ENVITEC
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Non Invasive Blood Pressure
OEM board

NIBP 2010

with

PULSE OXIMETRY
Type Chipox

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General

This document describes and defines specifications for the NIBP2010 - OEM Bloodpressure and the ChipOx.

Blood pressure part of NIBP2010

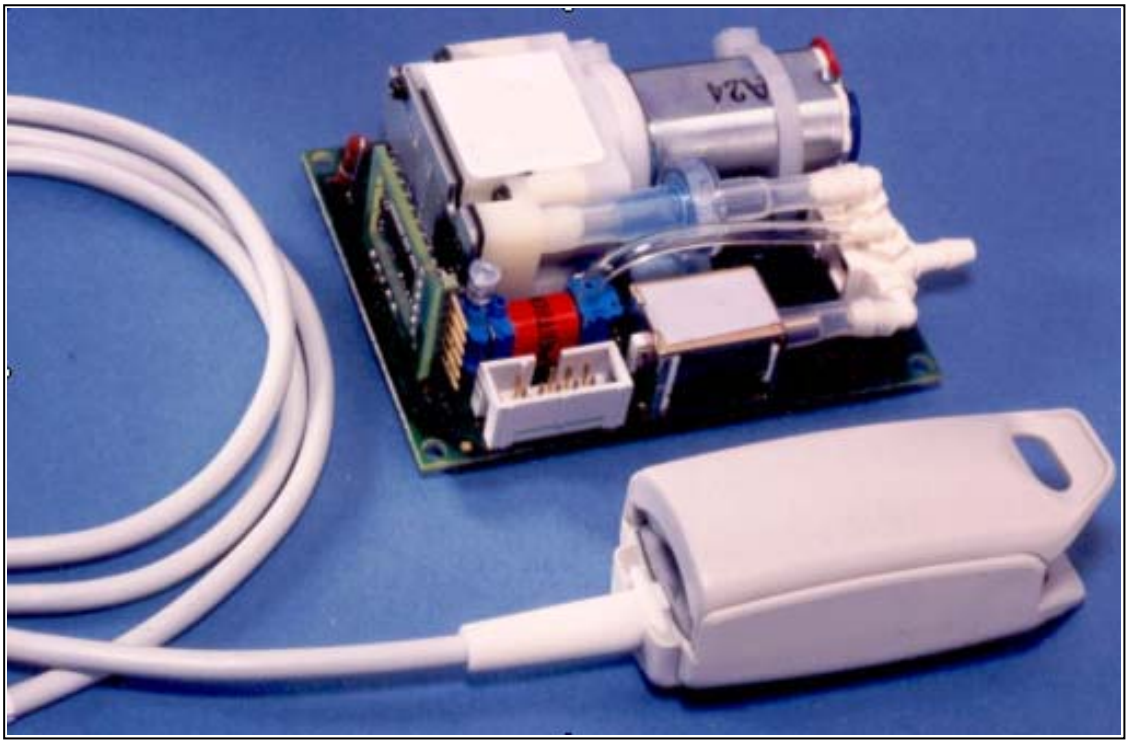
- Software compatible to NIBP2000
- New power down modus and better suppression of artefacts
- CE-certification of the NIBP2010 Module
- the NIBP2010 operates very reliably and extremely patient-safe in the adult and neonatal mode (dual safety circuits for pumps, valves and pressure sensors)
- the accuracy 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 (over 80 test persons each with 6 readings parallel to sphygmomanometer evaluation)
- the measuring time (patient involvement/contact) is short
- the generated noise has been reduced to a minimum
- 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
- short term automatic 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

Pulse Oximetry part of NIBP2010 / ChipOx

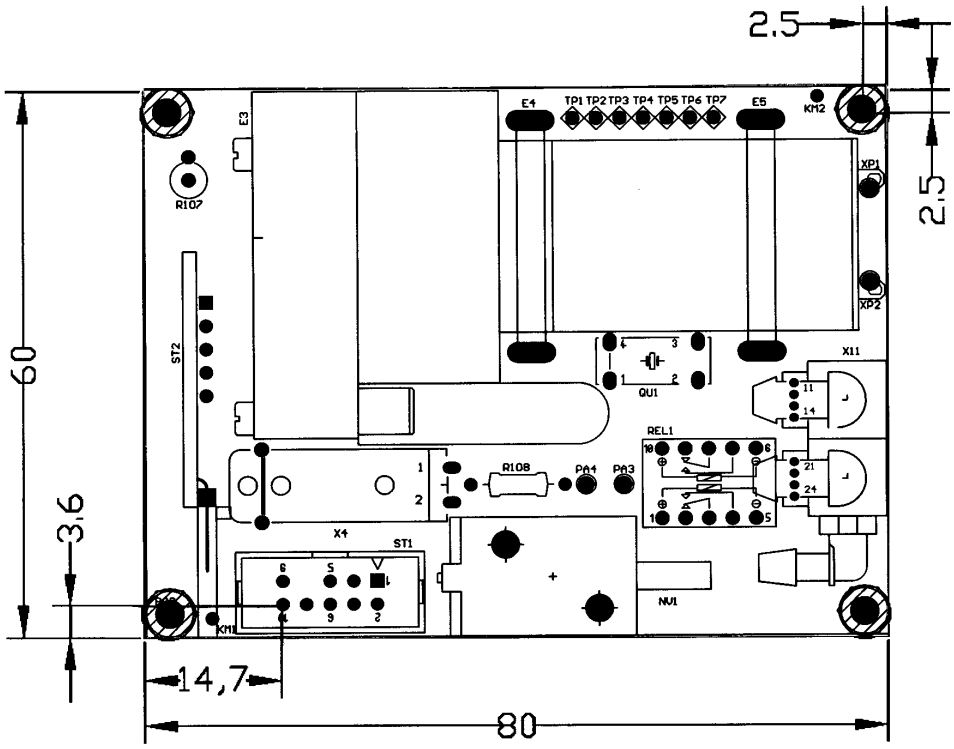
- The ChipOx features pulse oximetry technology in a very small and low powered design.
- The board consists of a multilayer PCB with surface-mounted components with a total size of 77 x 65 x 12 mm.
- The system architecture and signal processing electronics are based on the EnviteC´s pulse oximeter units.
- A new enhanced split-pulse-wave algorithm with fuzzy logic control technology is integrated and provides high quality and best results.
- The ChipOx connects to transducers specified and provides oxygen saturation, pulse rate, quality signal, pulse waveform and other output information via the serial digital interface.

- The ChipOx operates on a split-pulse-wave algorithm. Additional plausibility calculations provide exact measurements.

- Depending on the application 3 different response modes are available: sensitive, normal 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 ChipOx requires certain signal quality for high accuracy. Several criterias are implemented to detect the human pulse wave forms. Signals which do not meet these criteria, e.g. due to high motion artefacts, provide a low detection quality.
- For each measurement a quality signal is given to evaluate the measured oxygen saturation and pulse rate. This quality reaches from 0 to 10 and indicates the degree of artefacts.



Mechanical dimensions



Technical Data (Specifications)

Mechanical data:	see board drawing Module dimensions: 80 x 60 x max 25 mm (l x w x h) One 10-pin twin-row plug for all connections Weight 107g
Attachment	four M2.5 screws in the corners of the PCB
Operating voltage:	+5 VDC (4.8 V... 7.0 V) **or** +12 VDC (11.0 V...13.0 V)
Max. operating current:	750mA (5 V), 500mA (12 V)
Temperature range:	+10°C...+55°C
Relative humidity: Atmospheric pressure:	30...75%, 90% no condensation 700...1060 mbar
Operating mode:	non-supervised continuous operation

Blood pressure part of NIBP2010

Type of measurement:	oscillometric
Pressure range:	0...300 mmHg
Measurement ranges for adults:	- pSYS: 25 - 280 mmHg - pDIA: 10 - 220 mmHg - pMAP: 15 - 260 mmHg
Measurement ranges for neonates:	- pSYS: 20 - 150 mmHg - pDIA: 5 - 110 mmHg - pMAP: 10 - 130 mmHg
The leakage rate of the system is	< 3 mmHg / minute
Overpressure limits	300 mmHg adult- and 150 mmHg neonatal -mode
Shutdown and pressure release after exceeding (first fault condition):	330 mmHg adult- and 165 mmHg neonatal -mode
Interface to host computer	RS232-TTL level, 19200 baud, hardware reset,
Time required for BD measurement:	typical (normal) 25s max.: adults 90s, max.: neonates 60s

Pulse Oximetry part of NIBP2010 / ChipOx

O_2-Saturation Range:	0 - 100 %
O_2-Saturation Accuracy:	SpO_2 > 85 % ± 1,5 % 75 % < SpO_2 < 85 % ± 2,0 % 50 % < SpO_2 < 75 % ± 3,0 %
Pulse Rate Range:	30 - 250 bpm
Pulse Rate Accuracy:	± 2 %
Quality Range:	10 (low) - 0 (high)

Response modes:	sensitive, normal, stable; adjustable by host system; default: normal
Alarms:	sensor disconnected, finger off, signal low, error messages. All alarms are detected in the module and reported to the host via the communication link.
Transmission:	resolution: saturation: 1 Hz pulse rate: 1 Hz quality signal: 1 Hz pulse wave: 100 Hz
Digital Filter:	50/60 Hz and 100 Hz neon light
Temperature:	0 - 45 °C
Humidity:	0 - 90 % (without condensation)
Isolation serial Interface:	input via opto coupler (optional).

Transport and Storage Conditions

Temperature range:	-40°C...+70°C
Relative humidity:	10...100%, no condensation
Atmospheric pressure:	500...1060 mbar

Standards

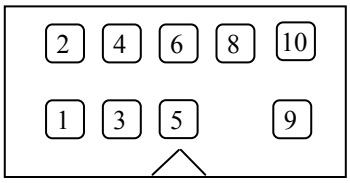
EN 60601-1 + A1 + A2
EN 60601-1-2
EN 55011, Class B
EN 60601-2-30
EN 1060-1
EN 1060-3
DIN 58130

Hardware Interfaces

Serial Transmission

The normal connection to the board is done via serial, asynchronous communication with a baudrate of 19200 baud. The interface lines operate on TTL voltage levels (0 and 5 volts). A bidirectional connection is necessary, since parameters like cycle rate, start of measuring also first have to be transmitted for the module to start measuring.

Interface Connector



Pin 1 Power supply Pump : + 5VDC **or** + 12VDC
Pin 2 Power supply Pump : + 5VDC **or** + 12VDC

Pin 3 Power supply Logic : + 5 VDC **or** + 12VDC

Pin 4 GND
Pin 5 NC
Pin 6 NC

Pin 8 Reset (TTL – Logic, High or Low, changeable)

Pin 9 RxD, TTL – Logic
Pin 10 TxD, TTL – Logic

Software Interface of the blood pressure part

Explanation of Terms

ASCII	Character Standard
Frames	Character strings which are exchanged as commands or messages between the computers.
Host	The computer, which controls the measuring unit. Interface to the user.
Slave	The measuring unit computer.
Cycle Mode	The measuring unit starts automatic readings. The user is free to select the readout intervals. This mode is controlled solely by the host computer.

General Conventions

All NIBP2010 commands and messages begin with a Start of Text character, **STX = 0xF2**, and close with an End of Text character, **ETX = 0xF3**. In this document the designation for Start of Text is: <STX> and End of Text <ETX>.

- The module sends every 10msec. data from ChipOx (see "Software Interface of the ChipOx" at page 17). This data flow can be interrupted by "blood pressure frames" at each time. All NIBP2010 - "blood pressure frames" come as a block, between STX and ETX.

- The blood pressure frames from slave to host 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.

Protocol Direction from Host to Slave

General Conventions

The measuring unit is controlled by the host via command frames. Should the slave 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	c0	c1	;	;	x0	x1	ETX

STX (Start of Text) = 0xF2,

c0 and c1 = command code (2 ASCII characters. Range of values 0 - 99)
; and ; = 2 times semicolon
x0 and x1 = checksum (2 ASCII characters)

ETX (End of Text) = 0xF3,

Example NIBP2010:
(all characters in inverted commas) for command code 02:

<STX>	"0"	"2"	";"	";"	"D"	"8"	<ETX>
0xF2	0x30	0x32	0x3B	0x3B	0x44	0x38	0xF3

this frame corresponds to the following Hex characters:

Command Code	Checksum	Function
00	D6	Reserve
01	D7	Start measuring
02	D8	Reserve
03	D9	Select manual measuring mode
04	DA	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
16	DD	Start reboot

17	DE	Leakage test
18	DF	Request data from slave
19	E0	Set start pressure to 100mmHg (only neonatal)
20	D8	Set start pressure to 120mmHg (only neonatal)
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)
24	DC	Select adult measuring mode
25	DD	Select neonatal measuring mode
27	DF	Continuous mode
29	E1	Version number (EPROM) – NIBP2010
51	DC	Extended mode

Remarks

- Commands 19, 20, 22, 23 are ignored if not appearing in the corresponding measuring mode (adult/neonatal).

- During measuring or leakage test or during the manometer mode all commands are ignored.
  Exception: Abort Command ASCII X (see “Abort Command”)

- Should the measuring unit receive command code 15, then a complete initialization is carried out. Subsequently the measuring unit assumes the mode as described in the paragraph regarding the Abort Command.

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 : <STX>"X" <ETX>

Sending "X" **also** suffices (pressing “X” during PC test).

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.

In the following cases a hardware reset or a reboot command is necessary :

- **All errors in auto - test mode and manometer mode, in leakage test and after system errors.**

Direction from Slave (NIBP2010) to Host

General Conventions

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

- 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).

Initialization Message

On power up the slave always generates a status frame within a few seconds. Immediately thereafter the host can initialize the slave.

Frame example (boot ok): <STX>,S0;A0;C00;Mxx;P---------;R---;T----;;AF<ETX>CR

Remark : Here Mxx represents the version information and not the error messages as in other operational modes. Example: M10 then means Version V1.0.

Cuff Pressure Transmission

This frame is permanently displayed during a current measuring.

Basic frame structure (real ASCII in inverted commas):
<STX>, d0, d1, d2, "C", c0, "S", a0,<ETX>, CR

Explanation of dummies:
STX = Start of Text

ETX = End of Text
CR = carriage return

d0, d1, d2 = 3 ASCII digits which represent the current cuff pressure measuring. Leading zeros are transmitted.

The '**C**'aution bit "c0" is used during a current measuring for the display of the cuff and corresponding measuring mode:

c0 = "1" module recognized the neonatal cuff in adult operation
c0 = "2" module recognized the adult cuff in neonatal operation
c0 = "0" all other cases

The „**S**"tatus bit „a0" displays the current operational mode:

a0 = "3" measuring
a0 = "4" manometer operation
a0 = "7" leakage test

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

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 in inverted commas) :
<STX>"999"<ETX>CR

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 host by pressing 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, ";", ";"
h0, h1,
<ETX>CR

Explanation:

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

a0 = ASCII digit

a0 = "0" auto - test in progress (only during booting)
a0 = "1" waiting for commands (standby), cycle counter stopped
a0 = "2" error (evaluation of error bits), cycle counter stopped
a0 = "3" measuring in progress
a0 = "4" manometer mode
a0 = "5" initialization (reboot) in progress
a0 = "7" leakage test
a0 = "8" reserve

b0 = ASCII digit for the operational mode

b0 = "0" adult mode
b0 = "1" neonatal mode

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

c0-c1 = 00 , no cycle selected

d0 and d1 = 2 ASCII digits for messages (after booting the version number appears here)
d0-d1 = 00 uninterrupted operation
d0-d1 = 02 auto - test failed (during initialization)
d0-d1 = 03 uninterrupted operation
d0-d1 = 06 cuff fitted too loosely or not connected
d0-d1 = 07 leakage (including sudden occurrence)
d0-d1 = 08 faulty slow loss of pressure
d0-d1 = 09 pulse not recognizable (cuff incorrectly fitted)
d0-d1 = 10 measurement range exceeded (physiological)
d0-d1 = 11 too strong movement artefact
d0-d1 = 12 excess pressure (in accordance with IEC limits)
d0-d1 = 13 pulse signal saturated (too large)
d0-d1 = 14 leakage determined during leakage test
d0-d1 = 15 system error in measuring unit

e0 to e8 = each 3 ASCII digits represent the values for pSystole, pDiastole, pMean.
All values not ascertainable are expressed in dashes.

f0, f1, f2 = 3 ASCII dummy characters for the heart rate

g0 to g3 = 4 ASCII dummy characters for the period in seconds until the next measurement (only cycle mode) in seconds in the cycle mode. If the cycle mode is not active, 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

Manometer mode

For the manometer mode send the commands:

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

In the manometer mode the offset pressure is transmitted first.

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.

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 300mmHg.

Example: for 150mmHg "<CR> 1. : 150 [mmHg] 2. : 150 [mmHg]"

Remark: If pressing over 300mmHg the valves will be opened and the module sends the message "E07, High pressure".

Leakage Test

Wind a cuff around a solid body with a diameter of about 7,5cm and connect it with NIBP2010.

Send the command for Leakage Test: **<STX>17;;DE<ETX>**

NIBP2010 inflates to 200mmHg and after 60 Seconds NIBP2010 sends the "Status string":

M00 "Leakage test **ok"** or

M14 "Leakage **not** ok", leakage in the system is > 3mmHg / 1Minute

Software Interface of the ChipOx

General

Every second a new pulse rate, oxygen saturation and quality value is transmitted. Pulse wave values (7 Bit, 0 - 127) are sent with 100 Hz.

ChipOx - Send Protocol

Identification

A command byte identifies the values. The following command bytes are defined:

pulse wave	0xF8
SpO_2	0xF9
pulse rate	0xFA
information	0xFB
quality	0xFC
gain	0xF4

Note: The commands for pulse wave and information are active as long as no other command is sent !!

Pulse Wave

After the command byte 0xF8 the pulse wave is sent by 7 data bits ranging from 0 to 127 and representing the amplitude of the plethysmogram curve. The pulse wave is sent as the inverse plethysmogram curve.

Information

The information is followed by one of the following bytes:

STATUS OK	0x00	after removing failures
SENSOR_OFF	0x01	probe disconnected
FINGER_OFF	0x02	no finger in the probe
SIGNAL_LOW	0x03	no analysis possible, i.e. very low perfusion or strong motion artefacts; if no pulse is available weak signal alarm is provided after 15 seconds
Pulse_Detected	0x04	proper pulse wave is detected (optional)
‘S’ ; code number	0x53	sent as soon as the module is connected to power followed by an 18 bytes long code number
‘E’ ; error code	0x45	Followed by 3 bytes: # ; 0x0D ; 0x0A # is an error code

The following error codes (#) may occur.

System	0x01	wrong EPROM checksum
	0x02	RAM cell error
	0x03	RAM address error
Code number	0x0B	code number device not present
	0x0C	code number CRC error
Sensor	0x0D	current device is not a code device
	0x15	wrong code number
	0x33	red LED defective
	0x34	infrared LED defective
	0x35	photo diode defective
	0x37	both LED´s or photo diode defective

The status "OK" is sent after removing failures.

If a particular situation occurs the information byte is transmitted followed by an information about the corresponding cause.

Example: ***The probe is disconnected. The bytes "FB, 01" will be sent. After reconnecting the sensor, the information "OK" is sent as "FB, 00".***

If no failure occurs then the information "OK" is not transmitted !

Quality

The quality of the signal is defined as follows:

Values 0 to 10 0x00 up to 0x0a

Meaning: 0: pulse rate and SpO2 are stable, quality = high
10: pulse rate and SpO2 are instable, quality = low

Gain

The gain is followed by a second byte stating amplification factor of the pulse wave. A gain information is sent as soon as the gain factor changes.

Example for a data stream:

0xF9 0x50 0xFA 0xA0 0xFB 0x03 0xFC 0x0a 0xF8 0x03 0x05 0x09 0x0f ....means:

0xF9 SpO2	80 %	0x50
0xFA Pulse rate	160 bpm	0xA0
0xFB Information (status)	3	0x03 low signal
0xFC Quality	10	0x0a instable values
0xF8 Pulse wave	3, 5, 9, ...	0x03, 0x05, 0x09, ...

The same Example for a data stream with blood pressure:

0xF9 0x50 0xFA *<STX>, d0, d1, d2, "C", c0, "S", a0,<ETX>, CR* 0xA0 0xFB 0x03 0xFC

0x0a 0xF8 0x03 0x05 0x09 0x0f…

see also "**Cuff Pressure Transmission**".

ChipOx - Receive Protocol

The ChipOx can receive commands for adjusting the response mode and selecting the pulse wave on/off.

First the command byte 0xFB has to be sent followed by one of the following bytes:

0x30	'0'	Examine the selected response mode
0x31	'1'	Setting the response mode to sensitive
0x32	'2'	Setting the response mode to normal
0x33	'3'	Setting the response mode to stable
0x70	'p'	Setting the plethysmogram curve ON/OFF
0x76	'v'	Requesting the software version
0x52	'R'	Generating a hardware reset
0x72	'r'	Generating a software reset

Example: Sending the bytes 0xFB '0'
The ChipOx responds by the code 0xFB followed by '1', '2' or '3' depending on the adjusted sensitivity mode.