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Revision History of this Document

Revision	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
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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

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1. General

Intended use:

The NIBP2020 UP module is intended for the automatic non-invasive measurement of blood pressure (systolic, mean, and diastolic value) and pulse rate on adults and neonates with the oscillometric method. This method requires cuffs, which have to be applied at the adult's upper arm on the same level of the heart. The required cuff pressure is generated by an electrical pump.

The module is determined to perform measurements on patients if the condition of the patient allows the non-invasive measurement of blood pressure. The evaluation, the preparation and application has to be performed through medically trained personnel such as doctors, medical technical assistants or nurses etc.

The NIBP2020 UP module is an accessory to a medical device in form of an electronic board designed to be installed in a host system by a system integrator. Thus, the module is a subsystem within a different superordinate medical device and is connected to the power supply and to an electrical serial interface. The control of the board is done by commands via this serial interface. Also the results of a blood pressure measurement and other information are transmitted via this serial interface.

The module has to be built in the host system by trained staff of the system integrator. The system integrator has to fulfil and test the general requirements of basic safety and essential performance (IEC 60601-1).

Features of the NIBP2020 UP module are:

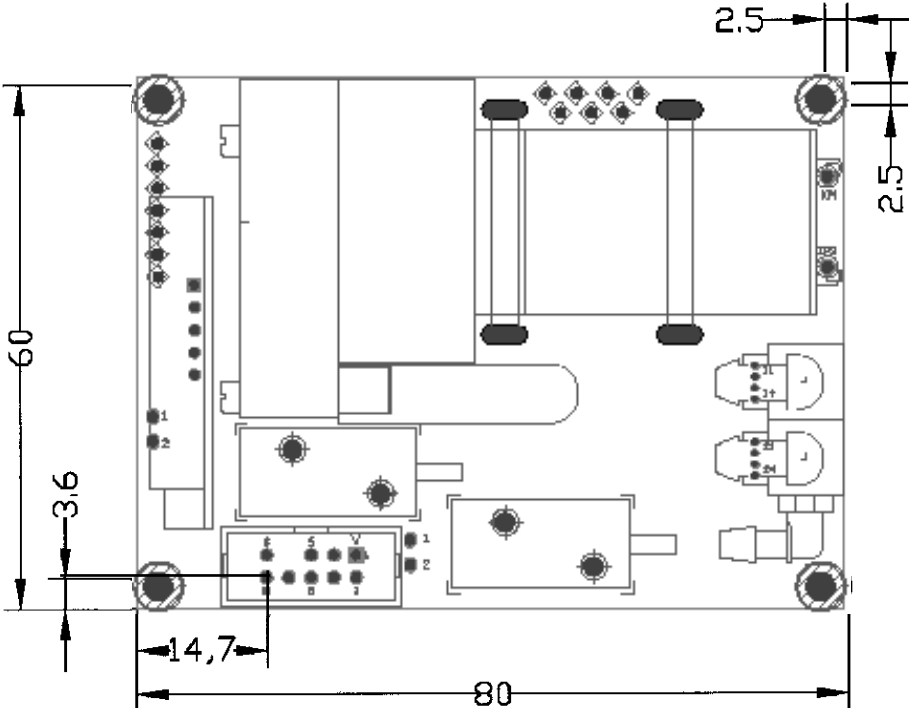
- Non-invasive blood pressure measurement by oscillometric measurement during deflation
- New additional measuring method possible: inflation measurement technology (IMT; blood pressure measurement already during inflation of the blood pressure cuff)
- New additional Programmable tourniquet mode for Pulse Wave Analysis (PWA)
- 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
- Low noise emission, the generated noise has been reduced to a minimum
- New power down modus and resistant against artefacts
- CE-certification of the NIBP2020 UP module
- The NIBP2020 UP operates very reliably and extremely patient-safe in the adult and neonatal mode (supervisor-system, dual safety circuits for pumps, valves and pressure sensors)

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- The accuracy and reproducibility of the measuring results is very good and has been demonstrated by extensive clinical tests:
 - The uniformity of results in the neonatal mode is very high through calibration with arterial reference measurements (clinical trials in the Charité hospital Berlin)
 - In the adult mode accuracy was achieved through a large number of test candidates 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 measuring
- 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 measurements will be carried out so much as possible within 5 minutes
- Determination of the heart rate from the oscillations transferred by the cuff
- Software compatible to NIBP2010 and NIBP2000

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2. Mechanical Dimensions



Picture 1: Module with flat pump



Picture 2: Module with round pump

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3. Technical Data (Specifications)

Mechanical data: (Module with flat pump)	see above mechanical dimension, picture 1 Module dimensions: 80 x 60 x max 25 mm (l x w x h) Weight 90g
Mechanical data: (Module with round pump)	see above mechanical dimension, picture 2 Module dimensions: 80 x 60 x max 33 mm (l x w x h) Weight 110g
Connector:	One 10-pin twin-row plug for all connections
Attachment:	four M2.5 screws in the corners of the PCB
Operating voltage:	+5 VDC Nominal (5.0VDC to 7.0VDC) or +12 VDC Nominal (11.0VDC to 13.0VDC)
Max. operating current:	750mA (5VDC) or 530mA (12VDC) Peak max. 1A (5VDC) or 750mA (12VDC)
Power down – mode:	less than 1mA
Temperature range:	0°C to 55°C
Relative humidity:	95% max, no condensing
Operating mode:	supervised continuous operation
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:	adults neonates
pSYS:	77 - 200 mmHg Measurement during
pDIA:	45 - 190 mmHg inflation not
pMAP:	56 - 193 mmHg applicable
Minimum difference between pSYS and pDIA:	10 mmHg ± 3 mmHg
Accuracy of pSYS, pDIA and pMAP (determined with 20 measurements done with the blood pressure analyser CuffLink from Fluke under laboratory conditions) mean difference:	max. ±3 mmHg or 3%, whichever is greater

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Table 1: results of clinical investigations

	Method 1: measurement during deflation	Method 2: measurement during inflation, IMT	Required according to international standards
Blood pressure measurement accuracy			
Systolic mean deviation:	0,39 mmHg	0,94 mmHg	max. \pm 5 mmHg
Systolic standard deviation:	2,57 mmHg	3,84 mmHg	max. 8 mmHg
Diastolic mean deviation:	0,43 mmHg	0,57 mmHg	max. \pm 5 mmHg
Diastolic standard deviation:	1,73 mmHg	3,17 mmHg	max. 8 mmHg
Pressure transducer accuracy:	\pm 1 mmHg		
Resolution:	1 mmHg		
Leakage rate of the system:	\leq 3 mmHg / minute		
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 15-20s, deflation mode 25-30s max.: adults 90s, max.: neonates 60s		
Heart rate range during deflation:	30 ... 240 bpm		
Heart rate range during inflation:	45 ... 200 bpm		
Accuracy of heart rate (determined with 20 measurements done with the blood pressure analyser CuffLink from Fluke under laboratory conditions) mean difference:	max. \pm 3 bpm or 3%, whichever is greater		
MTBF :	250.000 cycles of blood pressure measurements		
Interface to monitor:	RS232-TTL level, 4800 baud with standard protocol (CAS), also other baud rates and protocols available (e.g. Colin), hardware reset		
Calibration interval:	2 years		

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4. Transport and Storage Conditions

Temperature range: -20°C to +70°C

Relative humidity: 95% max, no condensing

5. Standards

The NIBP2020 UP module is an accessory to a medical device in form of an electronic board. It is a subsystem, which has to be built in a host system. Therefore, it is only possible for the module to fulfil only the relevant and applicable requirements of the following standards:

EN 1060-3	EN 80601-2-30
EN 1060-4	EN 14971
EN ISO 81060-2	ANSI/AAMI SP-10

6. Measuring Methods

6.1 Method 1: Measurement during deflation

The method provides an automatic, oscillometric blood pressure measurement with high accuracy. Required is the inflation of an external blood pressure cuff 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 (equals one oscillation) and simultaneously detecting the pressure values.

With measuring Method 1 in all three modes (next chapter) the user selects the start inflation pressure for the first measurement. 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.

When the module is switched on (power on), this measuring method is set by default. The user can switch the measuring method to measurement during inflation (Method 2) with the appropriate code.

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

6.2 Method 2: Measurement during inflation (IMT)

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 familiar application with Method 1 is also possible by switching the operation mode to measurement during deflation with the appropriate code. The inflation pressure is markedly reduced, because the method provides only inflation up to an adjusted pressure level minimal above the systolic pressure of the patient. The cuff deflation is started a few mmHg after achieving systolic pressure level, which reduces the measuring time.

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

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 \pm 3 mmHg
- The quality of oscillations is too less, e.g. caused by too heavy movement artifacts

7. Measuring Modes

The NIBP2020 UP module carries out blood pressure measurements at adults and neonates according to the oscillometric measuring method in 3 different modes.

7.1 Manual mode

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

7.2 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").

7.3 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.

7.4 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 hold 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.

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8. Safety/Calibration

The safety for the patient and user is achieved by several measures at the NIBP2020 UP 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 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.

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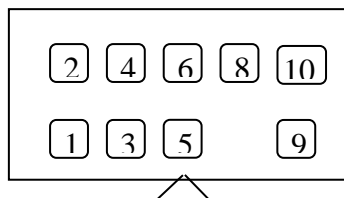
9. Hardware Interface

The system integrator is responsible for the correct installation of the NIBP202 UP 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 an RS232 interface (TTL level or ± 12 V, see below) After installation of NIBP2020 UP the system integrator is responsible for the basic safety according to the standard EN 60601-1 and 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 EN80601-2-30) are fulfilled by the module independent of the host system.

Serial Transmission

The normal connection to the board is done via serial, asynchronous communication with a baud rate of 4800 baud. The interface lines operate on TTL voltage levels (0 and 5 volts) or on RS232-level (± 12 volts). A bidirectional connection is necessary, because commands like cycle mode or start a measurement have to be transmitted to the module.

Interface Connector



Pin 1	Power supply Pump : + 5VDC	or	+ 12VDC
Pin 2	Power supply Pump : + 5VDC	or	+ 12VDC
Pin 3	Power supply Logic : + 5VDC	or	+ 12VDC
Pin 4	GND		
Pin 5	RxD (RS232-level)		
Pin 6	TxD (RS232-level)		
Pin 8	Reset (TTL – Logic, high active)		
Pin 9	RxD (TTL – level)		
Pin 10	TxD (TTL – level)		

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10. Software Interface

The following description is valid for firmware version 6.0 and higher.
It is described the standard protocol.
There are also other protocols available.

Explanation of Terms

ASCII	Character Standard
Frames	Character strings which are exchanged as commands or messages between the computers
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.

General Conventions

All commands and messages begin with a Start of Text character, ASCII 02, and close with an End of Text character, ASCII 03. In this document the designation for Start of Text is: <STX> and End of Text <ETX>. The frames from NIBP module to monitor are terminated by a carriage return, CR=ASCII 13.

Checksum

The checksum is achieved via a modulo 256 summation through all the previous characters of both checksum characters in the corresponding frame (string). The STX character is not included.

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11. Protocol Direction from Monitor to NIBP2020 UP

General Conventions

The measuring unit is controlled by the monitor via command frames. Should NIBP2020 UP 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.

Commands

A command consists of an 8 ASCII character frame. This includes a Start of Text and an End of Text character as well as 2 characters for the checksum.

Frame Schema:

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

STX (Start of Text) = 0x02,

c₀ and c₁ = command code (2 ASCII characters. Range of values 0 to 99)

; and ; = 2 times semicolon

x₀ and x₁ = checksum (2 ASCII characters)

ETX (End of Text) = 0x03,

Example for command code 01 (Start measuring)
(all characters in inverted commas):

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

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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 1 minute
05	DB	2
06	DC	3
07	DD	4
08	DE	5
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 60mmHg (only neonatal)
37	E0	Set start pressure to 80mmHg (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 80mmHg (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	Reserve
27	DF	Select continuous mode and start measurement
28	E0	Version number (EPROM)- short form

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29	E1	Version number (EPROM) – NIBP2020 UP
55	E0	Method 1: Measurement during deflation
56	E1	Method 2: Measurement during inflation (IMT)
57	E2	Select programmable tourniquet mode ⁴⁾
58	E3	Select programmable tourniquet mode following BP measurement ⁴⁾

Remarks

- It is not recommended to send commands during blood pressure measuring or leakage test or during the manometer mode.
Exception: Abort Command ASCII X (see “Abort Command”)
- 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 following measurement the start pressure is calculated to “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**”. NIBP2020 UP response 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

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>

Software Reset Command

The software reset command does the same as the power-on reset and the hardware reset. The software starts to run at the beginning. The module is set to the adult mode and the start pressure is set 160 mmHg. Finally the module is in the standby mode and 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.

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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 10ms

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12. Direction from NIBP2020 UP to Monitor

12.1 General Conventions

There are three types of frames which, in the different situations, are generated by the NIBP2020 UP.

- Cuff pressure transmission (5 times per second)
- End of cuff pressure transmission
- Status transmission

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

12.2 Initialization Message

On power up the NIBP module always generates a status frame within a few seconds. Immediately thereafter the monitor can communicate with the module.

Frame example: **<STX>S0;A0;C00;M10;P-----;R---;T ;;AF<ETX>CR**

12.3 Cuff Pressure Transmission

This frame is permanently displayed during a current measuring. Basic frame structure (real ASCII):

<STX>d0d1d2Cc0Sa0<ETX>CR

STX Start of Text

d0d1d2 3 ASCII digits which represent the current cuff pressure (leading zeros are transmitted)

C Identifier for the caution digit c

c0 caution digit:

c0 = 0 correct cuff (**inflation method**)

c0 = 1 module recognized the neonatal cuff in adult operation (**inflation method**)

c0 = 2 module recognized the adult cuff in neonatal operation (**inflation method**)

c0 = 3 correct cuff (**deflation method**)

c0 = 4 module recognized the neonatal cuff in adult operation (**deflation method**)

c0 = 5 module recognized the adult cuff in neonatal operation (**deflation method**)

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S Identifier for the status digit s

a0 status digit:

a0 = 3 measuring

a0 = 4 manometer operation

a0 = 7 leakage test

a0 = 8 inflating to SupraSystolic pressure

a0 = 9 holding SupraSystolic 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

12.4 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

12.5 Status Transmission

After booting, the leakage test and the measurement, it may be recognized from this 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.

Frame structure (real ASCII in inverted commas, all lines consecutive):

```
<STX>,
"S", a0, ";",
"A", b0, ";",
"C", c0, c1, ";",
"M", d0, d1, ";",
"P", e0, e1, e2, e3, e4, e5, e6, e7, e8, ";",
"R", f0, f1, f2, ";",
"T", g0, g1, g2, g3, ";", ";",
```

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h₀, h₁,
<ETX>CR

Explanation:

STX = Start of Text
ETX = End of Text
CR = carriage return

a₀ = 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	measuring 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 SupraSystolic pressure
a ₀ = 9	holding SupraSystolic pressure

b₀ = ASCII digit for the operational mode

b ₀ = 0	adult mode
b ₀ = 1	neonatal mode

c₀ and c₁ = 2 ASCII digits for cycle mode in minutes.

c ₀ -c ₁ = 00	no cycle selected
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d₀ and d₁ = 2 ASCII digits for messages (after reset 10 appears here)

d ₀ -d ₁ = 00	uninterrupted operation
d ₀ -d ₁ = 02	receiving invalid command
d ₀ -d ₁ = 03	uninterrupted operation
d ₀ -d ₁ = 06	cuff fitted too loosely or is not connected, time for pumping exceeded
d ₀ -d ₁ = 07	cuff leakage
d ₀ -d ₁ = 08	pneumatics faulty
d ₀ -d ₁ = 09	measuring time exceeded, current pressure smaller than the lower limit of diastole, too less oscillations detected
d ₀ -d ₁ = 10	systolic and diastolic value are outside the pressure range
d ₀ -d ₁ = 11	too strong movement artefact
d ₀ -d ₁ = 12	maximum pressure exceeded
d ₀ -d ₁ = 13	two saturated oscillation amplitudes are detected
d ₀ -d ₁ = 14	leakage during the leakage test
d ₀ -d ₁ = 15	system error

e₀ to e₈ = each 3 ASCII digits represent the values for pSystole, pDiastole, pMean.

If the last measurement did not succeed in determining values, these digits will reported as dashes.

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f₀, f₁, f₂ = 3 ASCII digits for the heart rate. If there is no heart rate determined, these digits will be reported as dashes.

g₀ to g₃ = 4 ASCII digits for the period in seconds until the next measurement starts (only in cycle- or continuous mode). If the cycle- or continuous mode has finished or is not active, 4 blanks are displayed.

h₀ and h₁ = ASCII digits for the checksum

Example:

<STX>S1;A0;C03;M00;P125090080;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,
125	last pSystole: 125mmHg,
080	last pDiastole: 80mmHg,
090	last pSystole: 90mmHg,
R075	last heart rate: 75mmHg,
T0005	the next measurement begins in 5 seconds,
D2	checksum.
<ETX>	end of Text: "0x03"
CR	carriage return

12.6 Error Messages

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, then the module goes into the standby-mode and is ready to receive and answer further commands.

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M06 = 1. Cuff fitted too loosely or is not connected
2. Time for pumping exceeded

This error message occurs when inflating, a pressure must achieve at least 20 mmHg after 20 sec., and after 60 sec. 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 value are outside the pressure range (observed when deflating).

M11 = Too strong movement artefacts

M12 = The permitted maximum pressure is exceeded
(Adult: 300 mmHg, Neo: 150 mmHg, in accordance with IEC limits)

M13 = Two saturated oscillation amplitudes are detected

M14 = Leakage during the leakage test

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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 or 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 NIBP2020 UP module goes into the standby-mode. The module is ready to receive and answer further commands.

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13. 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>”

- “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 pressing over 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 NIBP2020 UP” 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.

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14. Manometer Mode (short version)

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 only of channel 1.

Remark: If pressing over 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 NIBP2020 UP” chapter “Error messages” and chapter “Status Transmission”).

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.

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15. Leakage Test

Wind a cuff around a solid body with a diameter of about 7,5cm and connect it with NIBP2020 UP.

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

NIBP2020 UP inflates to 200mmHg and after 60 Seconds NIBP2020 UP 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 to the module the command “Request data from module”. The module will answer with one of the following “Status Transmission”:

<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)

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16. Programmable Tourniquet for Pulse Wave Analysis (PWA)

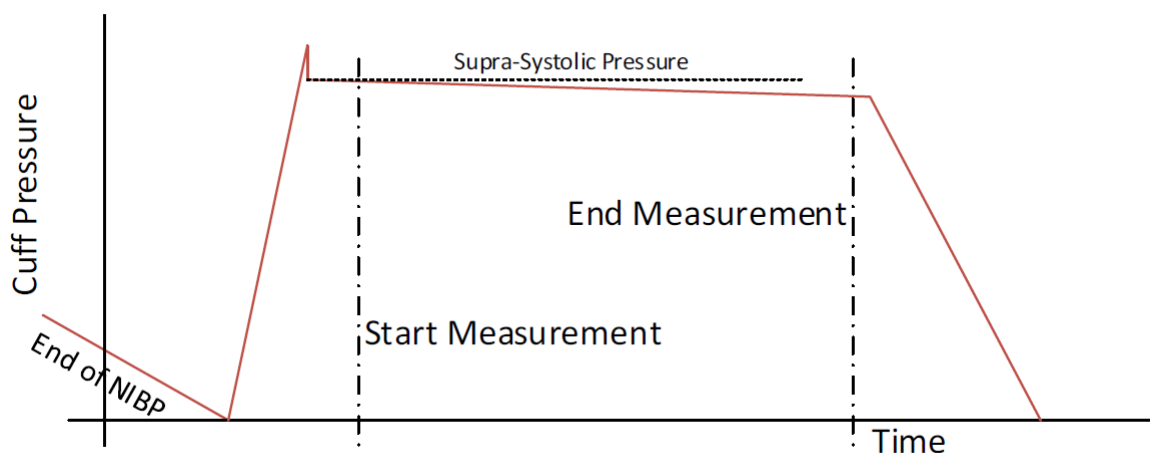
16.1 Programmable Tourniquet without BP measurement

In this mode the host specified directly to the NIBP module a cuff pressure and a hold time. The controller of the NIBP module responds to the host command(s) and 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 hold time or the safety rules (less than 180 seconds above 15 mmHg) terminates the programmable tourniquet. The NIBP module notifies the host 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 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 system.

Typically the host will let the cuff pressure settle at the SupraSystolic pressure for 2 seconds, followed by 10 seconds of pulse pressure wave measurement by the host. Graphically the pressure in the cuff would follow the following profile (red line). It's assumed that the upper-arm systolic pressure was determined in some way prior to the SupraSystolic measurement.

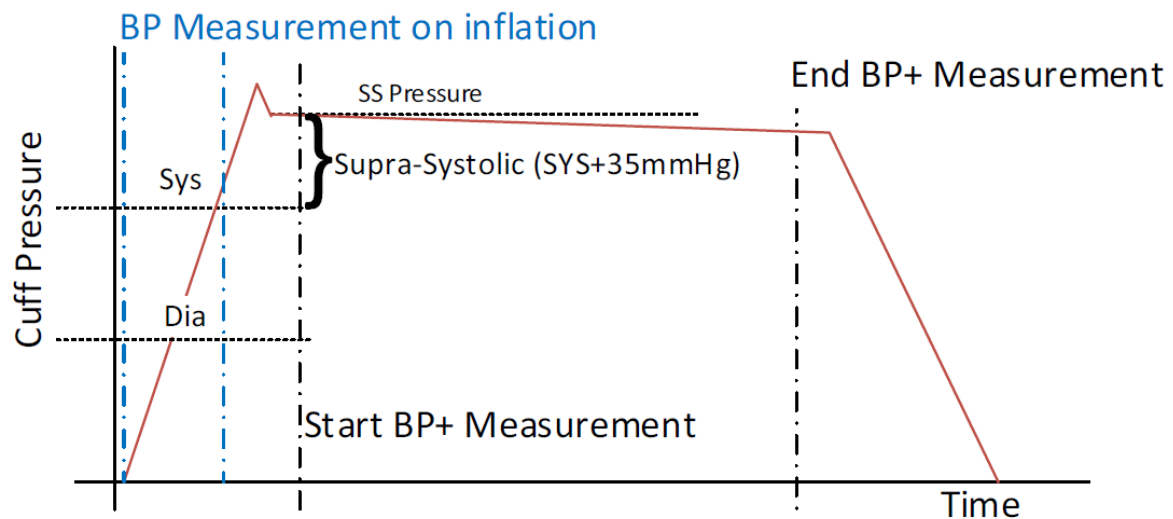


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16.2 Programmable Tourniquet following BP measurement

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 SupraSystolic pressure without first deflating the cuff. This saves the time needed to deflate the cuff and re-inflate to the required SupraSystolic pressure. The command has a SupraSystolic 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 figure below (red line) if measurement on inflation is successful. The blue time markers show the period when the upper arm BP is measured, following which the cuff is inflated to the SupraSystolic pressure at the specified margin (mmHg) above the measured upper arm systolic pressure.



The NIBP 2020 UP reports the current cuff pressure to the host for optional display to the end user. The NIBP 2020 UP reports the BP values as it goes into Status 8 to inflate the cuff to SupraSystolic 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:

The NIBP 2020 UP does not attempt to inflate to SupraSystolic pressure if that will knowingly violate the safety limits. The NIBP first reports the measured brachial BP values (see above), then issue a BP range error. In the event the initial measurement on inflation is not successful, the NIBP abort the operation with an error.

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16.3 Parameters for Programmable Tourniquet without BP measurement

The Command “57” enables the programmable tourniquet. Following the command “57” the host is permitted to set duration and target pressure. The default values for these parameters are 0 sec and 0 mmHg. At least programmable tourniquet starts with the command “01”. It is possible to change duration and target pressure while the NIBP 2020 UP 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 2020 UP 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>n0n1n2Tc0c1<ETX>**
n0n1n2 duration in the range 000 through 180 (in steps of 1 second)
T identification for the duration (Time)
c0c1 checksum (see chapter 10)
- 3) **<STX>n0n1n2+c0c1<ETX>**
n0n1n2 target pressure in the range 000 through 299 (in steps of 1 mmHg)
+ Sign of preceding target pressure (only + possible)
c0c1 checksum (see chapter 10)

NOTE: If the NIBP 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>**

Leaving the programmable tourniquet mode before duration time has elapsed:

After sending the **Abort Command:**

<STX>X<ETX>

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

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

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16.4 Parameters for Programmable Tourniquet with BP Measurement

Following the 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 2020 UP 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 2020 UP 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>n0n1n2Tc0c1<ETX>**

n0n1n2 duration in the range 000 through 180 (in steps of 1 second)
T identification for the duration
c0c1 checksum (chapter 10)

3) **<STX>n0n1n2s0c0c1<ETX>**

n0n1n2 numeric offset in the range 0 through 299 (in steps of 1 mmHg)
s0 Sign of preceding margin above Systolic pressure (+ or -)
c0c1 checksum (chapter 10)

NOTE: If the NIBP 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>**

Leaving the programmable tourniquet mode before duration time has elapsed:

After sending the **Abort Command:**

<STX>X<ETX>

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

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