UP

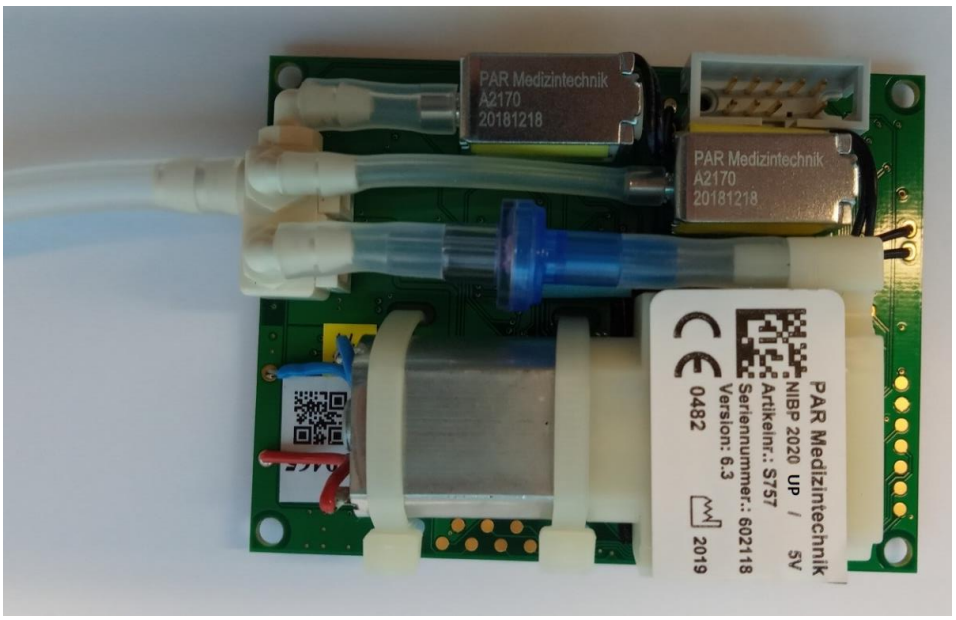


Figure 2: Module NIBP 2020 UP with flat pump

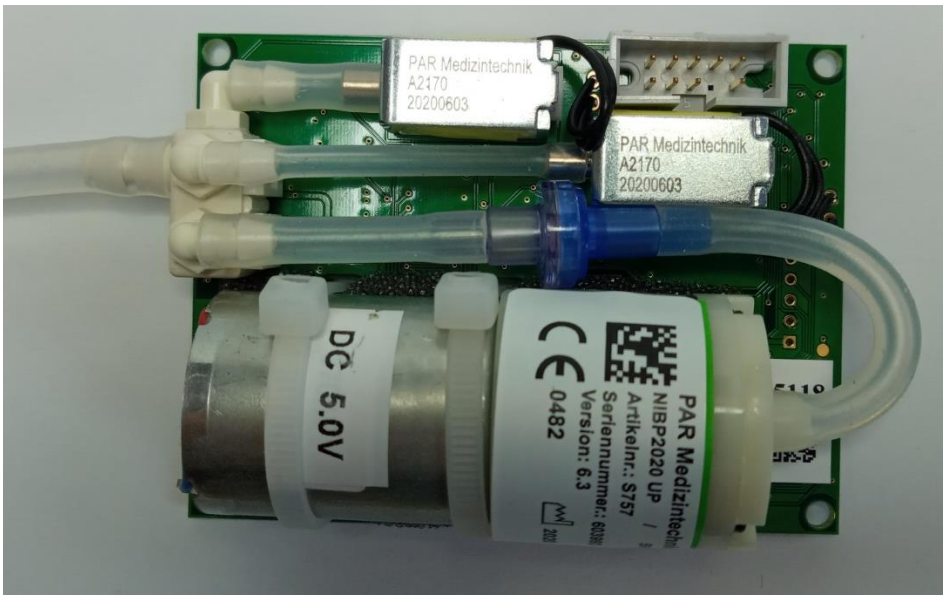


Figure 3: Module NIBP2020 UP with round pump

Figure 4: Module NIBP2020 UP with additional SpO_2-module on the right-hand side

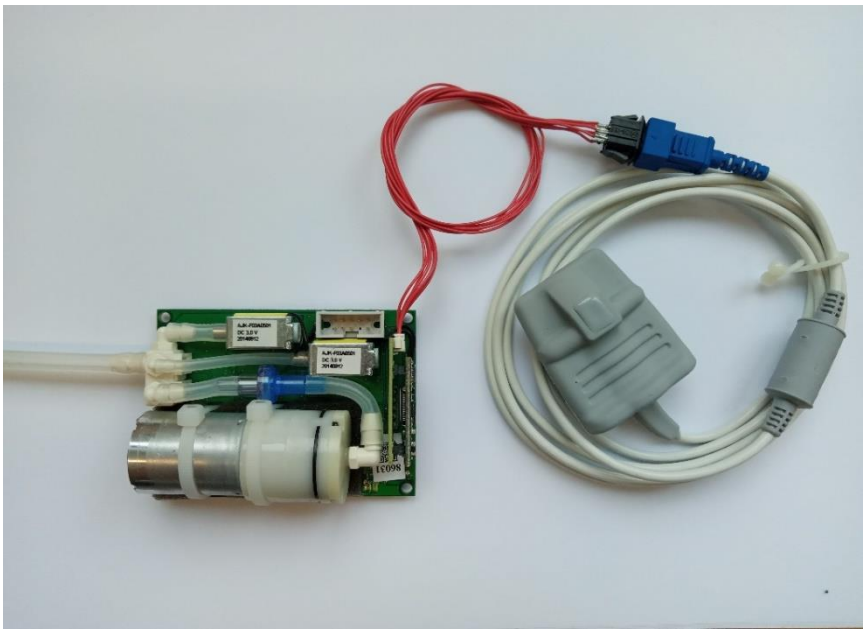


Figure 5: NIBP2020 UP with SpO_2-module, connection cable with MiniMed connector and finger sensor

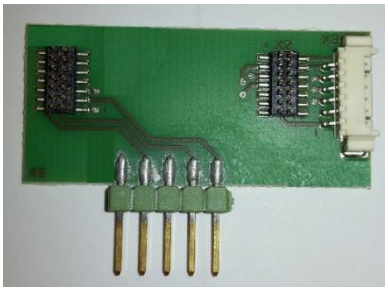
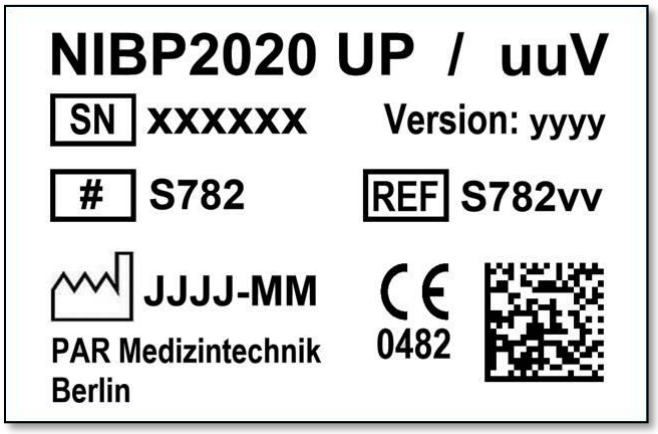


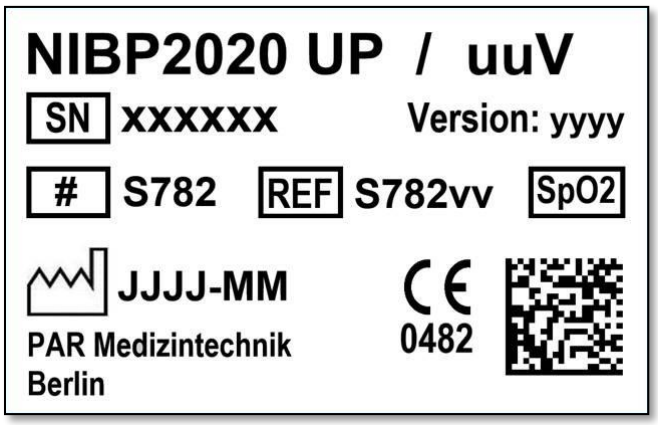
Figure 6: SpO2-module

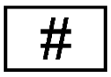
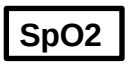
Figure 7: NIBP2020 UP Module, HW B

2.3 Module Label

The module labels have the following design:

<table>
<tr><th>Design</th><th colspan="2">Explanation of the Symbols</th></tr>
<tr><td rowspan="6"> 




</td><td> 
</td><td>Article number</td></tr>
<tr><td> 
</td><td>Model number</td></tr>
<tr><td> 
</td><td>Serial number</td></tr>
<tr><td>  </td><td>Date of manufacturing</td></tr>
<tr><td> 
</td><td>NIBP2020 UP with additional SpO_2-module</td></tr>
<tr><td> 
</td><td>CE-Symbol with number of Notified Body</td></tr>
<tr><td colspan="3">uu, xxxxxx, yyyy, vv, and JJJJ-MM are place holders for the voltage, serial number, version number, article number and manufacturing date, respectively. This label is attached on the pump of the board and on the protection bag.</td></tr>
</table>

2.4 Optional accessory

For the NIBP2020 UP, there is a housing as optional accessory available.

2.4.1 Technical data

Dimensions	Width × Length × Height = 85 × 113 × 43 mm
Connectors	• USB-C (according to USB-C specification) for power supply and data transfer from and to the module. The USB-C connector is connected to the interface connector of the module (see Chapter 10.2.2). • NIBP Connector for the Cuff

2.4.2 Pictures of the housing

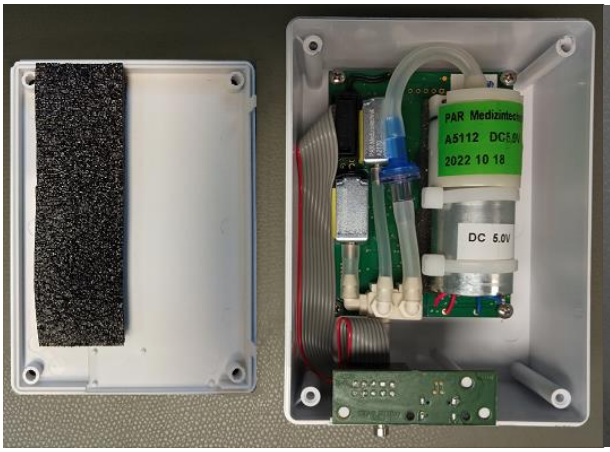


Figure 8: Housing with NIBP2020 UP, HW A1

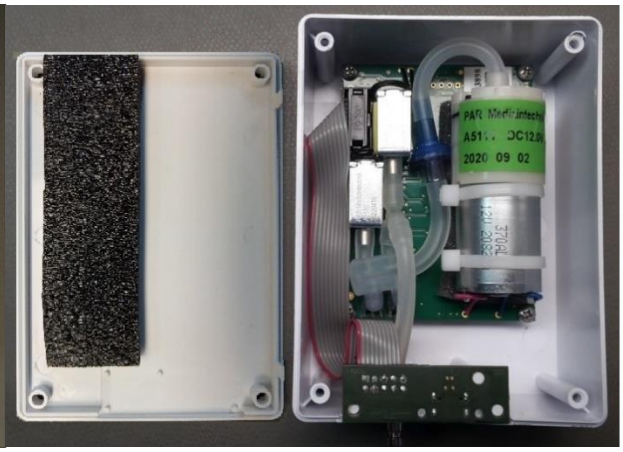


Figure 9: Housing with NIBP2020 UP, HW B

Figure 10: Housing

3 Technical Data (Specifications)

Mechanical data: (Module with flat pump)	Module dimensions: 80 mm × 60 mm × max 25 mm (l × w × h) Weight: NIBP2010: 107 g (117 g with SpO_2-Functionality) NIBP2020 UP: 90 g (100 g with SpO_2-Functionality) Deflation mode only (see Chapter 7). See also Figure 1 and Figure 2.	
Mechanical data: (Module with round pump)	Module dimensions: 80 mm × 60 mm × max 33 mm (l × w × h) Weight: 110 g (120 g with SpO_2-Functionality) See also Figure 3.	
Connector:	One 10-pin twin-row plug for all connections	
Attachment:	Four M2.5 screws in the corners of the PCB	
Operating voltage (DC):	+5 V Nominal (5.0 V to 7.0 V) or +12 V Nominal (11.0 V to 13.0 V)	
Max. operating current (DC):	750 mA (@ 5 V) or 530 mA (@ 12 V) Peak max. 1 A (@ 5 V) or 750 mA (@ 12 V)	
Power down – mode:	Less than 1 mA	
Temperature range:	0 °C to 60 °C	
Relative humidity:	95 % max, no condensing	
Operating mode:	Supervised continuous operation	

From these specifications, the requirements on the host system follow immediately.

Type of measurement:	Oscillometric	
Pressure range:	0 … 300 mmHg	
Measurement ranges during deflation:	Adults	Neonates
pSYS:	25 – 280 mmHg	20 – 150 mmHg
pDIA:	10 – 220 mmHg	5 – 110 mmHg
pMAP:	15 – 260 mmHg	10 – 130 mmHg
Measurement ranges during inflation: (NIBP2020 UP)	Adults	Neonates
pSYS:	77 – 200 mmHg	Measurement during
pDIA:	45 – 190 mmHg	inflation not applicable
pMAP:	56 – 193 mmHg	
Minimum difference between pSYS and pDIA:	10 mmHg ±3 mmHg	

Pressure accuracy in static measurements (e.g. manometer mode) and accuracy of pSYS, pDIA and pMAP (determined with 20 measurements over the measurement range of the module done with the vital sign simulator CuffLink or ProSim from Fluke under laboratory conditions), mean deviation:	max. ±3 mmHg or 2%, whichever is greater	According to IEC 80601-2-30 Clause 201.12.1.102 **Remark:** See Service Manual chapter 3.4 for vital sign simulator settings

Pressure transducer accuracy:	± 1 mmHg
Resolution:	1 mmHg
Leakage rate of the system:	≤ 3 mmHg / min
Overpressure limits:	300 mmHg adult mode and 150 mmHg neonatal mode
Shutdown and pressure release after exceeding (first fault condition):	330 mmHg adult mode and 165 mmHg neonatal mode
Time required for BD measurement:	Typical (normal) inflation mode 15-20 s, Deflation mode 20-30 s max.: adults 90 s, max.: neonates 60 s
Heart rate range during deflation:	30 … 240 bpm
Heart rate range during inflation:	45 … 200 bpm
Accuracy of heart rate (determined with 20 measurements over the measurement range of the module done with the vital sign simulator CuffLink or ProSim from Fluke under laboratory conditions), mean deviation:	Max. ±3 bpm or 3%, whichever is greater
MTBF :	250 000 cycles of blood pressure measurements
Interface to monitor:	Default: TTL (5 V) level Optional: Serial RS-232 (± 12 V) Hint: The usage of the optional serial RS-232 interface requires a hardware change. A variant of the module that supports the optional interface has to be ordered from the manufacturer. 4800 baud with standard protocol, also other baud rates and protocols available (e.g. Colin or others), hardware reset
Calibration interval:	2 years

3.1 Blood Pressure Part of NIBP2020 UP with SpO_2 – Functionality (if different from above)

Interface to monitor:	Default: TTL (5 V) level Optional: Serial RS-232 (± 12 V) Hint: The usage of the optional serial RS-232 interface requires a hardware change. A variant of the module that supports the optional interface has to be ordered from the manufacturer. 19200 baud, hardware reset

3.2 Pulse Oximetry Part of NIBP2020 UP with SpO_2 – Functionality

O_2-Saturation range:	0 – 100 %
O_2-Saturation accuracy:	60 … 100 %: $A_{rms} \leq 2$ % (no motion) 60 … 100 %: $A_{rms} \leq 2$ % (low perfusion, no motion) 70 … 100 %: $A_{rms} \leq 3$ % (motion condition) < 60 %: unspecified
Heart rate range/accuracy: 30 – 240 bpm	$A_{rms} \leq 2$ bpm (no motion) $A_{rms} \leq 2$ bpm (low perfusion, no motion) $A_{rms} \leq 3$ bpm (motion condition)
Quality range:	1 % … 100 %
Response modes:	stable, standard (default), sensitive adjustable by monitor
Status information:	for details see SpO_2-Communication Protocol Status information are detected in the module and reported to the monitor via the communication link.
Transmission:	Resolution: SpO_2-Value: 1 Hz Pulse rate: 1 Hz Quality signal: 1 Hz Plethysmogram: 75 Hz (Sample rate)
Connector:	MiniMed
Temperature:	-25 °C to 60 °C (operating) -40 °C to 70 °C (storage)
Humidity	15 % to 95 % (operating, non-condensing) 10 % to 95 % (storage, non-condensing)

3.3 Measurement Accuracy (from Clinical Investigations)

3.3.1 Results of Clinical Investigation according to ISO 81060-2

- Patient group: **Children (age > 3 years) and adults (age ≥ 12)**

Measurement	Mean deviation	Standard deviation
Inflation Method		
Systolic Blood Pressure	+ 0.36 mmHg	4.27 mmHg
Diastolic Blood pressure	- 0.12 mmHg	3.78 mmHg
Deflation Method		
Systolic Blood Pressure	+ 0.10 mmHg	3.24 mmHg
Diastolic Blood pressure	- 0.20 mmHg	2.95 mmHg

- Special patient group: **Neonates and Infants (age ≤ 3 years)**, deflation method only.

Measurement	Mean deviation	Standard deviation
Systolic Blood Pressure	+ 0.47 mmHg	2.93 mmHg
Diastolic Blood pressure	+ 1.52 mmHg	3.77 mmHg

- Special patient group: **Pregnant women**, inflation method

Measurement	Mean deviation	Standard deviation
Systolic Blood Pressure	+ 0.70 mmHg	5.28 mmHg
Diastolic Blood pressure	+ 0.08 mmHg	4.26 mmHg

- Special patient group: **Dialysis patients**, deflation method

Measurement	Mean deviation	Standard deviation
Systolic Blood Pressure	+ 0.39 mmHg	2.57 mmHg
Diastolic Blood pressure	+ 0.43 mmHg	1.7 mmHg

3.3.2 Results of Clinical Investigation according to the ESH-Protocol

- Patient group: **Adults,** inflation method[1]

Measurement	Mean deviation	Standard deviation
Systolic Blood Pressure (SBP)	- 0.2 mmHg	4.6 mmHg
Diastolic Blood pressure (DBP)	+ 0.6 mmHg	3.1 mmHg

Of the 99 differences, 86/92 (SBP/DBP) are ≤ 5 mmHg, 95/99 ≤ 10 mmHg, 97/99 ≤ 15 mmHg. In 33/31 test subjects, at least 2 of 3 comparative measurements achieved differences ≤ 5 mmHg, none of the test subjects reached differences > 5 mmHg in all three comparisons.

[1] The report is publicly available under https://journals.lww.com/bpmonitoring/Abstract/2019/04000/Validation_of_noninvasive_oscillometric_blood.10.aspx

3.4 Disposal

The module must not be disposed of with the household waste, but separately with the electronic waste disposal. For information on the disposal of the storage medium, please contact the customer service of PAR Medizintechnik GmbH & Co. KG (service@par-berlin.com).

WEEE-Reg.-Nr.: DE63208995

The cuffs can be disposed as contaminated hospital waste.

4 Transport and Storage Conditions

Temperature range:	-25 °C to +70 °C
Relative humidity:	95% max, no condensing

5 Standards

The NIBP module is a medical device in form of an electronic board. It is a subsystem, which has to be built in a host system. The manufacturer of the host system is responsible that the total host system fulfils the essential safety and performance requirements of the MDR. The following standards are fulfilled as far as they can be applied to the NIBP module as a subsystem.

EN ISO 81060-2

IEC 80601-2-30

ISO 80601-2-61 (SpO_2- measurement)

IEC / EN 60601-1

IEC 60601-1-2

EN ISO 14971

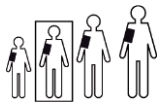
EN ISO 13485

6 Application of the Cuff

The module is used in combination with a suitable cuff (and an extension tube, where applicable) for a blood pressure measurement. In the following Sections, the use of the cuffs is explained. Only cuffs and tubes provided by PAR Medizintechnik are admitted for the use in combination with the module, because only the combination with these cuffs are clinically validated and the conformity according to the MDR can be declared only for these combinations.

6.1 Symbols used on the Cuff

Follow the instructions given in the operator manual.



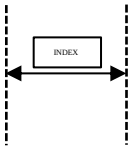
Blood pressure cuff fits adult patient of the size marked by the frame (Small, Standard, Large, or Extra-large).

Blood pressure cuff is suitable for the indicated arm circumference.

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

When the blood pressure cuff is applied, this arrow must be located over the brachial or femoral artery.

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



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

Latex-free blood pressure cuff.

CE marking, cuff fulfils EU regulation.

6.2 Cleaning the Cuffs

The admitted cuffs are reusable on multiple patients if not otherwise stated on the cuff. Before reuse, the cuffs shall be cleaned and disinfected.

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

6.3 Applying the Cuff

- Select the appropriate cuff size (see cuff label). When the cuff is too small, the blood pressure values will be overrated, when it is too big, the measured values will be too low.

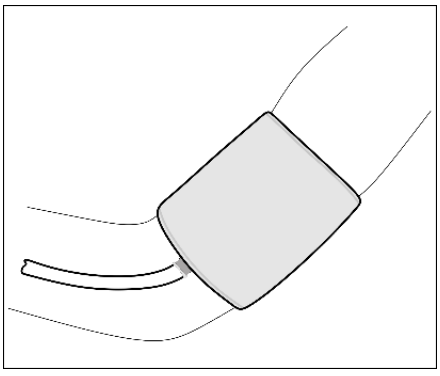


Figure 11: Applying the Cuff

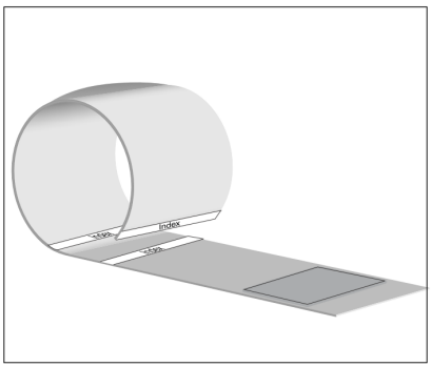


Figure 12: Relevance of the index

Caution

Incorrect measurements:

- *Replace cuffs on a regular basis. Damaged hook-and loop-fasteners may cause incorrect readings.*
- *When using a small cuff, only the deflation measurement method should be used.*

- Place the cuff on that arm of the patient, which is used less frequently during normal daily activities: on adults about two fingers' breadth above the bend of the elbow, on children a little closer. Bending the arm must not change the cuff level. Verify that:
  - The cuff tubing points down, see Figure 11.
  - No compression or restriction of connection tubing can occur.
  - The side with the Patient label is on the skin.
  - The arrow is located above the brachial or femoral artery.
  - The dashed white line at the end of the cuff is located between the two dashed Index Lines, when you close the cuff (if this is not the case, select another cuff size, see Figure 12)
  - The cuff fits snugly around the arm, but does not compress the blood vessels.
  - The cuff and the NIBP module are used inside the ambient conditions for operation and inside the measuring range (see chapter "Technical Specifications").

Warning

Risk to Person:

- *The effect of blood flow interference can result in a harmful injury to the patient caused by continuous cuff pressure due to connection tubing kinking.*
- *Too frequent measurements can cause injury to the patient due to blood flow interference.*
- *The application of the cuff over a wound can cause further injury. The application of the cuff and its pressurization on the arm on the side of a mastectomy is not recommended.*
- *The pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.*
- *By watching the limb, it is necessary to check that operation of the NIBP2020 UP does not result in prolonged impairment of patient blood circulation.*

6.4 Patient Information

Advice your patient

- not to move while a measurement is being taken to avoid motion artefacts that may lead to erroneous readings and to keep the cuff inflation time as short as possible
- That the pressure tubing may only be removed in emergency situations (see warning above)

6.5 Absolute Contraindications

The application of the cuff is prohibited on an arm with

- Dialysis shunt
- Fresh operation wounds
- Mastectomy

6.6 Relative Contraindications

If the doctor ascertains a positive benefit-risk ratio, the application of the cuff is allowed on the arm with:

- Lymphedema
- Paresis or plegia
- Arterial or venous vascular access

Other diagnostic or therapeutic measures do not negatively affect the blood pressure measurement.

7 Measuring Methods

7.1 Method 1: Measurement during deflation

The method provides an automatic, oscillometric blood pressure measurement with high accuracy. An external blood pressure cuff is inflated up to a defined pressure markedly above the systolic blood pressure of the patient. Blood pressure is measured during deflation by deflating the cuff in small steps of about 2 – 3 mmHg/sec and simultaneously detecting the pressure values.

When using Method 1 in the Manual, Cycle or Continuous mode (see Chapter 8), the default value for the first measurement is 160 mmHg, if this value is not suitable, the user can change the start inflation pressure for the first measurement. After restart or reset, the module switches to 160 mmHg. For the following measurements (in the cycle- and continuous mode), the module sets automatically the inflation pressure to the last measured systolic value plus 15 mmHg.

The user can switch the measuring method to measurement during inflation (Method 2) with the appropriate code (see Table 4 in Chapter 12) and vice versa.

Within the neonatal mode, the module always works with Method 1.

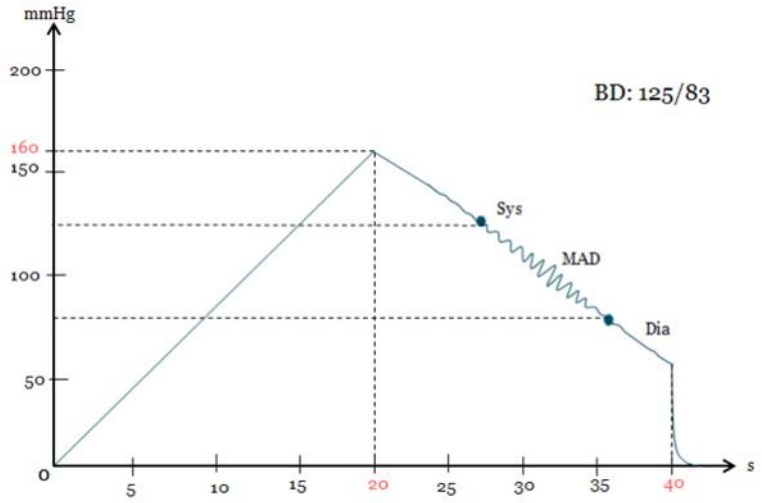


Figure 13: Waveform representing the pressure in the cuff during a measurement using the deflation measurement method: systolic pressure at 125 mmHg, diastolic pressure at 83 mmHg

7.2 Method 2: Measurement during inflation (IMT, NIBP2020 UP)

The method provides an automatic, oscillometric blood pressure measurement with high accuracy. Blood pressure measurement is made already during inflation of the blood pressure cuff. The inflation pressure is markedly reduced, because the method provides only inflation up to a pressure level minimal above the systolic pressure of the patient. Immediately, the cuff deflation starts, which reduces the measuring time to typically 20 seconds. The characteristics of the pressure trend are shown in Figure 14.

When using Method 2, the inflation pressure is set automatically in all modes and the measurement is completed one oscillation above systolic blood pressure.

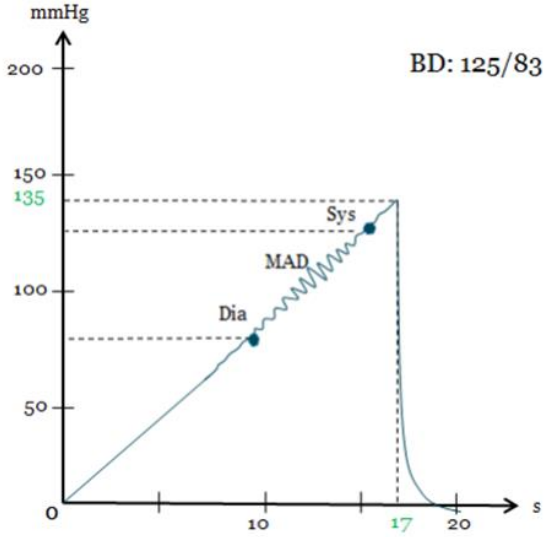


Figure 14: Waveform representing the pressure in the cuff during a measurement using the inflation measurement method: systolic pressure at 125 mmHg, diastolic pressure at 83 mmHg

When the module is switched on (power on), this measuring method is set by default. The familiar application with Method 1 is also possible by switching the operation mode to measurement during deflation with the appropriate code (see Table 4 in Chapter 12) and vice versa.

If at least one of the following circumstances occurs, the modules switches automatically from Method 2 to Method 1:

- Systolic pressure out of the range 77 -200 mmHg
- Diastolic pressure out of the range 45 -190 mmHg
- Heartrate out of the range 45 -200 bpm
- Number of detected oscillations < 8
- Difference between systolic and diastolic pressure < 10 mmHg ± 3 mmHg
- The quality of oscillations is too low, e.g. caused by too strong movement artefacts

7.3 Measurement during Inflation with Selection of the Maximum Start Pressure (NIBP2020 UP)

It is possible to select the maximum pressure during inflation by sending the command “66” after starting the module (see Chapter 12.4 for a list of the commands). The default value for the maximum pressure is then set to 160 mmHg. Then, the module will pump to a maximum pressure of 160 mmHg + peak. If no oscillations are found, the module will switch to the deflation mode.

In this mode, the user can change the start pressure by sending a start pressure command (see Chapter 12.4) in the range between 120 mmHg and 200 mmHg. Commands for lower (higher) maximum start pressures will be ignored and a value of 120 mmHg (200 mmHg) is set as maximum start pressure.

The maximum start pressure can be changed by sending a new start pressure command. After reset of the module, the command “66”-mode is left and 200 mmHg are set as the usual default maximum start pressure.

7.4 Method 3: Measurement during deflation with self-adapted inflation pressure (NIBP2020 UP)

This deflation method uses the inflation method at the beginning of a measurement. The start inflation pressure is determined by the module itself, namely during the cuff inflation by method 2 (IMT). The cuff deflation starts 15 mmHg higher than the expected systolic value. The module switches automatically from Method 2 to Method 1. The advantage is that this method is more comfortable for the patient because the cuff is not inflated to unnecessary high pressures.

7.5 Conducting blood pressure measurements

In order to measure the blood pressure, a blood pressure cuff wrapped around the upper arm needs to be inflated and subsequently deflated. It is important to select the fitting cuff size and to apply the cuff in the correct way, see Chapter 6 for more details. The blood pressure is determined either during deflation of the cuff or, by using the novel and faster technology, already during inflation of the cuff. With this technique, the cuff is inflated to a pressure, which must be clearly above the expected systolic value. During blood pressure measurements, the cuff must be at heart level. If this is not ensured, the hydrostatic pressure of the liquid column in the blood vessels will lead to incorrect results. (Each 10 cm difference

result in a pressure deviation of 8.0 mmHg.) When the patient is sitting, lying, or standing during measurements, the cuff is automatically at the correct level.

7.6 On the interpretation of NIBP simulator data

A NIBP simulator (or patient simulator) simulates the oscillometric cuff pulses during inflation and / or deflation of the cuff of a NIBP monitor. It is not used to substitute clinical evaluations but to test the performance stability of the monitor (see [1]), i. e the repeatability of measurements. The accuracy of a NIBP monitor is demonstrated in clinical investigations according to a specified protocol, f. e. ISO 81060-2 [4].

If one checks a NIBP monitor with a NIBP simulator, one has also to take the measurement error of the simulator into account. The total measurement error should be smaller than 2 mmHg related to the mean value.

A NIBP monitor can be tested statically using a hand bulb for the pressure generation or dynamically using a NIBP simulator[2]. One advantage of a NIBP simulator is its generation of repeatable signals simulating healthy patients or patients with pathological findings or other artefacts. If a NIBP simulator generates physiological as well as pathological signals then a suitable designed measurement series can be used to substitute parts of a clinical trial [2]. A NIBP simulator can only simulate a limited group of patients.

The deviation of the measured blood pressure with the monitor from the pre-set value at the simulator in a static measurement shall be ≤ 3 mmHg. At each pressure level, there shall be conducted at least three measurement and then form the mean value as the measurement result.

In a dynamical test, the limits from ISO 81060-2 apply: The mean of the pair-wise differences shall be ≤ 5 mmHg, the standard deviation ≤ 8 mmHg. This mean deviation can be interpreted as a systematical offset of the device from the “true” value, the standard deviation the scattering around this offset. This means f. e. for a device with mean deviation 0 mmHg and standard deviation 8 mmHg that 68 % of the measured values are within the ± 8 mmHg limits (± 1 standard deviation), and 95 % within ± 16 mmHg (± 2 Standard deviations). Deviations of 5 – 10 mmHg from the “exact” value set at the simulator are to be expected, as long as the limits from ISO 81060-2 are met in a large sample.

[2] Statical tests are possible using a NIBP simulator.

One cannot expect that a NIBP monitor measures and displays identical values using different patient simulators with the same settings. The reason is that different simulators use different algorithms.

One should also keep in mind that the classical sphygmomanometry, recommended as gold standard in validation procedures (f. e. [4]), has its limitations. This procedure depends on the hearing abilities of the operator, the amplitude and wave form of the Korotkoff sounds and the sensitivity of the stethoscope [5].

According to German law, the NIBP module as a medical device with a measuring function must be calibrated every two years [3]. This is also recommended by Ref. [1].

7.7 Literature

[1] International Recommendation OIML R 16-2. Non-invasive automated Sphygmomanometers, 2002.

[2] White Paper: Non-Invasive Blood Pressure (NIBP) Monitoring and Testing. Fluke Biomedical.

[3] Medizinproduktebetreiberverordnung

[4] ISO 81060-2: Non-invasive sphygmomanometers – Part 2: Clinical investigation of intermittent automated measurement type

[5] Celler BG, Argha A, Le PN, Ambikairajah E (2018). Novel methods of testing and calibration of oscillometric blood pressure monitors. PLoS ONE 13(8): e0201123. https://doi.org/10.1371/journal.pone.0201123

8 Measuring Modes

The NIBP module carries out blood pressure measurements at adults and neonates according to the oscillometric measuring method in four different modes.

8.1 Manual Mode

The user decides when he would like to trigger a measuring and starts a single measuring. If a current regular measuring is not finished yet, a new manual measuring is carried out after completion of the regular.

8.2 Cycle Mode (Long-term Automatic Mode)

The user selects the temporal distance between the single measurements and starts a series of measurements. The module provides automatically a minimum distance of 30 seconds between the single measurements. This mode can be stopped with a command (Abort Command "X").

8.3 Continuous Mode (Short-term Automatic Mode)

The user starts this mode and the module carries out as many measurements within 5 minutes as possible. A distance of 5 seconds is provided between the single measurements. This mode can be stopped with a command (Abort Command "X"). After 5 minutes, the module leaves the continuous mode automatically and goes into a standby-mode.

8.4 Programmable Tourniquet Mode

The user defines a pressure and a hold time and starts programmable tourniquet. Optionally the user selects to make a single blood pressure measurement followed by programmable tourniquet. After the holding time at the specified pressure has elapsed or after receiving the abort command “X”, the module stops the current measurement and goes into a standby-mode.

9 Safety / Calibration

The safety for the patient and user is achieved by several measures at the NIBP module.

- Two independent pressure measuring channels on the circuit board are permanently compared against each other.
- There are two valves on the module, if the deflation valve fails, a second valve (safety valve) deflates the cuff. The function of the safety valve is supervised separately from the deflation valve.
- The driving circuits of the pump are supervised.
- After power on or reset of the module, the program is verified by a self-test with calculating a checksum.
- The program flow is supervised by a watchdog.
- There is a second processor, called “Supervisor”, which supervises measuring time, duration of each measurement and the time interval between two measurements in a series of measurements.

In order to achieve a steady safety, effectiveness and accuracy, the user should arrange a calibration of the module every two years. The calibration can be done automatically with commands or manually. A detailed description for calibrating the module is available in the Service Manual.

10 Hardware Interface

The system integrator is responsible for the correct installation of the NIBP module into the host system. It should be performed by trained staff of the system integrator. The host system must have place and a mounting option for the module. Furthermore, the host system has to provide a proper voltage and current supply (see Chapter 3: Technical Specifications). For the control of the module, the host must have a TTL (5 V) or serial RS-232 (± 12 V) interface. The available interface depends on the ordered variant of the module (see chapter 3 "Interface to monitor"). After installation of the NIBP module, the system integrator is responsible for the basic safety according to the standard EN 60601-1 & the EMC compatibility according to the standard EN 60601-1-2. The power supply of the host system must be a medical power supply. The specific safety requirements for blood pressure measurements (see IEC 80601-2-30) are fulfilled by the module independent of the host system.

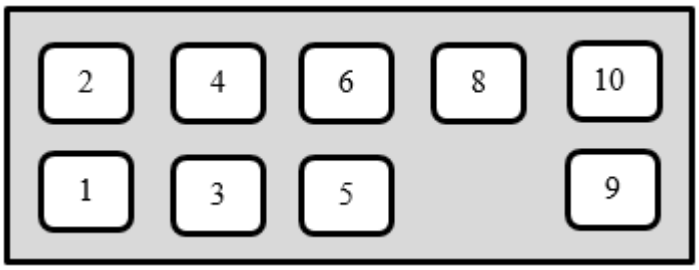
10.1 Serial Transmission

The normal connection of the NIBP module without SpO_2-functionality to the board is done via serial, asynchronous communication with a baudrate of 4800 Baud (19200 Baud for the NIBP module with SpO_2-functionality). The interface lines operate on TTL voltage levels (5 V) or on serial RS-232-level (± 12 V) that depends on the ordered variant of the module (see chapter 3 "Interface to monitor"). A bidirectional connection is necessary, because commands like cycle mode or start a measurement have to be transmitted to the module.

10.2 Interface Connector and Explanation of the Pins

10.2.1 NIBP 2010

Interface Connector



Pin 1	Power supply (DC) Pump: + 5 V	or	+ 12 V
Pin 2	Power supply (DC) Pump: + 5 V	or	+ 12 V
Pin 3	Power supply (DC) Logic: + 5 V	or	+ 12 V
Pin 4	GND		
Pin 5	NC		
Pin 6	NC		
Pin 8	Reset (TTL – Logic, high active), minimum duration of high active: 500 ms		
Pin 9	RxD (TTL – level)		
Pin 10	TxD (TTL – level)		

DIL-Switch

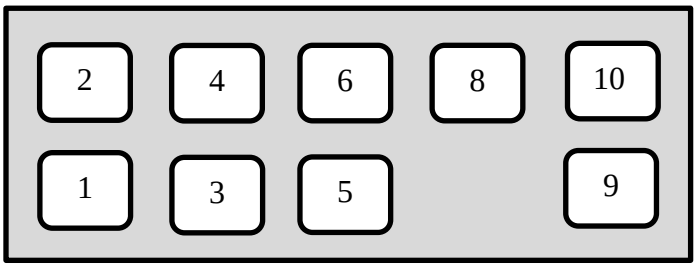
The position of the 8 switches depends on the operation voltage and on the hardware reset logic:

SW1 and SW3 have always to be **off**

Operating voltage 5 V:	SW2 = **on**	SW4 = **on**	SW5 = **on**
Operating voltage 12 V:	SW2 = **off**	SW4 = **off**	SW5 = **off**

Reset logic active high:	SW6 = **on**	SW7 = **off**	SW8 = **off**
Reset logic active low:	SW6 = **off**	SW7 = **on**	SW8 = **on**

10.2.2 NIBP2020 UP



Pin 1	Power supply (DC) Pump: + 5 V	or	+ 12 V
Pin 2	Power supply (DC) Pump: + 5 V	or	+ 12 V
Pin 3	Power supply (DC) Logic: + 5 V	or	+ 12 V

Pin 4 GND

Pin 5 NC, optional: RxD (RS232-level)

Pin 6 NC, optional: TxD (RS232-level)

Pin 8 Reset (TTL – Logic, high active), minimum duration of high active: 500 ms

Pin 9 RxD (TTL – level)

Pin 10 TxD (TTL – level)

Hint: If you use the NIBP2020 UP with the optional housing (see Chapter 2.4), the USB-C specifications apply, see Figure 15.

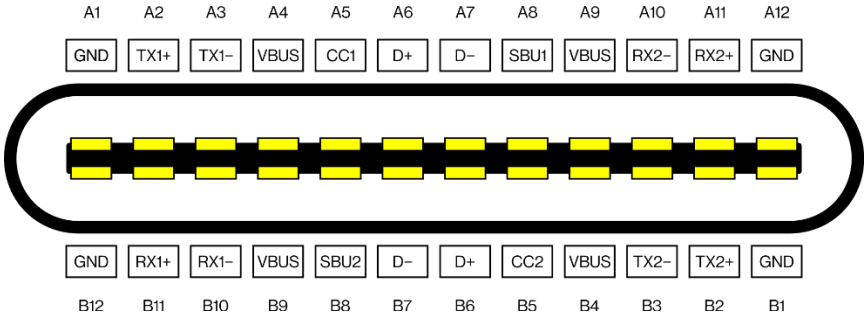


Figure 15: Pin assignment of an USB-C connector

11 Software Interface of the NIBP module (Blood Pressure Part)

11.1 Explanation of Terms

ASCII	Character Standard
Frames	Character strings which are exchanged as commands or messages between host and module
Cycle Mode	The measuring unit starts automatic readings. The user is free to select the readout intervals. This mode is controlled solely by the monitor

11.2 General Conventions

All commands and messages begin with a Start of Text character, 0x02, and close with an End of Text character, 0x03. In this document, the designation for Start of Text is <STX> and End of Text <ETX>. The frames from the NIBP module module to monitor are terminated by a carriage return, <CR>= 0x0D.

11.3 Checksum

The checksum is calculated via a “modulo 256” summation through all the previous characters and then concatenated at the end of the string. The <STX> character is not included.

12 Protocol Direction from Monitor to the NIBP module

12.1 General Conventions

The measuring unit is controlled by the monitor via command frames. Should the NIBP module receive unexpected commands these will be ignored. In addition to this, false or unknown commands as well as violations of the timeout criteria will abort the current session in progress. All data and commands are verified via checksum.

12.2 Commands

A command consists of an eight ASCII character frame. This includes a Start of Text and an End of Text character as well as two characters for the checksum.

12.3 Frame Scheme

Table 1: Format of a Frame

Char 1	Char 2	Char 3	Char 4	Char 5	Char 6	Char 7	Char 8
<STX>	c_0	c_1	;	;	x_0	x_1	**<ETX>**

Table 2: Explanation of the Frame scheme

<STX> (Start of Text)	= 0x02 (without SpO_2) = 0xFD (with SpO_2)
c_0 and c_1	= command code (2 ASCII characters. Range of values from 00 to 99)
; and ;	= 2 times semicolon
x_0 and x_1	= checksum (2 ASCII characters)
<ETX> (End of Text)	= 0x03 (without SpO_2) = 0xFE (with SpO_2)

Table 3: Example for command code 01 (Start BP measurement)

Command Code	**<STX>**	0	1	;	;	D	7	**<ETX>**
Hex Notation	0x02	0x30	0x31	0x3B	0x3B	0x44	0x37	0x03

12.4 Command codes for the NIBP module

Command Code	Checksum	Function
00	D6	Reserve
01	D7	Start BP measurement with a start pressure calculated by the module [1] (Start tourniquet measurement, if tourniquet mode is selected before)
02	D8	Reserve
03	D9	Select manual measuring mode
04	DA	Select cycle mode 01 minute
05	DB	02
06	DC	03
07	DD	04
08	DE	05
09	DF	10
10	D7	15
11	D8	30
12	D9	60
13	DA	90
14	DB	Select manometer mode
15	DC	Power down mode [2]
16	DD	Software reset
17	DE	Leakage test
18	DF	Request data from module [3]
36	DF	Set start pressure to 060mmHg (only neonatal)
37	E0	Set start pressure to 080mmHg (only neonatal)
19	E0	Set start pressure to 100mmHg (only neonatal)
20	D8	Set start pressure to 120mmHg (only neonatal)
30	D9	Set start pressure to 080mmHg (only adult)
31	DA	Set start pressure to 100mmHg (only adult)
32	DB	Set start pressure to 120mmHg (only adult)
21	D9	Set start pressure to 140mmHg (only adult)
22	DA	Set start pressure to 160mmHg (only adult)

23	DB	Set start pressure to 180mmHg (only adult)
33	DC	Set start pressure to 200mmHg (only adult)
34	DD	Set start pressure to 220mmHg (only adult)
35	DE	Set start pressure to 240mmHg (only adult)
38	E1	Set start pressure to 280mmHg (only adult)
24	DC	Select adult measuring mode
25	DD	Select neonatal measuring mode
26	DE	Reserved
27	DF	Select continuous mode and start measurement
28	E0	Version number (EPROM)- short form
29	E1	Version number (EPROM) – NIBP module
57	E2	Select programmable tourniquet mode [4]
58	E3	Select programmable tourniquet mode following BP measurement [4]
NIBP2020 UP specific commands		
55	E0	Method 1: Measurement during deflation
56	E1	Method 2: Measurement during inflation (IMT)
65	E1	Method 3: Measurement during deflation with self-adapted inflation pressure
66	E2	Select the Maximum Start Pressure (IMT) [5]
71	DE	Request Serial number
73	E0	Request PCB number
90	DF	Set pumping time to 30 s [5]
91	E0	Set pumping time to 45 s [5]

Table 4: Command code with checksum and its function for NIBP module without SpO_2-Functionality

Remarks

It is not recommended to send commands during blood pressure measuring or leakage test or during the manometer mode.

Exception: Abort Command "X" (see "Abort Command")

The minimal time distance between two commands must be greater than 1 second.

[1] For the first measurement, the start pressure is 160 mmHg (adult) and 120 mmHg (neonate), unless a "set start pressure" command is sent before. For a follow-up measurement, the start pressure is calculated as "last systolic value plus 15 mmHg".

[2] Power down mode is not possible in the cycle mode. Power down mode can be terminated by sending the "**Abort Command"**. The NIBP module responds with sending a status frame, see "**Status Transmission"**.

[3] Important: wait for an answer of the module before sending another command.

[4] The modes 57 and 58 can be left by a software reset.

[5] NIBP 2020 UP with FW 6.4 only

Command codes for NIBP2020 UP with SpO_2-Functionality (if different from Table 4)

Command Code	Checksum	Function
60	DC	Set start pressure to 080 mmHg (only adult)
61	DD	Set start pressure to 100 mmHg (only adult)
62	DE	Set start pressure to 120 mmHg (only adult)
30	D9	SpO_2 data stream off
31	DA	SpO_2 data stream on

Table 5: Command code with checksum and its function for NIBP2020 UP with SpO_2-Functionality if different

12.5 Abort Command

Regardless of the operational mode, the session can be terminated by sending (the) "X" (character). The measuring unit immediately reverts to the mode: Standby. The pneumatic system discharges.

Example: **"X" or <STX>X<ETX>**

12.6 Software Reset Command

The software reset command is: **<STX>16;;DD<ETX>**.

The software starts to run at the beginning. The module is set to the adult mode. Finally, the module is in the standby mode. The measurement method is kept and the module is ready to receive and answer further commands, e.g. start a measurement.

If the module has detected an incorrect checksum of the program (then the module transfers the error message M15, see chapter “Error Messages”), the software reset does not work. In this case, the module resets only by a power-on reset or hardware reset.

12.7 Timing and Error Correction

During all operational modes, the excess pressure detection and system error detection are activated. In the following cases, the measuring unit reacts as under the item **"Abort command".**

Reception of:

- Mutilated frames
- Erroneous checksum
- Unknown command
- Violation of timeout criterion
- The period between two characters of a receive frame exceeds 10 ms.

12.8 Setting the Pumping time

The maximum pumping time can be changed by sending one of the following commands:

- **<STX> 90;;DF<ETX>:** sets the maximum pumping time to 30 s
- **<STX> 91;;E0<ETX>:** sets the maximum pumping time to 45 s

After power-on and after soft or hardware reset, the pumping time is set to its default value 15 s.

12.9 Request serial and PCB number

- The serial number can be read out by sending the command **<STX> 71;;DE<ETX>**.
- The PCB number can be read out by sending the command **<STX> 73;;E0<ETX>**.

The module responds with **<STX> XXXXXX<ETX><CR>** (serial number) or

<STX> XXXXX<ETX><CR> (PCB number), where X denotes a digit from 0 – 9 encoded as hex-value.

13 Direction from the NIBP module to Monitor

13.1 General Conventions

There are three types of frames, which, in different situations, are generated by the NIBP module:

- Cuff pressure transmission (5 times per second, 200 ms)
  The transmission period is about 200 ms. Since measurement and safety functions are prioritized in the module, the module only transmits when it is not busy with such tasks. Therefore, the transmission period can deviate from 200 ms.
- End of cuff pressure transmission
- Status transmission

Depending on the operational status, the status frame shows the version number or the error code in within the message code (see under remarks of the various points).

13.2 Initialization Message

On power up, the NIBP module always starts a self-test of the module (hardware and software) and generates a status frame within a few seconds. Immediately thereafter, the monitor can communicate with the module. From this message, the user can recognise if the module is working correctly, especially when the module is just built in and is started for the first time.

Message after Power on: **<STX>S5;A0;C00;M10;P---------;R---;T ;; B4<ETX><CR>**

Message after sending of command “Request data from module”:

<STX>S1;A0;C00;M00;P---------;R---;T ;;AF<ETX><CR>

For further explanation, see Chapter 13.5.

13.3 Cuff Pressure Transmission

This frame is permanently displayed during a current measurement. The basic frame structure is (using ASCII-characters):

<STX>$d_0d_1d_2Cc_0Sa_0$<ETX><CR>

Note, that there is a <CR> at the end of frame.

<STX>	Start of Text
$d_0d_1d_2$	3 ASCII digits which represent the current cuff pressure (Leading zeros are transmitted)
C	Identifier for the caution digit c_0
c_0	Caution Digit:
$c_0 = 0$	Correct cuff **(Inflation method)**
$c_0 = 1$	Module recognized the neonatal cuff in adult operation **(Inflation method)**
$c_0 = 2$	Module recognized the adult cuff in neonatal operation **(Inflation method)**
$c_0 = 3$	Correct cuff **(Deflation method)**
$c_0 = 4$	Module recognized the neonatal cuff in adult operation **(Deflation method)**
$c_0 = 5$	Module recognized the adult cuff in neonatal operation **(Deflation method)**
S	Identifier for the status digit a_0
a_0	Status Digit:
$a_0 = 3$	Measuring
$a_0 = 4$	Manometer operation
$a_0 = 7$	Leakage test
$a_0 = 8$	Inflating to supra-systolic pressure
$a_0 = 9$	Holding supra-systolic pressure
<ETX>	End of Text
<CR>	Carriage return

Example: **<STX>035C0S3<ETX><CR>**

<STX>	Start of Text: “0x02”
035	Current cuff pressure 35 mmHg
C0	Correct cuff is connected

S3 Module is in the measuring mode

<ETX> End of Text: “0x03”

<CR> Carriage return

13.4 End of Cuff Pressure Transmission

This message is generated after the cuff pressure transmission has been completed and thus after the blood pressure has been measured. The measuring unit then reverts to standby.

Frame structure (real ASCII):

<STX>999<ETX><CR>

13.5 Status Transmission

After booting, the leakage test, and a measurement, it may be recognized from a frame, whether it was a successfully or unsuccessfully completed action. This is expressed in the error code field.

The status is displayed on request by the monitor by sending command code 18.

The frame structure is (real ASCII in inverted commas, all lines consecutive):

<STX>,

"**S**", a_0, ";",

"**A**", b_0, ";",

"**C**", c_0, c_1, ";",

"**M**", d_0, d_1, ";",

"**P**", e_0, e_1, e_2, e_3, e_4, e_5, e_6, e_7, e_8, ";",

"**R**", f_0, f_1, f_2, ";",

"**T**", g_0, g_1, g_2, g_3, ";", ";"

h_0, h_1,

<ETX><CR>

Explanation:

<STX> = Start of Text

<ETX> = End of Text

<CR> = Carriage Return

a_0 = ASCII Digit

$a_0 = 0$ Auto - test in progress (immediately after reset)

$a_0 = 1$ Waiting for commands (standby), cycle counter stopped

$a_0 = 2$ Error (evaluation of error bits), cycle counter stopped

$a_0 = 3$ Measurement in progress

$a_0 = 4$ Manometer mode

$a_0 = 5$ Initialization (immediately after reset) in progress

$a_0 = 6$ Cycle-/continuous- mode

$a_0 = 7$ Leakage test

$a_0 = 8$ Inflating to supra-systolic pressure

$a_0 = 9$ Holding supra-systolic pressure

b_0 = ASCII Digit for the Operational Mode

$b_0 = 0$ Adult Mode

$b_1 = 1$ Neonatal Mode

c_0 and c_1 = 2 ASCII Digits for Cycle Mode in Minutes (for admissible values, see Table 4 in Chapter 12)

$c_0c_1 = 00$ No cycle selected

d_0 and d_1 = 2 ASCII Digits for Messages (After reset, “10” appears here)

$d_0d_1 = 00$ Uninterrupted operation

$d_0d_1 = 02$ Receiving invalid command

$d_0d_1 = 03$ Uninterrupted operation

$d_0d_1 = 06$ Cuff fitting too loosely or is not connected, time for pumping exceeded

$d_0d_1 = 07$ Cuff leakage

$d_0d_1 = 08$ Pneumatics faulty

$d_0d_1 = 09$ Measuring time exceeded, current pressure smaller than the lower limit of diastole, too less oscillations detected

$d_0d_1 = 10$ Systolic and diastolic value are outside the pressure range

$d_0d_1 = 11$ Too strong movement artefact

$d_0d_1 = 12$ Maximum pressure exceeded

$d_0d_1 = 13$ Two saturated oscillation amplitudes are detected. Waveform check

$d_0d_1 = 14$ Leakage during the leakage test

$d_0d_1 = 15$ System error

e_0 to e_8 = each 3 ASCII digits represent the values for pSystole (systolic pressure), pDiastole (diastolic pressure), pMean (mean pressure).
If the last measurement did not succeed in determining values, these digits will be reported as dashes.

f_0, f_1, f_2 = 3 ASCII digits for the heart rate. If there is no heart rate determined, these digits will be reported as dashes.

g_0 to g_3 = 4 ASCII digits for the period in seconds until the next measurement starts (only in cycle- or continuous mode). If the cycle or the continuous mode have finished or are not active, 4 blanks are displayed.

h_0 and h_1 = ASCII digits for the checksum

Example:
<STX>S1;A0;C03;M00;P125080090;R075;T0005;;D2<ETX><CR>

<STX>	start of Text: “0x02”
S1	waiting for commands, module is in the standby mode
A0	adult mode
C03	cycle mode with 3 minutes
M00	uninterrupted operation, no errors
P125	last systolic pressure: 125 mmHg
080	last diastolic pressure: 80 mmHg
090	last mean pressure: 90 mmHg
R075	last heart rate: 75 bpm
T0005	the next measurement begins in 5 seconds
D2	checksum
<ETX>	end of Text: “0x03”
<CR>	carriage return

13.6 Error Message

If a fault appears during or between the blood pressure measurements, an error message will be sent upon request. The following error messages can occur:

M00, M03 = Uninterrupted Operation.
The module continues its measuring in the selected mode

M02 = Receiving invalid command
An invalid command can be

- An interrupted command or
- A command with a wrong format or
- A wrong timing of the bytes within a command

After appearing M02, the module resets automatically, and then the module goes into the standby-mode and is ready to receive & answer further commands.

M06 = 1. Cuff fits too loose or is not connected
2. Time for pumping exceeded
This error message occurs during inflating; a pressure of at least 20 mmHg must be reached after 20 s. After 60 s, the final pressure must be reached.

M07 = Cuff leakage (including sudden occurrence), appears when inflating.

M08 = Pneumatics faulty, because of:
1. Faulty slow loss of pressure
Occurs, if the pressure deflation is too small in the deflation phase (e. g. because of a faulty deflation valve or because of a blockage)
2. Faulty high loss of pressure
Occurs, if the pressure deflation is too big (> 50 mmHg e.g. because of a leakage).
3. Offset pressure has changed too much.
The offset pressure is measured always shortly before the pump starts for a new blood pressure reading. M08 occurs if this offset pressure has changed too much against the initial offset reading (the initial offset pressure reading is done after power on the module or after a hardware reset or after a software reset, therefore it is recommended to eliminate this error with a reset)

M09 = 1. Measuring time exceeded (adult: 90 sec/neo: 60 sec)
2. The current pressure is smaller than the lower measuring range limit for the diastole pressure limit
3. Too less oscillations detected (cuff incorrectly fitted)

M10 = Systolic and diastolic pressure value are outside the pressure range (observed when deflating).

M11 = Too strong movement artefacts

M12 = The permitted maximum pressure is exceeded.
(Adult: 300 mmHg, Neonates: 150 mmHg, according to IEC 80601-2-30 limits)

M13 = Two saturated oscillation amplitudes are detected.

M14 = Leakage during the leakage test

M15 = System error, because of:

1. Faulty safety valve
2. Pump driving circuits faulty
3. Pressure channel faulty
4. In this leakage test the pressure increases for 30 seconds
5. Check sum of the program incorrect

The check sum will be checked after the module is powered on, after a hardware reset, or after a software reset. If the check sum is incorrect, the module goes into the sleep mode. The module is not ready to receive and answer further commands, therefore a blood pressure measurement is not possible and a software reset will not work.
The module will leave the sleep mode after power off/on or after a hardware reset.

At the appearance of M02 to M15 (except case 5 of M15), the NIBP module goes into the standby-mode. The module is ready to receive and answer further commands.

Example for an error message if there was no previous successful blood pressure measurement:

<STX>S2;A0;C05;M07;P---------;R---;T ;;BC<ETX><CR>

<STX>	Start of Text: “0x02” (without SpO_2) “0xFD” (with SpO_2)
S2	Error occurred; cycle counter stopped
A0	Adult mode
C05	Cycle mode with 5 minutes
M07	Cuff leakage during inflation
P---	No value for the systolic pressure

---	No value for the diastolic pressure
---	No value for mean pressure
R---	No value for heart rate
T	No value (4 blanks)
BC	Checksum
<ETX>	End of Text: “0x03” (without SpO_2) “0xFE” (with SpO_2)
<CR>	Carriage return

Example for an error message if the previous blood pressure measurement was successful:

In this case, the values pSystole, pDiastole, pMean and the heart rate of the previous measurement are shown in the error message:

<STX>S2;A0;C00;M07;P120078090;R060;T ;;FC<ETX><CR>

<STX>	Start of Text: “0x02”
S2	Error occurred; cycle counter stopped
A0	Adult mode
C00	No cycle selected
M07	Cuff leakage during inflation
P120	Last pSystole: 120 mmHg
078	Last pDiastole: 78 mmHg
090	Last pMean: 90 mmHg
R060	Last heart rate: 60 bpm
T	No value (4 blanks)
FC	Checksum
<ETX>	End of Text: “0x03”
<CR>	Carriage return

14 Manometer Mode (Extended Version)

For this manometer mode, send the commands:

1. **<STX>51;;DC<ETX>**
2. **<STX>14;;DB<ETX>**

The module answers with the following “Status Transmission”:

<STX>S4;A0;C00;M00;P---------;R---;T ;;B2<ETX><CR>

Then the module transmits the offset pressure.

Example: Offset for channel 1: 70 steps and channel 2: 75 steps

“Offset [0] : 70 [Stufen] Offset [1] : 75 [Stufen] <CR>”

- Remark: “Stufen” means “steps”.

The offset pressure range should be between 50 and 90 steps.

After sending the **Abort Command <X>,** the module sends the pressure of channel 1 and channel 2. Connect the pressure indicator and pump up to pressure around 250 mmHg

Example: for 250 mmHg “<CR> 1. : 250 [mmHg] 2. : 250 [mmHg]”

Remark: If pressure exceeds 300 mmHg, the valves will be opened and the module leaves the manometer mode by sending the “End of Cuff Pressure Transmission”- message. If the module receives the command “Request data from module” the module will answer with a “Status Transmission”, which shows an error (S2: an error has occurred, M12: the error is maximum pressure exceeded, see “Technical Description NIBP module” chapter “Error messages” and chapter “Status Transmission”).

Leaving the manometer mode:

After sending the **Abort Command: <X>** once more, the module leaves the manometer mode by answering with the “End of Cuff Pressure Transmission”-message.

After 10 min without sending the Abort Command, the module will leave the manometer mode automatically also by answering with the “End of Cuff Pressure Transmission”-message.

After leaving the manometer mode and before sending new commands, a “Power off and on” or a “Hardware-Reset” or a “Software-Reset” has to be done. Notice, that the cuff pressure is 0 mmHg at this moment.

15 Manometer Mode (Short Version)

15.1 Starting the manometer mode

For the manometer mode (short version), send the command:

<STX>14;;DB<ETX>

The module sends permanently the “Cuff Pressure Transmission” - string, according to the pressure of channel 1 only.

Remark: If pressure exceeds 300 mmHg, the valves will be opened and the module leaves the manometer mode by sending the “End of Cuff Pressure Transmission”- message. If the module receives the command “Request data from module” the module will answer with a “Status Transmission”, which shows an error message (S2: an error has occurred, M12: “Maximum pressure exceeded”, see “Technical Description NIBP module” chapter “Error messages” and chapter “Status Transmission”).

15.2 Leaving the manometer mode

After sending the **Abort Command: <X>**, the module leaves the manometer mode by answering with the “End of Cuff Pressure Transmission”- message.

After 10 min without sending the Abort Command, the module will leave the manometer mode automatically also by answering with the “End of Cuff Pressure Transmission”- message.

After leaving the manometer mode and before sending new commands, a “Power off and on” or a “Hardware-Reset” or a “Software-Reset” has to be done. Notice, that the cuff pressure is 0 mmHg at this moment.

16 Leakage Test

Wrap a cuff around a solid body with a diameter of about 7.5 cm and connect it with NIBP module.

Send the command for leakage test: **<STX>17;;DE<ETX>**.

The NIBP module inflates the cuff up to 200 mmHg and, after 60 Seconds, the NIBP module sends the “End of Cuff Pressure Transmission”- message, leaves the leakage test and returns to the standby mode. In order to get a result of the leakage test, send the command “Request data from module” to the module. The module will answer with one of the following “Status Transmission” messages:

<STX>S1;A0;C00;M00;P---------;R---;T ;;AF<ETX>CR

S1: The leakage test has detected no leakage error

M00: The result of the leakage test is ok (leakage is ≤ 3 mmHg/minute)

<STX>S2;A0;C00;M14;P---------;R---;T ;;B5<ETX>CR

S2: The leakage test has detected a leakage error

M14: The result of the leakage test is not ok (leakage is > 3 mmHg/minute)

17 NIBP2020 UP with SpO_2 functionality

The SpO_2-module together with the SpO_2-sensor provides the SpO_2-functionality and is described in detail in the document [SCP], see Chapter 17.4 for the reference.

17.1 Data Structure

The Chapter "Data packet structure" of [SCP] describes the format of a data packet sent from the SpO_2-module.

17.2 Relevant SpO_2 -Channel

For the interaction of the NIBP2020 UP module with the SpO_2 -module, Channel 10 of the SpO_2 -module is relevant. Its functionality is described in the Chapter "SpO_2 -Channel 0x10" of [SCP].

17.2.1 Applicable Identifiers

For an explanation of SpO_2 identifiers, see the Chapter "Data packet structure" of [SCP].

The applicable identifiers are listed in the following Table 6.

Table 6: Applicable Identifiers

Identifier	Meaning
0x01	Status information
0x02	Auto scaled plethysmogram with pulse peep indicator
0x04	Results and indicators

17.2.2 Warning

Do not change the default baud rate of the SpO_2 -module. Otherwise, the NIBP module will not work. Do not any programming outside the range described in this document.

17.3 Application of the SpO_2-Sensor

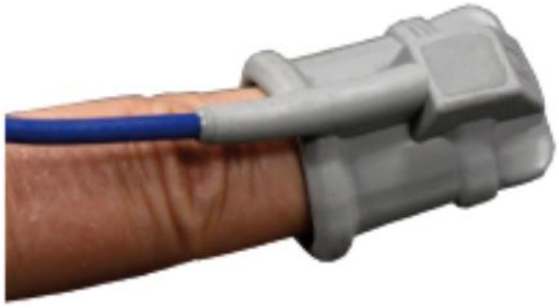


Figure 16: Application of the SpO_2-Sensor

- The pulse oximeter equipment is calibrated to display functional oxygen saturation.
- Connect the sensor cable directly to the monitor.
- Insert the patient's digit into the sensor (see Figure 16). The preferred digit to use for adults is the index finger. Alternative sites depend on finger sizes.
- The digit is correctly inserted when
  - The tip of the digit touches the rear guide posts.
  - The sensor cable extends along the top of the patient's hand.
- Secure the sensor cable with medical tape.

Visually monitor the sensor site to ensure the integrity of the skin.

17.4 Cleaning the SpO_2-Sensor

The instructions for cleaning and disinfection of the SpO_2-sensors follow the instructions of the manufacturer of the SpO_2-sensor [ISpO2].

17.4.1 Cleaning

Use 70 % Isopropyl alcohol as cleaning agent.

- Disconnect the sensor from the monitor before cleaning or disinfection.
- Distilled water rinse, of sensor, cable, and connector for two minutes.
- Surface clean cable with 70 % Isopropyl alcohol, wipe cable with cotton pad soaked in 70 % Isopropyl alcohol.
- Immerse sensor housing in 70 % Isopropyl alcohol for five minutes.
- Air dry – 10 minutes minimum.
- Repeat till specified number of cleaning cycles have been achieved.

17.4.2 Low level disinfection (1:10 bleach)

- Disconnect the sensor from the monitor before cleaning or disinfection.
- Distilled water rinse, of sensor, cable, and connector for two minutes minimum.
- Wipe cable with cotton pad soaked with 1:10 bleach solution.
- Immerse sensor housing in 1:10 bleach solution for five minutes.
- Distilled water rinse, of sensor, cable, and connector for five minutes.
- Drying, 10 minutes minimum.
- Repeat till specified number of cycles have been achieved.

17.4.3 High level disinfection

- Rinse sensor to remove dirt from the surface – the sensor housing may be fully immersed in liquid. Caution: Do not immerse the sensor cable connector in liquid.
- Clean the sensor and patient contact surfaces. Prolystica is recommended as a cleaning agent. Follow the manufacturer's instructions for use. Immerse sensor housing in the solution and wipe the inner and outer surfaces with a soft brush or cloth to remove any visible soil. Rinse sensor with water following cleaning and wipe dry prior to disifection.
- Cidex OPA is recommended for high level disinfection. Follow the manufacturer's instructions for use. Immerse sensor housing in the solution for 12 minutes and remove.

- Thoroughly rinse the sensor with water following disinfection (5 minutes minimum distilled water rinse/soak). Manually dry the sensor and verify that the sensor, cable, and connector are dry prior to use.

17.5 Warnings and Precautions

The following **WARNINGS** are specified in the instructions for use of the **SpO_2 -module**:

- The SpO_2 -module is designed and tested within the described operating parameters. Changes of the conditions and parameters may lead to faulty measurements or damage the module.
- The SpO_2 -module and all accessories may only be used by persons with sufficient expertise.
- The SpO_2 -module is only to be integrated in a host system and operated by qualified personnel.
- ESD protection for the SpO_2 -module boards should be provided by the host system. The SpO2 -module boards contain static sensitive devices and therefore should itself be treated as a static sensitive device. The module is not defibrillator proof.
- There is no patient isolation on the SpO_2 -module boards. The host system must provide electrical isolation for all connections to the module to meet the requirements of EN 60601-1 medical electrical equipment safety requirements and other electrical safety specifications as applicable. The sensor isolation must not be considered when evaluating patient isolation. The silicon layers on the LEDs and receiver do not qualify as insulation, since they can be damaged if not used as intended.
- For the SpO_2 measurement, the monitor uses red and infrared light (wavelengths 660 nm and 905 nm) with specific fixed wavelengths. Consider that these wavelengths might influence diagnostic parameters of other optical applications.
- The SpO_2 -module can show faulty measurements or can be damaged if it will be used outside the specification or environmental conditions.
- The SpO_2 -module may not be submerged in liquids, have liquids poured on it or be cleaned with liquid detergents. SpO_2 -module should be protected from condensation and humidity.
- Do not apply excessive tension to any of the monitor cables.
- Any radio frequency transmitting equipment or other nearby sources of electrical noise may result in disruption of the monitoring system.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the host monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The use of accessories, sensors, and cables other than those specified or provided could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.
- Only pulse oximeter accessories, sensors, and cables listed in the SpO_2 -module compatibility list may be used together with SpO_2 -module integrated in a host monitor. Sensors and accessories must be in undamaged condition. If other sensors and accessories are used, it could lead to malfunctions, problems with biocompatibility and create invalid readings. The operator is responsible for checking compatibility prior to use.
- Do not use sensors, cables or lines that appear to be damaged by transport or other means. Do not use sensors when optical components are exposed. Do not use a sensor or cable that appears damaged. Replace it immediately in cases of visible damage.
- Always disconnect the monitor and probes from the patient during magnetic resonance imaging (MRI) scanning. An induced current could potentially cause burns.
- Do not autoclave or steam sterilize the SpO_2 -module or its accessories? Refer to the specific 'Instructions for Use' of the used SpO_2 sensor for correct cleaning and/or sterilization.
- If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternative means, then ensure that the SpO_2 -module is functioning correctly.
- To prevent damage, avoid undue bending of the sensor cable.
- A functional tester (like Index II or equivalent) may not be used to validate SpO_2 accuracy. A functional tester can be used to verify the function of pulse oximeter probes.

The following **WARNINGS** are specified in the instructions for use of the **SpO_2 - sensors**:

- Pulse oximeter probes and extension cables are designed for use with specific monitoring systems. Incompatible components can result in degraded performance and electromagnetic incompatibility, or patient injury. The operator is responsible for checking compatibility prior to use.
- A functional tester cannot be used to assess the accuracy of pulse oximeter probes.
- Check the patient skin condition for reusable sensors at least every 6 hours and reposition to an alternative location if skin integrity changes.
- Misapplication of a pulse oximeter probe with excessive pressure (e.g. sensor too small or applied too tight) and for prolonged periods can cause pressure injury.
- Avoid application of the sensors to areas with poor skin integrity.
- Do not sterilize by irradiation, steam, or ethylene oxide – refer to cleaning and disinfection instructions. Use of agents other than specified may damage the sensor.
- Do not use the sensor or extension cable if it is damaged. Use of a damaged sensor or extension cable could cause patient injury or equipment failure.
- Excessive patient motion, excessive ambient light, electromagnetic interference (e.g. stacking and location to other medical equipment), dysfunctional hemoglobin, intravascular dyes, fingernail polish and long or artificial fingernails may affect the sensor performance and the accuracy of the measurement.
- Do not alter or modify the sensor or extension cable. Alterations or modifications may affect performance or accuracy.
- Do not use the SpO2 -module sensor, or extension cable or other oximetry sensors during MRI scanning. Conducted current may cause burns.

The following **CAUTIONS** are specified in the instructions for use of the SpO2 -module Sensors:

- Avoid possible interference from sources of electromagnetic interference such as, but not limited to: Cellular phones, radio transmitters, motors, telephones, lamps, electrosurgical units, defibrillators, and other devices. Interference may cause inaccurate measurements. If you are unsure if your device is working properly, contact your clinician.
- Sensors or extension cables may work with different monitors. Refer to the specific monitor instructions for use for essential performance, accessories, compliance information (EMC) and electrosurgical applications.

17.6 List of SpO_2-sensors and accessories

Article number PAR	Product name
A3332-s	SpO_2 - Extension Cable 1.2 m
A3336-s	SpO_2 - Softsensor SC7500 1,2 m, Minimed
A3337-s	SpO_2 - Softsensor SCM7500 1,2 m, Minimed

17.7 Contraindications

The SpO2-sensors are contraindicated for use on mobile patients or prolonged periods of use. They must be removed and repositioned to a different monitoring site at least every 4 hours.

17.8 Relevant Document

[SCP] SpO_2 - Communication Protocol

[ISpO2] Instruction for Use Reusable Pulse oximetry sensors

18 Programmable Tourniquet for Pulse Wave Analysis (PWA)

18.1 Programmable Tourniquet without BP measurement

In this mode, the host transmits directly a cuff pressure and a hold time to the NIBP module. The controller of the NIBP module responds to the host command, closes the valves, and runs the pump to inflate the connected upper arm cuff to the specified pressure. Safety features are enabled, as well as any other checks for air leaks, wrong size cuff (Adult mode with neonate cuff), etc. Once at the specified pressure, the pump is stopped and the valves remain closed. The host is able to terminate the programmable tourniquet by command. Otherwise, the elapsed holding time or the safety rule (less than 180 seconds above 15 mmHg) terminate the programmable tourniquet. The NIBP module notifies the host that it has entered the pressure hold state. The host may request a new cuff pressure or a new hold time without first cancelling the in-progress command. The NIBP module will then use the valves and/or pump to adjust the pressure in the cuff to the new set point. Safety checks remain active even if multiple set points are requested by the host. The controller of the NIBP module does not automatically adjust the cuff pressure after the NIBP module has reached the specified pressure.

E.g.: If the patient flexes their arm muscle or moves during a measurement, the controller ignores the temporary pressure changes.

If the pressure goes above the maximum permitted pressure value defined by the safety systems (300 mmHg), the dump valve opens and the cuff pressure is released as per the normal safety procedures for a NIBP module.

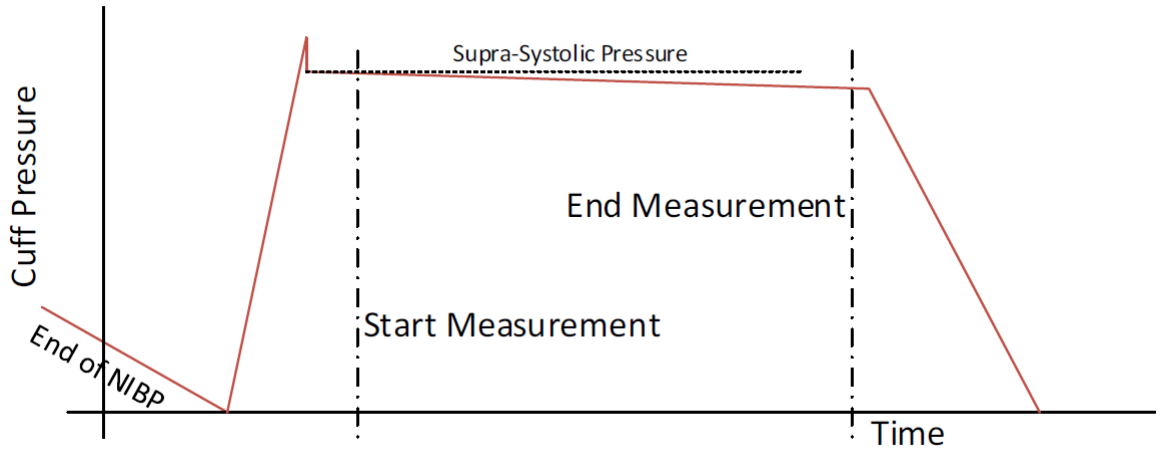


Figure 17: Graphical representation of pressure in the cuff

Typically, the host will let the cuff pressure settle at the supra-systolic pressure for 2 seconds, followed by 10 seconds of pulse pressure wave measurement by the host. Graphically, the pressure in the cuff would follows the red line, see Figure 17. It is assumed that the upper-arm systolic pressure was determined in some way prior to the supra-systolic measurement.

18.2 Programmable Tourniquet following BP measurement

It is possible to optimize the measurement time and patient comfort with a command that performs the upper arm BP measurement in inflation mode, then immediately inflates the cuff to a supra-systolic pressure without first deflating the cuff. This saves the time needed to deflate the cuff and re-inflate to the required supra-systolic pressure. The command has a supra-systolic margin as a parameter of the command and the host can change the value if desired.

Graphically, the pressure in the cuff would follow a profile similar to the red line in Figure 18 below if measurement on inflation is successful. The blue time markers show the period when the upper arm BP is measured, followed by inflation to the supra-systolic pressure at the specified margin (mmHg) above the measured upper arm systolic pressure.

The NIBP – module reports the current cuff pressure to the host for optional display to the end user. The NIBP – module reports the BP values as it goes into Status 8 to inflate the cuff to supra-systolic pressure and before it reaches Status 9 to hold the pressure. The pump controller issues status updates to the host to inform the host as it completes each stage of the overall measurement:

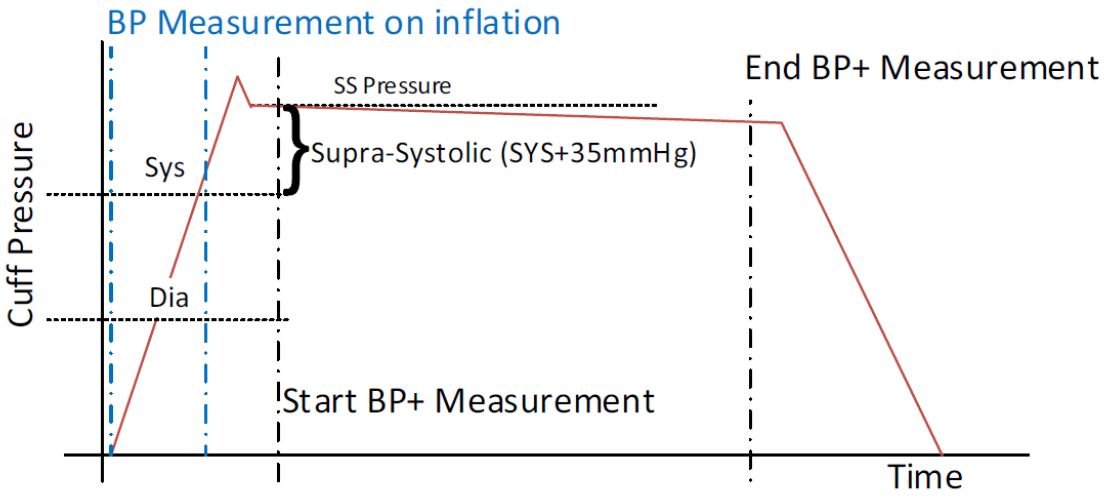


Figure 18: Graphical representation of the cuff pressure in the inflation mode

The NIBP – module does not attempt to inflate to supra-systolic pressure if that will knowingly violate the safety limits. The NIBP – module first reports the measured brachial BP values (see above), then issues a BP range error. In the case that the initial measurement on inflation is not successful, the NIBP – module aborts the procedure with an error.

18.3 Parameters for Programmable Tourniquet without BP measurement

The Command "57" enables the programmable tourniquet. After the command "57" is sent, the host is permitted to set duration and target pressure. The default values for these parameters are 0 s and 0 mmHg. The programmable tourniquet starts with the command "01".
It is possible to change duration and target pressure while the NIBP - module is busy with command "57". The host can change duration and target pressure by sending only the second or third part of the command, respectively (see below).
The host can also terminate the current tourniquet measurement by sending the abort command "X". Otherwise, the NIBP – module terminates the tourniquet measurement when the time limit is reached.

The command is always split in 4 parts:

1. <**STX>57;;E2<ETX>**
2. <**STX>$n_0n_1n_2$Tc_0c_1<ETX>**

$n_0n_1n_2$	Duration in the range 000 through 180 (in steps of 1 second)
T	Identification for the duration (Time)
c_0c_1	Checksum (see Chapter 11.3)

3. <**STX>$n_0n_1n_2$+c_0c_1<ETX>**

$n_0n_1n_2$	Target pressure in the range 000 through 299 (in steps of 1 mmHg)
+	Sign of preceding target pressure (only + possible)
c_0c_1	Checksum (see Chapter 11.3)

NOTE: If the NIBP - module is busy with this command 57 and if you want to change the target Pressure, send only the third part of the command 57. If you want to change the duration, send only the second part of command 57.

4. <**STX>01;;D7<ETX>**

It is possible to leave the programmable tourniquet mode before duration time has elapsed by sending the Abort Command:

<STX>X<ETX>

The module aborts the current measurement, but does not leave the programmable tourniquet mode.

After sending the hardware reset or software reset command “16” from the monitor, the module leaves this mode and goes into a standby-mode.

18.4 Parameters for Programmable Tourniquet with BP Measurement

With command “58”, the host is permitted to set duration and margin above Systolic pressure. The default values for these parameters are 0 sec and 0 mmHg. At least the BP measurement with the following programmable tourniquet starts with the command “01”.

It is possible to change duration and margin above Systolic pressure while the NIBP -module is busy with command “58”. The host can change duration and margin above Systolic pressure by sending only the second or third part of the command respectively (see below).

The host can also terminate the current tourniquet measurement by sending the abort command “X”. Otherwise, the NIBP -module terminates the tourniquet measurement when the time limit is reached.

The command is always split in 4 parts:

1. **<STX>58;;E3<ETX>**
2. **<STX>$n_0n_1n_2Tc_0c_1$<ETX>**

   $n_0n_1n_2$ Duration in the range 000 through 180 (in steps of 1 second)

   T Identification for the duration (Time)

   c_0c_1 Checksum (see Chapter 11.3)
3. **<STX>$n_0n_1n_2s_0c_0c_1$<ETX>**

   $n_0n_1n_2$ Numeric offset in the range 0 through 299 (in steps of 1 mmHg)

   s_0 Sign of preceding margin above Systolic pressure (+ or -)

   c_0c_1 Checksum (see Chapter 11.3)

NOTE: If the NIBP module is busy with command 58, and if you want to change the Target Pressure, send only the third part of command 58. If you want to change the duration, send only the second part of command 58.

4. **<STX>01;;D7<ETX>**

It is possible to leave the programmable tourniquet mode before duration time has elapsed by sending the Abort Command:

<STX>X<ETX>

The module aborts the current measurement, but does not leave the programmable tourniquet mode.

After sending the hardware reset or software reset command “16” from the monitor, the module leaves this mode and goes into a standby-mode.