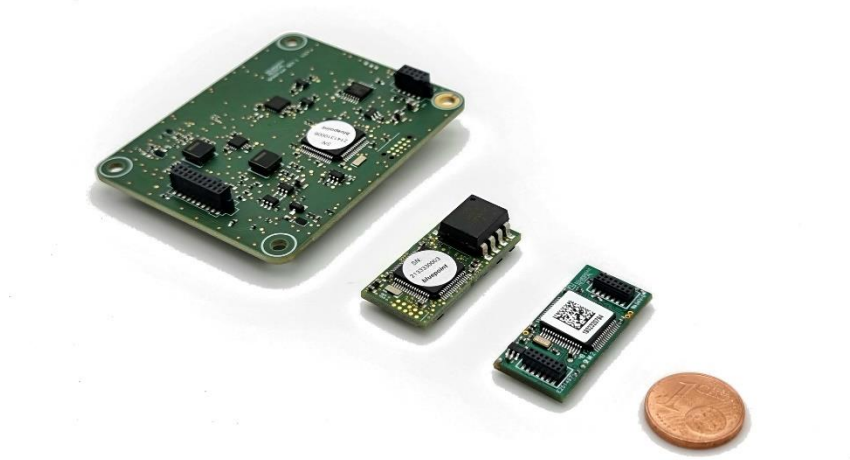
SMARTsat® OEM I/ II/ III

Integration Guide



MODULE SPECIFICATION AND TECHNICAL INFORMATION

COMPANY CONFIDENTIAL

SMARTsat® Integration Guide

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MODULE SPECIFICATION AND TECHNICAL INFORMATION IS VALID FOR THE FOLLOWING HW AND SW VERSIONS:

Part number (REF)	Module	Hardware (HW)	Software (SW)	Host Protocol
8110502001	SMARTsat® OEM I	V1.4 REV.5A V1.4.1 REV 5A	BM.01.A17.A25.1S BM.01.A18.A25.1S	Rev.12
9110100001	SMARTsat® OEM II	V3.0 REV A V3.1 REV A	BM.07.A17.A25.1S BM.07.A18.A25.1S	Rev.12
8110140011	SMARTsat® OEM III	V4.2_Rev.A	BM.03.B42.A28.1S	Rev.16

The information in this document is subject to change.

NOTE: Throughout this document, a point is used as the decimal separator.

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bluepoint MEDICAL GmbH & Co. KG owns the following registered trademarks:

SMARTsat®, SoftCap®, SoftFlap® and SoftWrap®

Table of Contents

1 Introduction

1.1 Overview and intended use

The bluepoint MEDICAL SMARTsat® pulse oximetry module is a small printed circuit board assembly with the new SMARTsat® technology for non-invasive and continuous measurement of functional oxygen saturation in arterial blood (SpO_2) and pulse rate (PR) of adults, pediatrics, infants and neonates.

SMARTsat® is intended to be used in following application areas; considering safety instructions:

- **Professional health care facility environment** like pre- und postoperative monitoring, aesthesia, intensive care units (ICU), sleep medicine, pulmonology and sports medicine
- **Transport and home health care environment** like emergency medicine, ambulance service and home monitoring

The SMARTsat® boards are small low power pulse oximetry modules, designed for OEM use and support the full range of bluepoint MEDICAL SMARTsat® pulse oximeter sensors as SoftCap®, SoftFlap®, SoftWrap®, Earprobe and disposable sensors in different sizes (see section 8.2).

The SMARTsat® technology provides a motion tolerant algorithm to measure SpO_2 and pulse rate under low perfusion and motion conditions. The sensors, depending on type, are applied to various parts of the patient's body (e.g. finger, ear, neonatal foot). See the respective sensor instructions for use for more information.

Available SMARTsat® boards are listed in the table below.

Module	Part Number (REF)	Description
SMARTsat® OEM I	8110502001xx	Low perfusion performance and motion tolerant, active ambient light compensation (AAC), equipped with EMI filter for optional direct sensor connection
SMARTsat® OEM II	9110100001xx	Compact, low perfusion performance and motion tolerant, active ambient light compensation (AAC)
SMARTsat® OEM III	8110140011xx	Compact, motion tolerant and low power
SMARTsat® EB	On request	SMARTsat® OEM III implemented in an external housing with interface cable.

xx: Indicates customized FW versions (e.g. customized start-up settings / sensor coding)

Fig. 1-1: SMARTsat® OEM I (left), OEM II (middle) OEM III (right)

As alternative to the internal SMARTsat® module, the SMARTsat® EB can be externally used with integrated SMARTsat® OEM III. It allows an easy connection to a host system via USB or UART.

Fig. 1-2: SMARTsat® EB

The following parameters are available via the Host Interface:

- Functional arterial oxygen saturation (SpO_2)
- Pulse rate
- Normalized pulse waveform and perfusion index (based on 905 nm)
- Signal quality indicator
- Pulse search indicator
- Interference indicator
- Sensor disconnect indicator
- Probe off patient indicator
- Loss of pulse indicator

By default the normalized pulse waveform, the **A**uto **S**caled **P**lethysmogram (ASP) sampled at 75 Hz, is send to the host. The waveform is automatically adjusted to the pulse strength; therefore, a waveform of good amplitude should be visible at all times. The host system may correlate the waveform reading with the perfusion index to reflect the signals condition.

For applications which calculate the PTT (Pulse Transit Time) however, activation of the raw plethysmogram (RP/ RP2) at 300Hz sample rate is recommended.

Note*:* Upon activation of the raw pleth options (RP, RP2), a minimum baud rate of 115200 Bd is required.

SMARTsat® OEM modules communicate with a host system via a serial communication interface. The detailed protocol and the electrical interface are described in this integration guide and in a separate document SMARTsat® Communication Protocol [1].

The figure below presents a schematic of the integration of SMARTsat® into a host system.

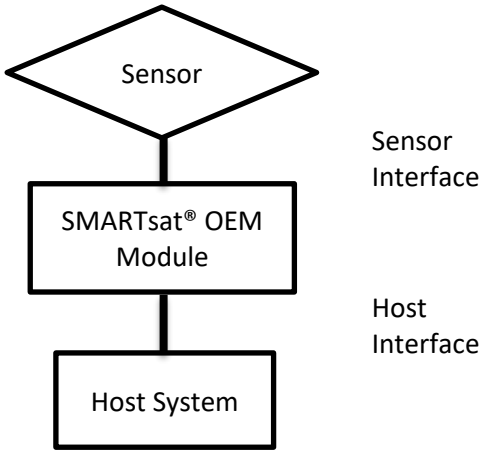


Fig. 1-3: SMARTsat® integration into a host system

1.2 References

ID.	Doc. number	Description / Title	Rev.
[1]	O-07-00-002	SMARTsat® Communication Protocol – SMARTsat® OEM III	12/ 16A
[2]	O-07-00-003	SMARTsat® I-III Protocol Implementation Checklist	4

1.3 Terms and definitions

Item	Description
AAC	Active Ambient light Compensation
AM	Alarm monitor
Appl.	Application
ASP	Normalized Auto Scaled Plethysmogram
BPM	Beats per minute
CM	Continues measurement
CO	Carbon monoxide
COHb	Carboxyhemoglobin
EMC	Electromagnetic compatibility
ESD	Electrostatic discharge
HW	Hardware
HRP	High Resolution Plethysmogram Mode, a feature in Host Protocol rev.8 [1]
IR	Infrared
MetHb	Methemoglobin
MDD	Medical Device Directive 93/42/EEC
MDR	Medical Device Regulation 2017/745
N/A	Not applicable
Pleth/ Plethysmogram	Sensor signal waveform of the absorption of light (wavelength 905 nm) at the measurement site reflecting the relative pulsation strength.
PI	Perfusion index (PI) is the ration of the pulsatile infrared part of the plethysmogram (AC)/ Non-Pulsatile part (DC). It represents the pulsation strength (blood circulation) at the measurement site and is an indicator for good signal quality if > 1%.
PR	Pulse rate
PTT	Pulse Transit Time
RP	Raw Plethysmogram of the infrared LED (IRpleth) at selected sample rate.
RP2	Raw Plethysmogram of the infrared LED (IRpleth) and the red LED (REDpleth) at selected sample rate.
SpO2	Functional oxygen saturation of arterial hemoglobin
SW	Software

1.4 Symbols

Symbol	Description
	Accompanied with "**Warning:** *Supplementary text*." within this document. Warnings indicate potential harmful conditions that may lead to injury or death.
	Accompanied with "**Caution:** *Supplementary text*." within this document. Cautions indicate conditions that may lead to damage to or malfunction of the device.
Note:	Denoted as "**Note:** *Supplementary text*." within this document. Notes inform the user to relevant facts and conditions in connection with the device.
	Consult User Manual for detailed operating information.
	Manufacturer
	Catalogue number
	Serial number
	Storage temperature limitation
	Do not dispose in the consumer waste. Electrical and electronic equipment shall be collected and recycled in accordance with (Directive 2002/96/EC)
	Electrostatic sensitive device
	Box of 50 piece
	Keep Dry

1.5 Safety information

1.5.1 Warnings

SMARTsat® has been developed to meet the requirements of the standards listed in section 4.8 as applicable. All corresponding standards are to be taken into consideration during integration in a host system. Any influences on or from the host system are not considered.

Warnings in connection with the integration and use of SMARTsat® are listed below. In addition, consult the additional warnings listed in the instructions for use provided together with the specific SpO_2 sensor.

Warning:
These user instructions are a component of SMARTsat®. SMARTsat® should only be used for the purpose and in the manner described in this manual.

Warning:
SMARTsat® is designed and tested within the described operating parameters. Changes of the conditions and parameters may lead to faulty measurements or damage the module.

Warning:
SMARTsat® and all accessories may only be used by persons with sufficient expertise.

Warning:
SMARTsat® is only to be integrated in a host system and operated by qualified personnel.

Warning:
ESD protection for the SMARTsat® boards should be provided by the host system. The SMARTsat® boards contain static sensitive devices and therefore should itself be treated as a static sensitive device. The module is not defibrillator proof.

Warning:
There is no patient isolation on the SMARTsat® 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.

Warning:
For the SpO_2 measurement, the monitor uses red and infrared light with specific fixed wavelengths. Consider that these wavelengths might influence diagnostic parameters of other optical applications. The specifications of the wavelengths used are listed in the 'Instructions for Use' of the specific sensor.

Warning:
Certain environmental and physiological conditions, medical procedures, sensor application errors and external agents may interfere with the ability of SMARTsat® to detect and display accurate measurements (section 2.5 provides information on possible interferences).

Warning:
SMARTsat® can show faulty measurements or can be damaged if it will be used outside the specification or environmental conditions.

Warning:
SMARTsat® may not be submerged in liquids, have liquids poured on it or be cleaned with liquid detergents. SMARTsat® should be protected from condensation and humidity.

Warning:
Do not apply excessive tension to any of the monitor cables.

Warning:
Any radio frequency transmitting equipment or other nearby sources of electrical noise may result in disruption of the monitoring system.

Warning:
To prevent damage, avoid undue bending of the sensor cable.

Warning:
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.

Warning:
Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (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.

Warning:
The use of accessories, sensors, and cables other than those specified or provided by bluepoint Medical could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning:
Only pulse oximeter accessories, sensors, and cables offered by bluepoint Medical and listed in the SMARTsat® compatibility list may be used together with SMARTsat® 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.

Warning:
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.

Warning:
Always disconnect the monitor and probes from the patient during magnetic resonance imaging (MRI) scanning. An induced current could potentially cause burns.

Warning:
Disconnect the sensor from the patient throughout computed tomography, as during the active irradiation period, the reading might be inaccurate.

Warning:
Do not autoclave or steam sterilize the SMARTsat® or its accessories. Refer to the specific 'Instructions for Use' of the used SpO_2 sensor for correct cleaning and/or sterilization.

Warning:
If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternative means, then ensure that the SMARTsat® is functioning correctly.

Warning:
A functional tester (like Index II or equivalent) may not be used to validate SpO2 accuracy. A functional tester can be used to verify the function of pulse oximeter probes.

1.5.2 Contraindications

There are no known contraindications to the use of the device.

2 Features and performance

2.1 SpO_2 and pulse rate measurement accuracy

The SMARTsat® boards and SMARTsat® SpO_2 sensors are designed to meet the accuracy requirements in accordance with ISO 80601-2-61.

According to this standard, the approved pulse oximetry sensors are calibrated and evaluated against invasive references determined by a CO oximeter. The functional and fractional oxygen saturation was identical, which means that dyshemoglobin derivates as carboxyhemoglobin or methemoglobin were not present. Due to this method, a falsification of the reference caused by dysfunctional hemoglobin fractions can be eliminated. SMARTsat® has been clinically validated within the range of 60 % - 100 % SpO_2. The clinical accuracy claims are listed in section 7.

The SMARTsat® pulse rate range and low perfusion capability was validated with the Fluke ProSim 8 vital sign simulator. The pulse rate und SpO_2 accuracy under motion was tested with the Index II SpO_2 simulator at standard response time mode and standard pulse rate mode. To validate the SpO_2, accuracy-controlled hypoxia studies were conducted on a pool of consenting subject volunteers at an independent research laboratory. The pool consists of 12 subjects (4 female and 8 male) aged 21 to 32 years.

All subjects were healthy, non-smoking, light-to-dark-skinned and without anemia. Equally distributed in the range of 60 % – 100 % the measured SpO_2 values of the sensors are compared to SaO_2 values of drawn blood samples measured by a CO-oximeter. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61.

The clinical accuracy testing verifies that the bluepoint MEDICAL SMARTsat® Pulse Oximeter Technology in combination with the following SMARTsat® SpO_2 sensors, demonstrated clinical accuracy performance consistent with the requirements of the applicable international standard criteria for accuracy:

SoftCap® (SC7500), SoftFlap® (SF7500), SoftWrap® (W7500), Disposable Adult® (10-AP), Disposable Neonate (10-NP), Disposable Pediatric (10-PP), Disposable Infant (10-IP) and Ear Probe (EP7500).

Modified Bland and Altman plots (SpO_2- SaO_2) versus SaO_2) for each combination of representative SpO_2 sensor are listed in the sensor specific instructions for use. Those plots show the data for all subjects pooled, including upper 95 % and lower 95 % limits of agreement.

The table below presents the detailed measurement results of the pooled studies for each representative sensor respectively.

Table 1: Pooled Clinical SpO_2 accuracy validation results - SMARTsat® OEM I/II

	A_{rms} SpO_2 [%] by SaO_2-Rang[3)]				
Sensor type	**70–100 %**	**90–100 %**	**80–90 %**	**70–80 %**	**60-70%**
SC7500 [1]	1.6	1.1	1.7	1.8	1.9
SF7500	1.5	1.4	1.3	1.7	2.3
W7500	1.4	1.0	1.2	1.8	2.8
EP7500	2.1	1.0	1.7	2.8	3.5
10-AP [2)]	2.1	2.2	1.9	2.0	2.2

[1)] Results apply to equivalent sensors SCM7500 and SCP7500

[2)] Results apply to equivalent sensors 10-PP, 10-IP, 10-NP

[3)] Validation performed with SMARTsat® OEM II integrated in the bluepoint Medical CapnoTrue® multi-parameter monitor

Table 2: Pooled Clinical SpO_2 accuracy validation results – SMARTsat® OEM III

	A_{rms} SpO_2 [%] by SaO_2-Rang [c]					
Sensor type	**60–80 %**	**70–100 %**	**90–100 %**	**80–90 %**	**70–80 %**	**60-70%**
SC7500 [a]	1.8	1.6	1.5	1.8	1.7	2.4
SF7500	1.7	1.5	1.4	1.4	1.7	2.0
W7500	2.0	1.6	1.3	1.5	1.9	2.4
EP7500	2.3	1.8	1.4	1.7	2.3	2.5
10-AP[b]	2.8	2.4	2.1	2.3	2.6	3.4
10-PP	1.8	2.3	2.6	2.4	1.7	1.9
10-NP	2.4	1.9	1.7	1.6	2.3	2.9

[a] *Results apply to equivalent sensors SCM7500 and SCP7500*

[b] *Results apply to equivalent sensor 10-IP*

[c] *Validation performed with SMARTsat® OEM III integrated in the bluepoint Medical OxyTrue®A pulse oximeter monitor*

The table below presents the detailed motion performance results of the SMARTsat® at standard response time mode and enhanced pulse rate mode.

Table 3: SMARTsat® performance under motions tested with FLUKE Index II SpO_2 simulator

Fluke Index II SpO_2 simulator settings							**Measurement accuracy SMARTsat® OEM III** [1]	
	Motion pattern	**Motion Amplitude [%]**	**Motion Freq. [Hz]**	**PI [%]**	**SpO_2 [%]**	**Pulse rate [bpm]**	**SpO_2 [A_{rms}]**	**Pulse rate [A_{rms}]**
1.	Normal	0%	-	5.00	98	55	1	0
2.	Weak	0%	-	0.65	90	95	1	0
3.	Bradycardia	0%	-	5.00	88	45	1	0
4.	Hypoxic	0%	-	2.00	70	95	1	0
5.	Neonate	0%	-	1.00	90	180	1	0
6.	Tachycardia	0%	-	1.20	85	130	1	0
7.	Geriatric	0%	-	2.40	92	95	1	0
8	Obese	0%	-	3.00	93	90	1	0
9.	Normal/Tap	7%	2.5	5.00	98	55	1	1
10.	Normal/Shiver	15%	6.0	5.00	98	55	1	1
11.	Weak/Tap	1%	4.3	0.65	90	95	0	0
12.	Weak/Shiver	3%	6.0	0.65	90	95	1	0
13.	Brachy/Shiver	10%	6.0	5.00	88	45	1	1
14.	Hypoxic/Tap	3%	4.3	2.00	70	95	1	0
15.	Hypoxic/Shiver	8%	6.0	2.00	70	95	1	2
16.	Neonate/Shiver	5%	6.0	1.00	90	180	3	0
17.	BradyTap#2	0 / 4%	3.9	5.00	88	45	1	1

Fluke Index II SpO_2 simulator settings							Measurement accuracy SMARTsat® OEM III (1)	
	Motion pattern	Motion Amplitude [%]	Motion Freq. [Hz]	PI [%]	SpO_2 [%]	Pulse rate [bpm]	SpO_2 [A_{rms}]	Pulse rate [A_{rms}]
18.	HypoxTap#2	0 / 3%	4.3	2.00	70	95	1	1
19.	WeakTap#2	18%	1.0	0.90	80	95	2	2
20.	NormalTap#2	0 / 3%	2.5	5.00	93	55	1	1
21.	Asystole (2)	0 / 1.1%	-	2.00	0	0	0	0
22.	LowFreq1	0 / 4.2%	0.5	1.00	80	75	1	1
23.	LowFreq2	0 / 4.2%	0.5	1.00	70	75	1	0
24.	SlowTap	0 / 3.0%	2.0	1.00	80	75	1	0

(1) Results for OEM I/ II/ III are equivalent based on SW design. Test performed in enhanced pulse range mode (EPR ON), standard response time mode, 75Hz sampling rate and with the SC7500 SpO_2 sensor. Changing the Response Time Settings has significant influence on motion tolerance performance (see section 2.2.2, table 5).

(2) Result taken during the Asystole. In case cardiac massage is performed thereafter, the measurement results present the true saturation value and the heart rate represents the cardiac massage rate.

2.2 Measurement modes

2.2.1 Enhanced Pulse Rate Mode (EPR)

SMARTsat® offers a *standard* and *enhanced pulse rate (EPR)* mode.

The *standard pulse rate mode* offers a pulse rate measurement range of 30 – 240 bpm (beats per minute). By selecting the *enhanced pulse rate mode* (EPR) the pulse rate measurement range is significantly increased to 300 bpm. This mode is typically used in veterinary applications.

Both modes show high motion tolerance performance depending on the response time mode setting selected (see section 2.2.2, table 5).

2.2.2 Response Time Setting

Five different response time settings are available for selection depending on the application. Changing the response time mode has influence on the time delay of displayed SpO_2 and pulse rate measurement values.

Table 4: Average response time for each response time mode (refer to Fig. 2-1)

Response Time Mode	Motion tolerance performance	Average response time	
		SpO_2 (see Fig 2-1)	Pulse rate (@75bpm)
Stable	highly motion resistant	12 sec	12 sec
Standard (default)	motion resistant	8 sec	10 sec
Sensitive	reduced motion resistance	7 sec	8 sec
8-Beat averaging	no motion resistance	4 sec	5 sec
4-Beat averaging	no motion resistance	3 sec	4 sec

The figure below presents the time response for all possible response time modes at set pulse rate of 75 bpm.

After a stable baseline of 20 seconds the SpO_2 reference drops from 97 % down to 70 % within 36 seconds which corresponds to a slope of -0.75 %/ sec. Within 15 seconds the SpO_2 value increases back to 97 % which correspond to a slope of 1.8 %/ sec.

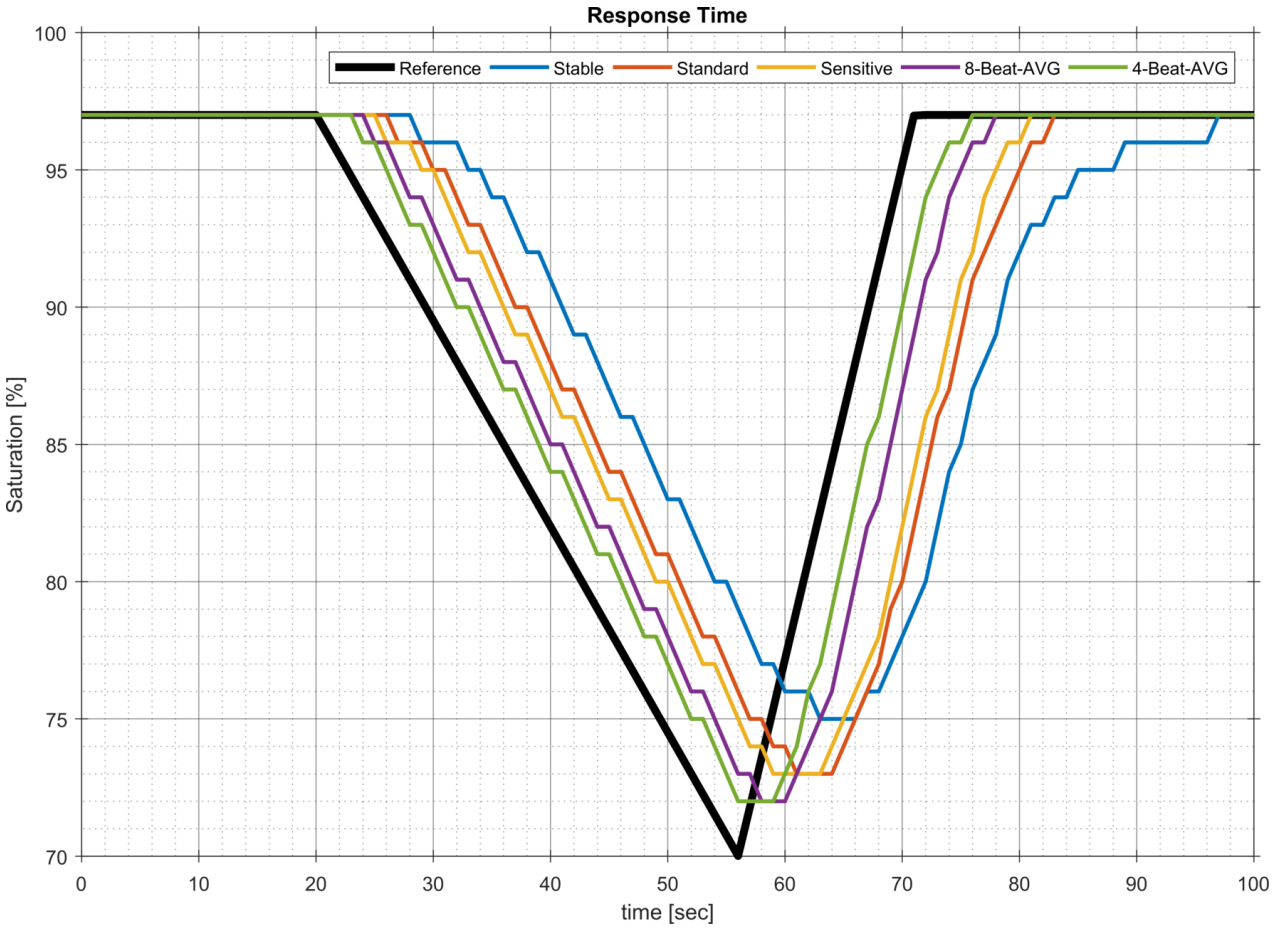


Fig. 2-1: SMARTsat® SpO_2 response time diagram

Note: Motion tolerance performance is significantly reduced for modes with short response time (8-Beat averaging, 4-Beat averaging). Table 4 presents the available modes listed in motion tolerance categories.

In a similar way the response time of the pulse rate is determined. After a stable baseline of 20 seconds the pulse rate reference increases from 20 bpm up to 300 bpm at 0.5 bpm/ sec. The average response time at a pulse rate of 75 bpm is listed in the table below.

SpO_2 and pulse rate values are calculated and updated continuously during measurement and averaged according to the selected Response Time Setting. In case of heavy signal distortion (motion artefacts, electromagnetic interference, low perfusion), the last valid value is transmitted. If the distortion continues for longer than the maximal Data Update Period, the data output of SpO_2 and pulse rate are set to “no valid value” (output = 0xFF).

NOTE: The maximal Data Update Period is 28 sec in all measurement modes.

2.2.3 Raw Plethysmogram (RP, RP2)

The Raw Plethysmogram (RP, RP2) is an optional feature which can be activated at all Response Time Settings and allows the output of a high resolution plethysmogram (RP = IRpleth, RP2= IRpleth and REDpleth) at the selected sampling rate. This plethysmogram is not normalized.

This mode is typically used by a host to calculate the PTT (Pulse Transit Time) based on additional designated host signals.

Note that due to the high sampling rate the RP, RP2 mode requires a minimum baud rate of 115200 Bd or larger and the total power consumption of the board is increased.

In case the actual used baud rate is below 115200 Bd the RP and RP2 mode are blocked and the host has to increase the baud rate to enable the feature. The RP and RP2 mode are available at both samples rates: 75 Hz and 300 Hz. For switching the plethysmogram and the sampling rate see document SMARTsat® Communication Protocol [1].

2.3 Status flags

The SMARTsat® continuously monitors the sensor and physiological conditions and reports the status (refer to [1]) Status flags include:

Status Information	Reason
Sensor disconnected	Sensor is not connected
Probe off	Sensor has been removed from the measurement site or slipped of the measurement site (finger or ear lobe)
Searching for pulse	No pulse detected in the signal. This could be due to no pulse present or artefacts in the signal.
Pulse searching longer than 30 sec	No pulse detected for longer than 30 seconds. This could be due to no pulse present or artefacts in the signal. No SpO_2 or pulse rate values are transmitted.
Loss of pulse	No pulse is detected and therefore no value is displayed; typically due to prolonged bad signal quality. Alarm monitors should give at least medium priority alarm if this bit is set.
Low perfusion index (low AC/DC ratio)	The perfusion index (PI) is below 1 %. PI = AC/ DC ratio of wavelength 905 nm. Low perfusion conditions are typical e.g. during patient shock conditions and cold hands.
Low transmission	The sensor signal is very small. Low signal transmission can occur if the absorption between LED and detector is large e.g. measurement at a neonatal foot or a dark thick finger.
Interferences detected	Interferences degrade signal quality and potentially cause incorrect measurement values e.g. electromagnetic or electrosurgical interference source.
Motion artefacts	Motion artefacts degrade signal quality and potentially result in wrong measurement values. This condition occurs during e.g. excessive motion at sensor site or moving the finger inside the sensor head.
Vital parameter out of range	Measurement values are invalid because they are outside the specified measurement range. Possible reasons are the use of intravascular dyes.
Supply voltage out of range	The supply voltage provided to the module is outside of the specified range. Under these conditions the measurement values are potentially incorrect.
Ambient light	Ambient light level exceeds the limit of possible compensation. The measurement is interrupted and the flag is sent.
Sensor defective	The sensor, its cable or the optical components are defective. The measurement is interrupted. Remove the sensor to reset the flag. Measurement is continued on connection of a new sensor.

Status Information	Reason
Wrong sensor	The connected SpO_2 sensor is not compatible with the SMARTsat® board. The connected sensor could result in wrong measurement values or electrical hazard to the patient.

2.4 Error channel

The SMARTsat® continuously monitors the functionality of software and hardware components. In case an error is detected the error message is send instantly via the error channel as long as the error condition is present at 1Hz. Error status includes e.g. Frame corrupt, CRC error, Buffer overflow etc. (refer to [1]).

2.5 Circumstances that can influence the measurement

Physiological conditions, medical procedures, or external agents that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:

Ambient light:

If the ambient light level exceeds a limit of compensation SMARTsat® interrupts the measurement and sends out the status flag “Ambient light”.

Shield the SpO_2 sensor application site with opaque material if the measurement is interrupted and the status flag “Ambient light” is send

Motion artefacts:

The SMARTsat® algorithm suppresses the influence of motion on the SpO_2 and PR measurement (see section 2.1). However long and continuous motion can lead to wrong measurements. SMARTsat® provides a Signal Quality and Motion indicator to inform the user if the measurement value is potentially incorrect.

Check the sensor site and prevent motion artefacts if SMARTsat® detects bad signal quality, motion artefacts, interferences etc. (see SMARTsat® status flags)

Dysfunctional hemoglobin **(e.g. COHb, MetHb):**

High concentration of dysfunctional hemoglobin which is not able to transport oxygen, as COHb or MetHb, can falsify the measurement. The indicated result seems to be normal but the patient can be hypoxic.

Intravascular dyes:

Taking medicine or other preparations which change blood color or the administration of intravascular dyes (such as methylene blue or indocyanine green, etc.) can drastically falsify the measurement results.

Other:

More conditions that may degrade pulse oximeter performance or affect the accuracy of the measurement include:

- Incorrect applications of the sensor
- Externally applied coloring agents such as nail polish or artificial nails,
- Placement of the sensor on an extremity with blood flow restrictors (arterial catheters, blood pressure cuffs, infusing lines, etc.),
- Low perfusion, venous pulsations, anemia or low hemoglobin concentrations
- Cardiac dysrhythmia like extrasystole or atrial / ventricular fibrillation
- Electromagnetic interference and electrosurgical interference

3 Guidelines for integration

3.1 SMARTsat® OEM I

3.1.1 Physical dimensions

The SMARTsat® OEM Boards are multi-layer PCBs with surface mount (SMT) components.

The SMARTsat® OEM I board dimensions are presented in the figures below. The drawings show the modules footprint and connectors location. It is recommended that the OEM customer uses an actual SMARTsat® module during the mechanical design process. 3-D files for the modules are available on request (STP).

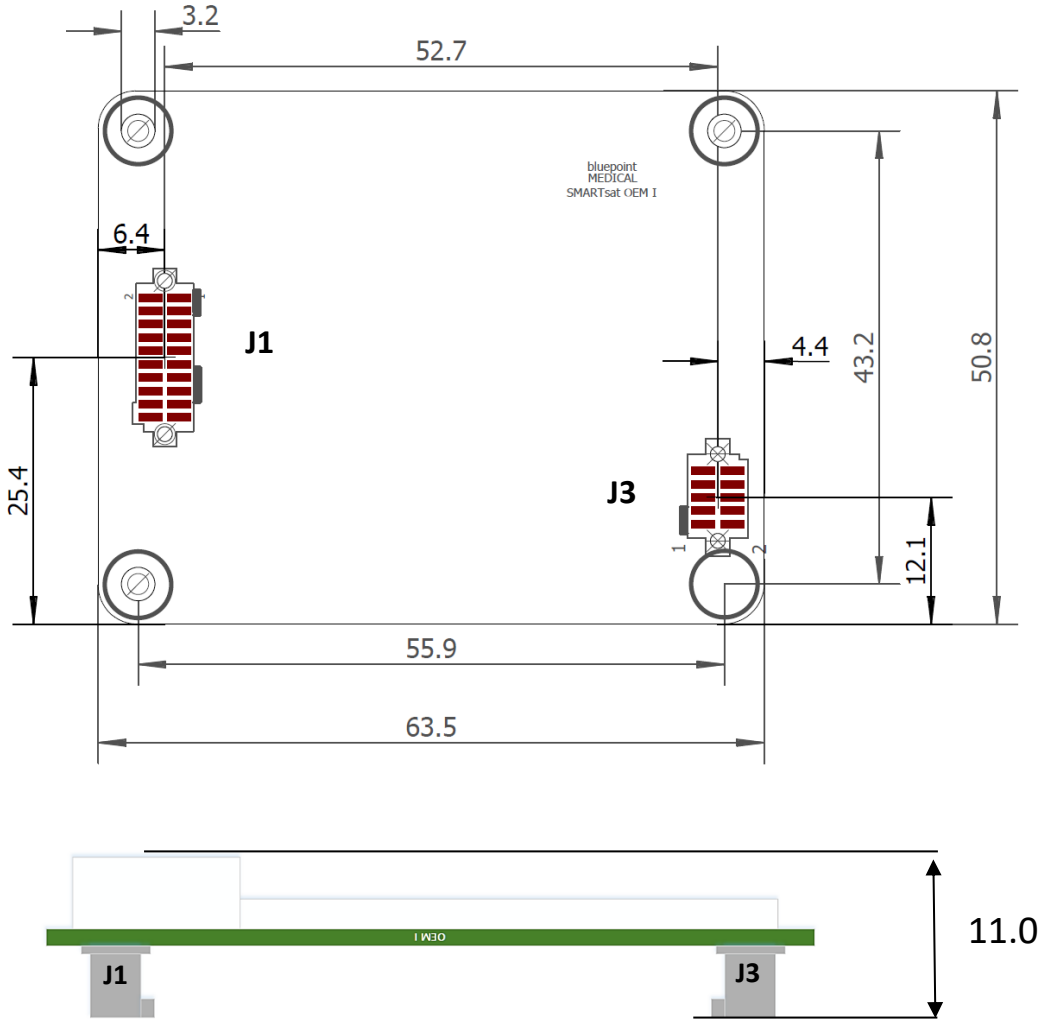


Fig. 3-1: SMARTsat® OEM I Board Physical Dimensions (in mm)

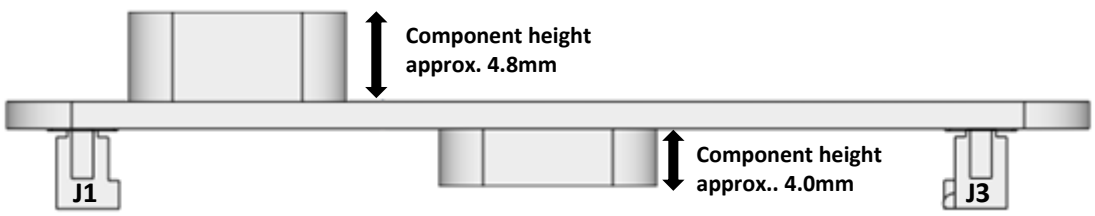
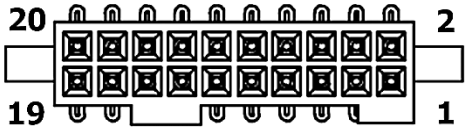


Fig. 3-2: SMARTsat® OEM I component height information (this information can be especially useful for host PCB layout)

3.1.2 Electrical interface

Sensor Connector J1:

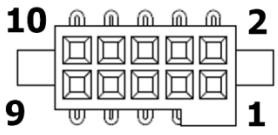


Part number: **Samtec SFML-110-T2-S-D-A**

PIN	Signal Description	PIN	Signal Description
1.	Detector Anode	11.	Reserved (Open)
2.	Detector Cathode	12.	Sensor ID
3.	Ground	13.	Reserved (Open)
4.	Ground	14.	Do not contact!
5.	Reserved (Open)	15.	RED LED
6.	Reserved (Open)	16.	Reserved (Open)
7.	Reserved (Open)	17.	Reserved (Open)
8.	Reserved (Open)	18.	Reserved (Open)
9.	Reserved (Open)	19.	IR LED
10.	Reserved (Open)	20.	Reserved (Open)

The mating parts for J1 on the host PCB is **Samtec TFML-110-02-L-D**

Power and Communication Connector J3:



Part number: **Samtec SFM-105-02-S-D-A**

PIN	Signal Description	PIN	Signal Description
1.	Input Power	6.	Ground
2.	Ground	7.	Reset
3.	Reserved (Open)	8.	Reserved (Open)
4.	Ground	9.	RxD (Receive data input)
5.	Reserved (Open)	10.	TxD (Transmit data output)

The mating parts for J3 on the host PCB is **Samtec TFM-105-02-L-D-A**

3.2 SMARTsat® OEM II and III

3.2.1 Physical dimensions

The SMARTsat® OEM Boards are multi-layer PCBs with surface mount (SMT) components. The SMARTsat® OEM II and OEM III board dimensions are presented in the figures below. The drawings show the modules footprint and connectors location. It is recommended that the OEM customer uses an actual SMARTsat® module during the mechanical design process. 3-D files for the modules are available on request (STP).

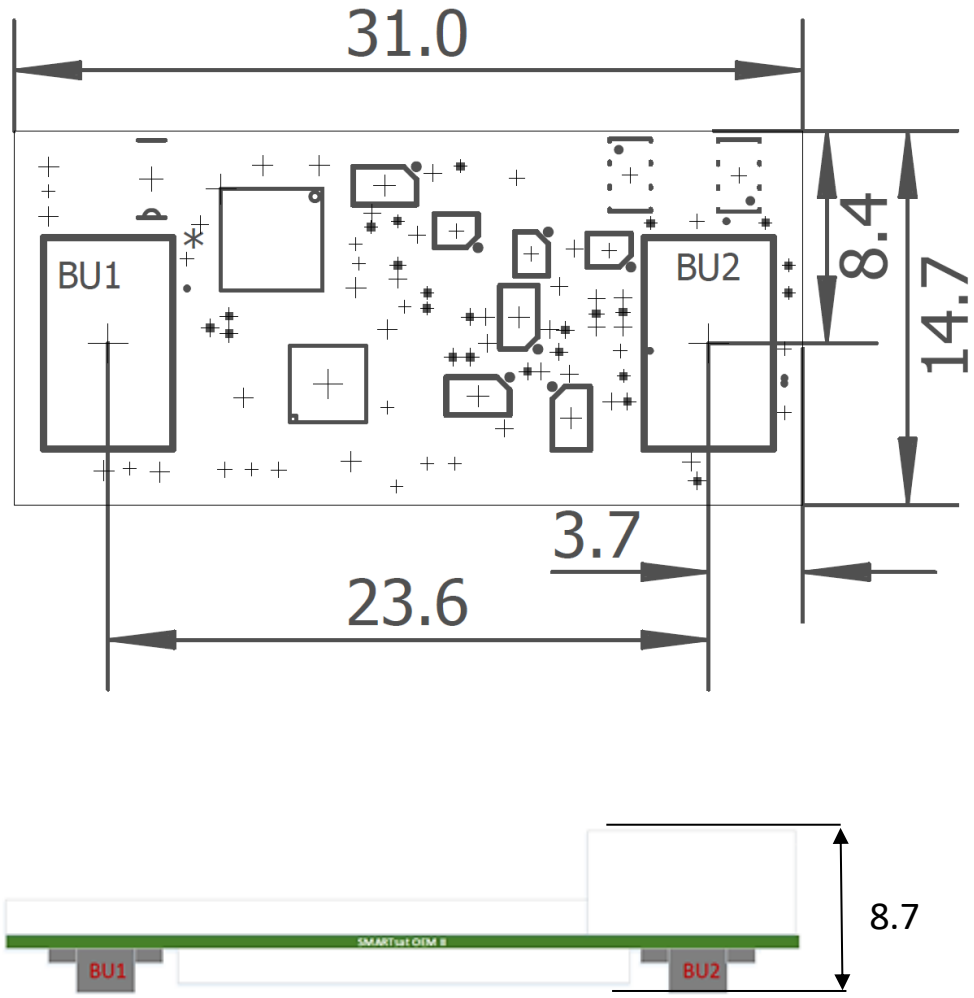


Fig. 3-3: SMARTsat® OEM II Board Physical Dimensions (in mm)

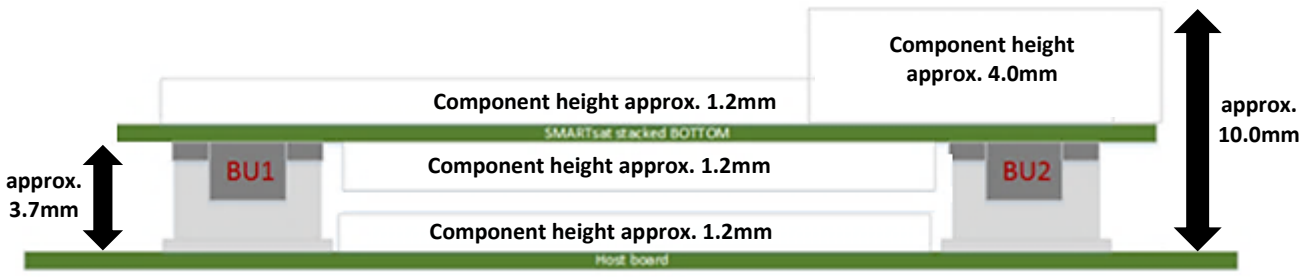


Fig. 3-4: SMARTsat® OEM II component height information (this information can be especially useful for host PCB layout)

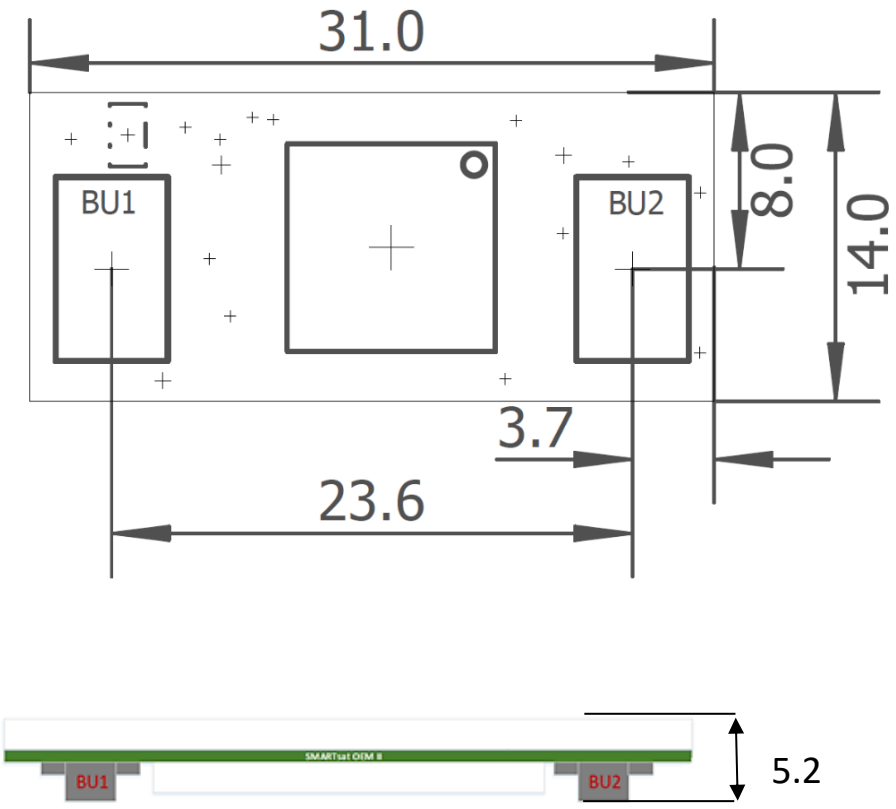


Fig. 3-5: SMARTsat® OEM III Board Physical Dimensions (in mm)

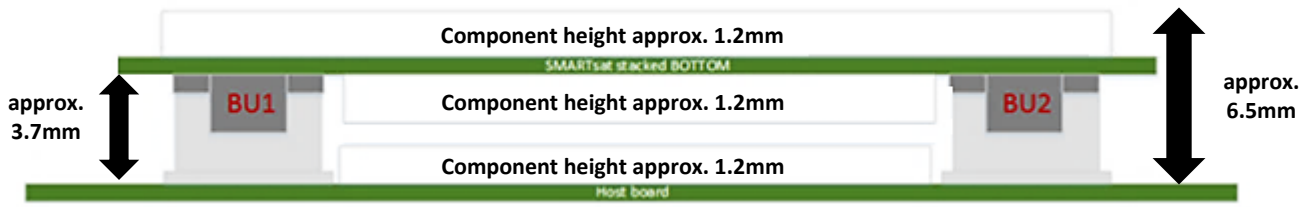


Fig. 3-6: SMARTsat® OEM III component height information (this information can be especially useful for host PCB layout)

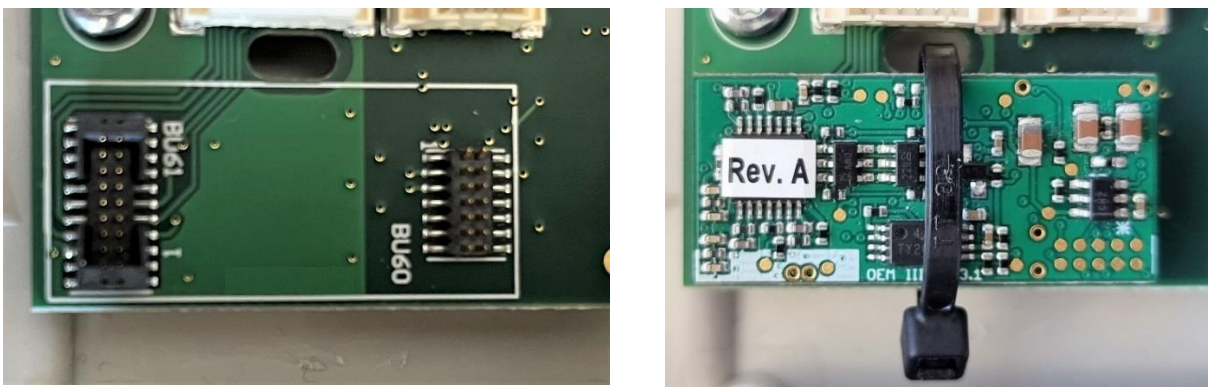
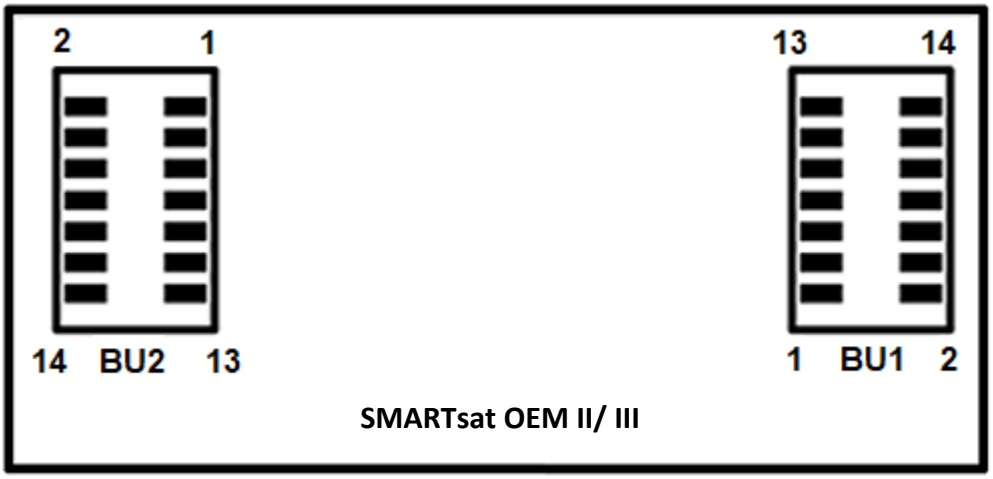


Fig. 3-7: Recommended fixation of the SMARTsat® module at the Host PCB

3.2.2 Electrical interface

The OEM II and OEM III module are pin to pin compatible and can be replaced with each other, provided the host system considered the minimal larger outer dimensions of OEM II compared to OEM III

Power and Communication Connector BU1 and Sensor connector BU2 (Bottom View):



BU1/ BU2 Part number: **Samtec CLM-107-02-L-D**

Host Interface Connector Pin Assignments (BU1 and BU2)

PIN	BU1 Signal Description	PIN	BU2 Signal Description
1.	VCC Power input	1.	Not connected
2.	Ground	2.	Shield
3.	Reset	3.	Sensor ID
4.	TxD (Transmit data output)	4.	Detector Anode
5.	RxD (Receive data input)	5.	Detector Cathode
6.	Not connected	6.	IR LED
7.	Not connected	7.	Red LED
8.	Not connected	8.	Not connected
9.	Do not contact!	9.	Not connected
10.	Do not contact!	10.	Not connected
11.	Do not contact!	11.	Not connected
12.	Do not contact!	12.	Not connected
13.	Not connected	13.	Not connected
14.	Do not contact!	14.	Not connected

The mating part for BU1/ BU2 on the host PCB is **Samtec FTM-107-02-L-DV** or **Samtec FTM-107-03-L-DV.**

3.3 External SMARTsat® EB

3.3.1 Physical dimensions

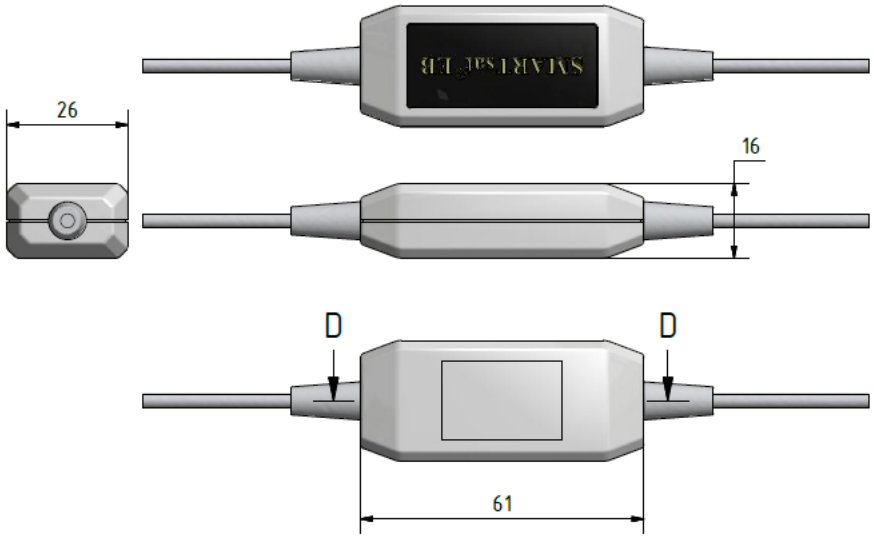


Fig. 3-8: SMARTsat® EB physical dimensions in mm

The cable length from the module to the host connector is 30cm and the overall length from host connector to sensor connector is 175cm.

3.3.2 Electrical interface

On one cable end the SpO2 sensor plug – 6 pin minimed (3.4.1) is available for the sensor connection. The SMARTsat® EB 4 PIN male host connector is on the other cable end which fits the SMARTsat® EB 4 PIN female host plug (REF: 205012004). Customized connectors are available on request.

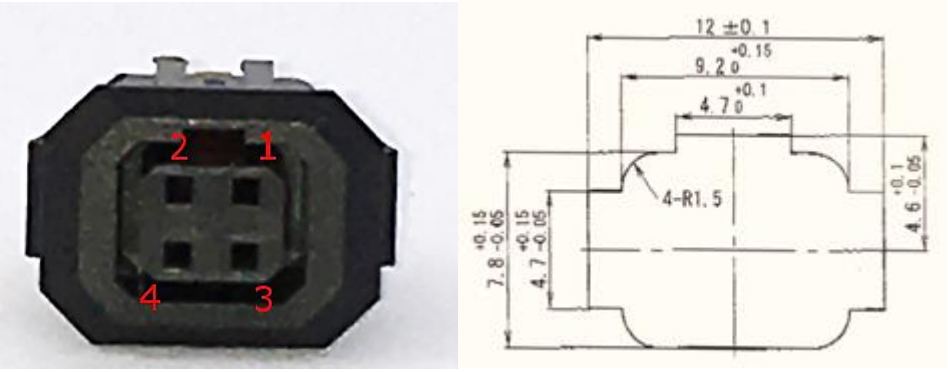


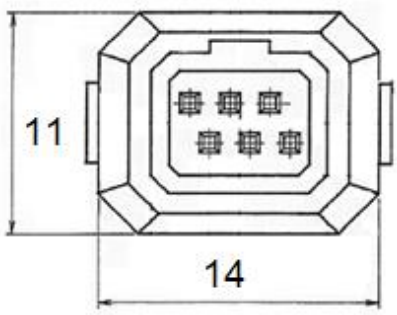
Fig. 3-9: SMARTsat® EB 4 PIN female host plug front view (left), dimensions mounting hole (right)

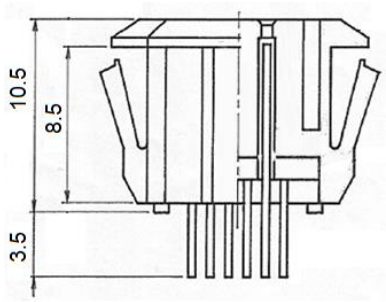
The SMARTsat® EB comes optional with an ***USB*** or ***UART*** interface.

PIN	Signal Description
1.	D+ (USB) / RX (UART)
2.	D- (USB) / TX (UART)
3.	Ground
4.	VCC (+5V)

3.4 SpO_2 sensor connection options

3.4.1 SpO_2 sensor plug – 6 pin minimed

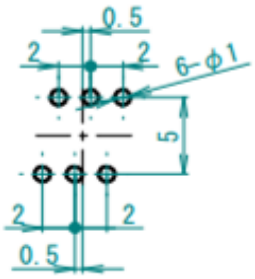




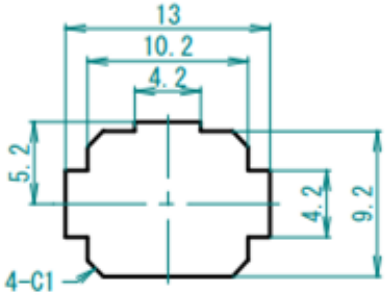
The connector is available as wire mount or pcb mount version:

Version	**Wire mount - gold plated**	**PCB mount - silver plated**
Order number (REF)	5020660002	10020660002
Image		

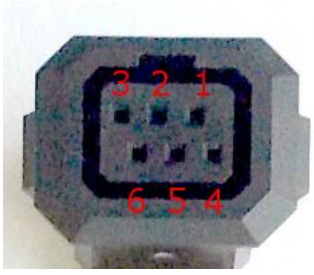
Mounting holes on PCB (thickness 1.6mm):

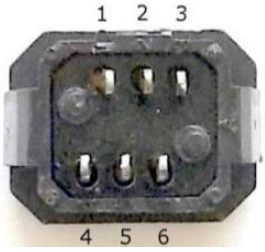


Mounting holes on Panel (thickness 1mm):



<u>SpO_2 sensor plug – 6 pin female - Pin Assignment</u>





PIN	Signal Description
1.	SENSOR ID
2.	LED RED ANODE
3.	LED IR ANODE
4.	Ground/Shield
5.	Detector Anode
6.	Detector Cathode

3.4.2 SMARTsat® SpO_2 sensor basic flex

The *SMARTsat®* SpO_2 *sensor basic flex cable* connects to a PCB flex connector

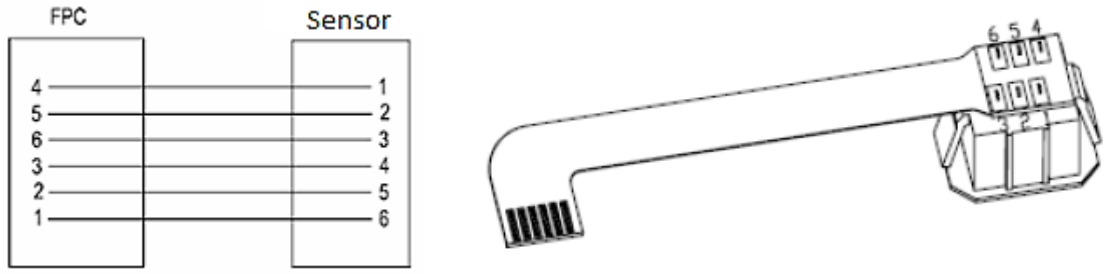


Fig. 3-10: SMARTsat® sensor basic flex cable with pin connector drawing (REF: 9020522001)

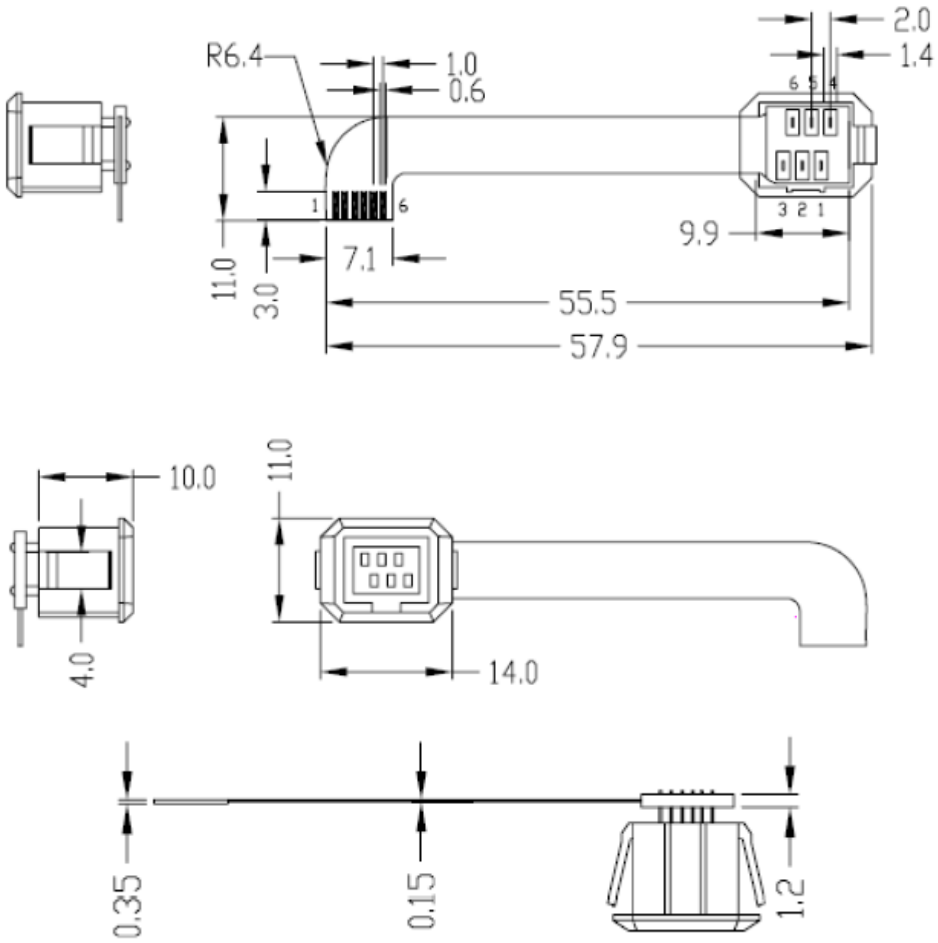


Fig. 3-11: SMARTsat® sensor basic flex cable dimensions

The mating connector for the flex cable is a 6 pin 1.0mm pitch FPC (e.g. **JST part # 06FMN-BMTTN-A-TF(LF)(SN)**).

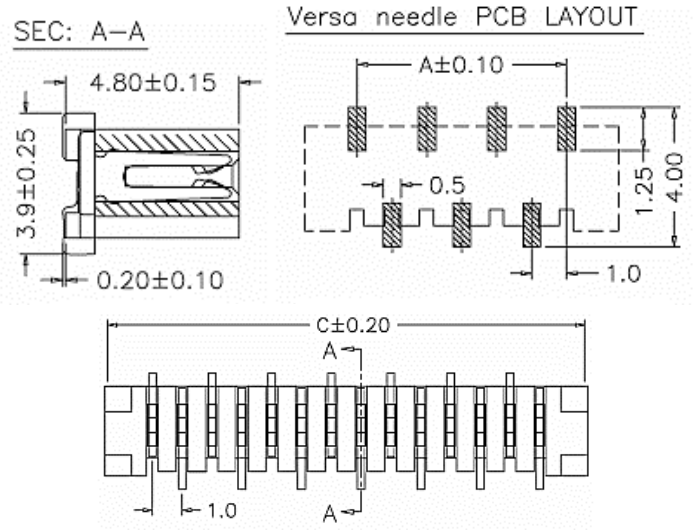


Fig. 3-12: PCB flex connector FPC1.0mm dimensions

3.4.3 SMARTsat® SpO_2 sensor low noise flex – OEM I

Directly connect the SpO_2 sensor to the SMARTsat® OEM I module at **J1** (**see 3.1.2**) with the SMARTsat® SpO_2 low noise flex - OEM I.

Fig. 3-13: SMARTsat® SpO2 low noise flex - OEM I (REF: 12110140001)

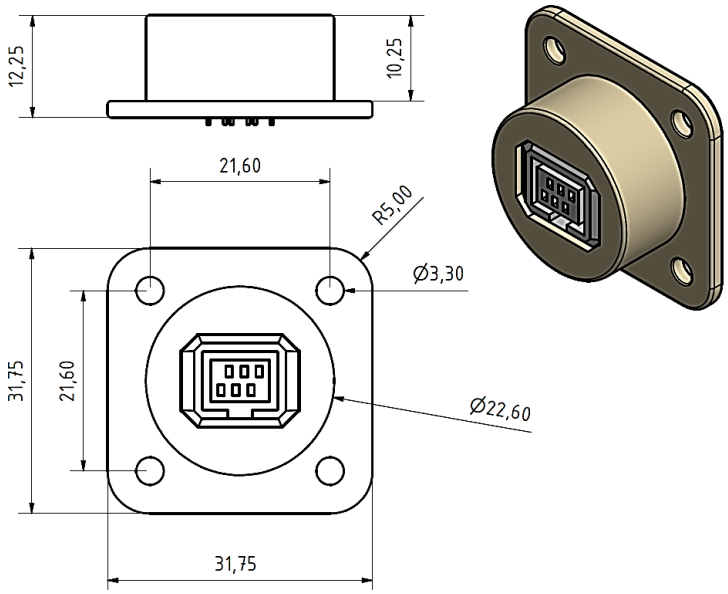


Fig. 3-14: SMARTsat® SpO2 low noise flex - OEM I - connector - dimensions in mm

Customized solutions on request.

4 HOST system considerations

4.1 Power supply requirements

It is the responsibility of the host system to guarantee that power supplied to the SMARTsat® module is within specification. A linear regulator is recommending for stabilizing the power supply (e.g. Texas Instruments REG113-3.3). SMARTsat® is monitoring the power supply and in case, that the voltage is outside the limits an error message will be send that indicates a potentially incorrect measurement.

The baud rate and sampling rate has significant influence on the total power consumption of the SMARTsat® OEM I and II modules.

The following table shows typical examples of the dependence between baud rate and maximum power consumption for all SMARTsat® modules.

Table 5: Dependence between baud rate and max. power consumption

<table>
<tr><th rowspan="2">Baud rate</th><th colspan="2">SMARTsat® OEM I
(Power supply 5V)</th><th colspan="2">SMARTsat® OEM II
(Power supply 3.3V)</th><th colspan="2">SMARTsat® OEM III
(Power supply 3.3V)</th></tr>
<tr><th>I[mA] @75Hz</th><th>I[mA] @300Hz</th><th>I[mA] @75Hz</th><th>I[mA] @300Hz</th><th>I[mA] @75Hz</th><th>I[mA] @300Hz</th></tr>
<tr><td>9600</td><td>29.5</td><td>47.0</td><td>29.6</td><td>47.1</td><td rowspan="6">12.3</td><td rowspan="6">27.5</td></tr>
<tr><td>19200</td><td>28.7</td><td>46.7</td><td>28.9</td><td>46.9</td></tr>
<tr><td>38400</td><td>28.5</td><td>46.6</td><td>28.7</td><td rowspan="2">46.7</td></tr>
<tr><td>57600</td><td>28.3</td><td>46.5</td><td rowspan="3">28.5</td></tr>
<tr><td>115200</td><td rowspan="2">28.2</td><td rowspan="2">46.4</td><td rowspan="2">46.6</td></tr>
<tr><td>230400</td></tr>
</table>

4.2 Power-ON initialization and self-test

After power on the SMARTsat®, board performs a self-test. The initialization time is approximately 1.5 sec. The self-test verifies the integrity of the hardware components like ROM, RAM, and CPU. SMARTsat® begins operation, if no error was detected during the self-test routine. If an error is detected, a status and/or error message will be send to the host system and the normal operation will be stopped.

4.3 Reset

There are three different ways to actively reset a SMARTsat® module:

- Power on reset at switch-on
- Software reset by host command (Refer to section 3.3 (ID 0x30) of [1])
- MCU Pin reset (Refer to section 3)

After reset, both the **SMARTsat® OEM I and OEM II** modules will start-up with the default settings for externally settable parameters independent of reset source. Customized FW versions will start with customized start-up settings. The externally settable parameters are listed in the communication protocol [1] in section 2.3.3.

However for **SMARTsat® OEM III** starting with HW v4.2, the behavior after reset is different. Depending on the source of reset, the user adjustable settings with which the SMARTsat® OEM III module starts differ as specified in the table below:

#	Reset source	Behavior regarding start-up settings
1	Power on reset at switch-on (performed if supply voltage drops below 2.7V)	Start-up with default settings [1)]
2	Software reset by host command (Refer to section 3.3 (ID 0x30) of [1])	
3	MCU pin reset (Refer to section 3.2.2, BU1 Pin) NOTE: Identical behavior, if the module automatically resets because of a watchdog reset	Start-up with the last selected settings before the reset occurred.

[1)] Customized FW versions start with customized start-up settings

The following information is applicable to SMARTsat® OEM I/ II and III:

The reset pin is low active and an open drain output. For normal operation, the reset pin should be at high level. You can leave the pin unconnected, all SMARTsat® OEM boards are equipped with a pull up resistor. After reset a Power-ON initialization and self-test (section 4.2) is performed.

NOTE: For safety reasons the host is recommended to perform a MCU pin reset, if measurement data is not continuously received in the last 2 seconds after module power on or during operation. Perform a power on reset, if after the MCU pin reset still no measurement data is received. If the defect continues, send the defective module to bluepoint MEDICAL.

4.4 Shielding/ Crosstalk

The currents in the two detector lines anode and cathode are in the nA range. Due to this fact the electric wiring requires adequate handling.

Disturbances due to inductive coupling on these lines have a direct effect on the measurement quality. Following points should be considered:

- should be kept as short as possible
- should be wired exactly parallel a short distance from each other
- should be kept away from electromagnetic noise sources
- should be surrounded by a ground plane

4.5 Electrostatic discharge (ESD) protection

ESD protection for the SMARTsat® boards must be provided by the host system. The SMARTsat® boards contain static sensitive devices and therefore should itself be treated as a static sensitive device.

4.6 Electromagnetic compatibility (EMC)

For certification of medical devices a verification of the host system with integrated SMARTsat® including connected sensor according to IEC 60601-1-2 is mandatory.

Following figure shows an example for a passive network which can be used in a host system to reduce the influence of radiated immunity. It is recommended that such a network is used for the LED and Detector lines.

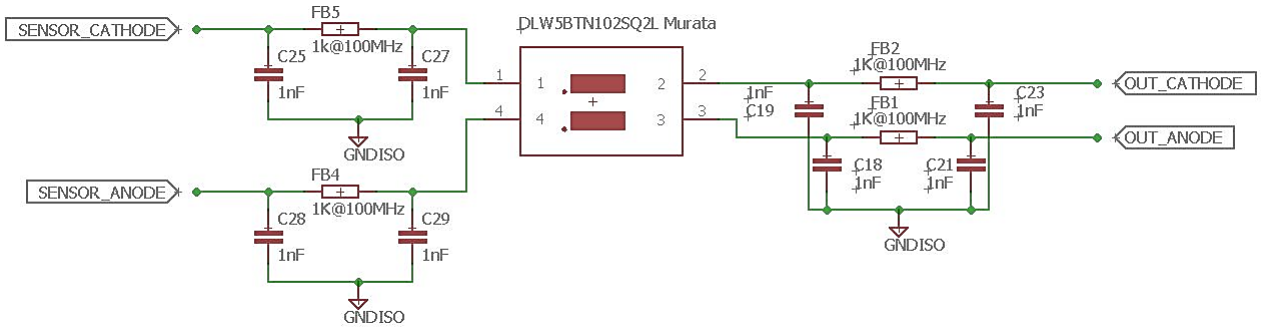


Fig. 4-1: Passive network for suppression of electromagnetic distortion at the sensor wires

The networks consist of three sections:

1. Discrete PI-Filter with a ferrite bead and an impedance of 1 kOhm at 100 MHz
2. Common mode choke “Murata - DLW5BTN102SQ2L”
3. Discrete PI-Filter with a ferrite bead and an impedance of 1 kOhm at 100 MHz

The SMARTsat® OEM I is already equipped with an EMI suppressor network. Depending on the host system additional measure may be necessary.

4.7 Patient isolation requirements

There is no patient isolation on the SMARTsat® 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 may not be considered when evaluating patient isolation.

4.8 Product standards

SMARTsat® has been developed to meet the requirements of the standards listed below.

Applied Standards	
SMARTsat® module	IEC 60601-1, Ed. 3.1 (excluding parts related to the host monitor) IEC 60601-1-2, 4th Ed (to be tested with intended host monitor) EN ISO 80601-2-61:2019 (excluding parts related to the host monitor)
SMARTsat® sensors	EN ISO 10993-1:2020; ISO 10993-5:2009; ISO 10993-10:2021; EN ISO 10993-23:2021

NOTE: All corresponding standards are to be taken into consideration during integration in a host system. Any influences on or from the host system are not considered.

4.9 Validation of host systems

All host devices with integrated SMARTsat® pulse oximeter modules and accessories shall be validated and approved by bluepoint medical before sale release. The host system validation by bluepoint medical does not replace the tests of certified testing laboratories. It is performed to verify that the risk mitigation measures described in the integration guide and implemented in the host protocol are implemented as intended.

The host validation at bluepoint medical involves testing the HW and SW integration regarding data representation, error handling, electrical safety and labelling.

The end user documentation is validated for correct implementation of sensor application instructions, warnings, technical specifications and cleaning instructions.

For host validation submit at least one fully integrated host system to bluepoint medical including your Host Validation Checklist (refer to Annex 1).

In addition, fill out the Protocol Implementation Checklist [2]. Based on the Risk Analysis of the host system, the implemented actions may differ from the suggestion in the Protocol Implementation Checklist [2], provided the risk has been addressed appropriately. Rationale in case a test is not applicable or accepted as fail.

NOTE: The legal manufacturer of the host device with integrated SMARTsat® module is responsible to ensure that the host system with integrated SMARTsat® Technology complies with regulatory requirements depending on the intended market.

5 Host Communication

5.1 Interface specification

The signals used for communication are the TX and RX signal lines. TX is an output line, used to transmit data to the Host. RX is an input line, used for receiving data from the Host.

Standard settings are: 115200 Bd, 8 data bits, no parity, 1 stop bit. No hard or software handshake is used.

The detailed communication protocol is described in the separate document "**SMARTsat® Communication Protocol**" [1].

5.2 Electrical properties RX/TX for

5.2.1 SMARTsat® OEM II and III

	V_{min}	V_{norm}	V_{max}
Logical 0	-0.3	0	0.99
Logical 1	2.31	3.3	3.6

5.2.2 SMARTsat®OEM I

	V_{min}	V_{norm}	V_{max}
Logical 0	-0.2	0	0.4
Logical 1	0.67*VCC	VCC	VCC+0.3

NOTE: Max3378 Lvl Shifter

5.3 Baud rate configuration

The default shipping baud rate of SMARTsat® is 115200 Bd. The host can change the baud rate using the communication protocol [1]. During this process the default value of 115200 Bd is overwritten by the new setting. Next time when SMARTsat® powers-up it starts with the last set baud rate setting.

***NOTE:* The baud rate can only be changed 1000 times in total.**

6 Development kit

bluepoint MEDICAL offers a development kit for analyzing the SMARTsat® performance and communication protocol using the PC based SMARTsat® Protocol Viewer.

The development kit includes:

- SMARTsat® development board
- SMARTsat® OEM module
- USB cable
- SoftFlap® SpO_2 sensor SF7500
- SMARTsat® Protocol Viewer PC-Software, SMARTsat® Emulator PC-Software, Integration guide (this document), Communication Protocol Specification [1] and Protocol Implementation Checklist [2].
-

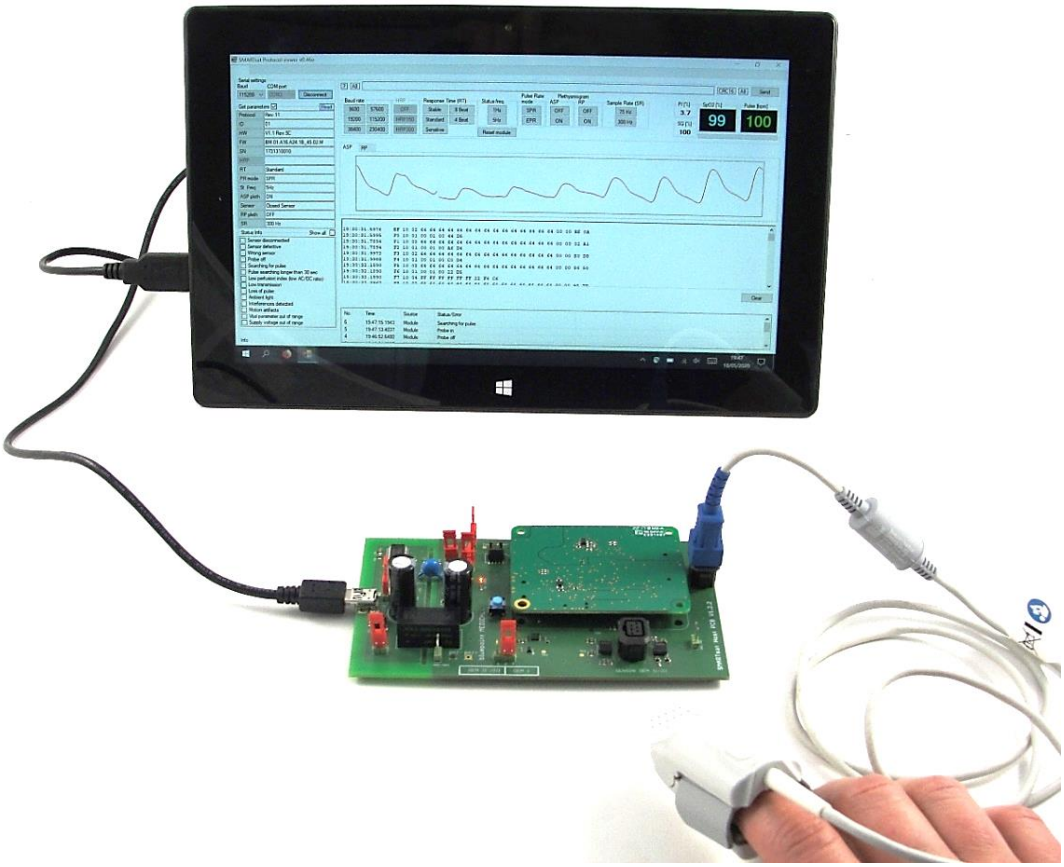


Fig. 6-1: SMARTsat® OEM I Development kit (tablet PC not part of delivery scope)

6.1 SMARTsat® development board

1) **Connect the SMARTsat® module and SpO_2 sensor to the development board.**

The development board including connectors and jumpers is pictured in figure 6-2. Module specific photos are available in Fig 6-3.

a) Connect the SMARTsat® module on the development board depending on the module type:
- OEM I/ II: BU1 and BU2 (green)
- OEM I: J1 and J3 (blue)

b) Connect the SpO2 sensor to the respective plug (OEMII/ III: green, OEM I: blue).

c) Ensure the correct module jumper is closed (OEMII/ III: green, OEM I: blue).

d) Ensure all general jumpers for OEM I/ II/ III are closed (purple) are closed (Vcc, Rx, Tx, JP1).

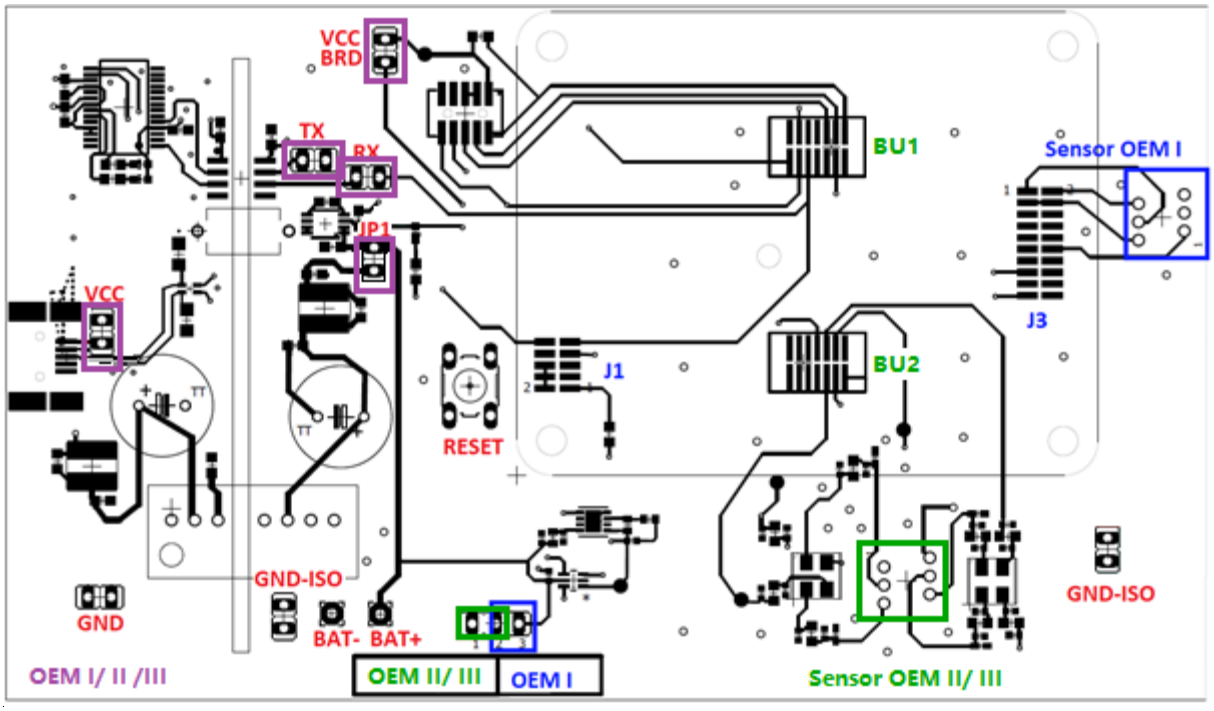


Fig. 6-2: Overview of SMARTsat® Host PCB V1.2.2

Name	Description
VCC	USB voltage 5 V (Jumper connected)
TX	Module UART TxD (Jumper connected)
RX	Module UART RxD (Jumper connected)
JP1	Isolated 5 V (Jumper connected)
VCC_BRD	Isolated LDO 3.3 V (Jumper connected)
OEM II / III	Use PCB with SMARTsat® OEM II/ III (Jumper)
OEM I	Use PCB with SMARTsat® OEM I (Jumper)
BU2 / BU1	OEM II/ III connectors
Sensor OEM II/ III	Connection to SpO2 sensor using *SMARTsat® sensor*
J1/ J3	OEM I connectors
Sensor OEM I	Connection to SpO2 sensor using *SMARTsat® sensor*
Reset	Perform hardware reset
BAT-/BAT+	Connection to use external power supply (JP1 must not be connected)

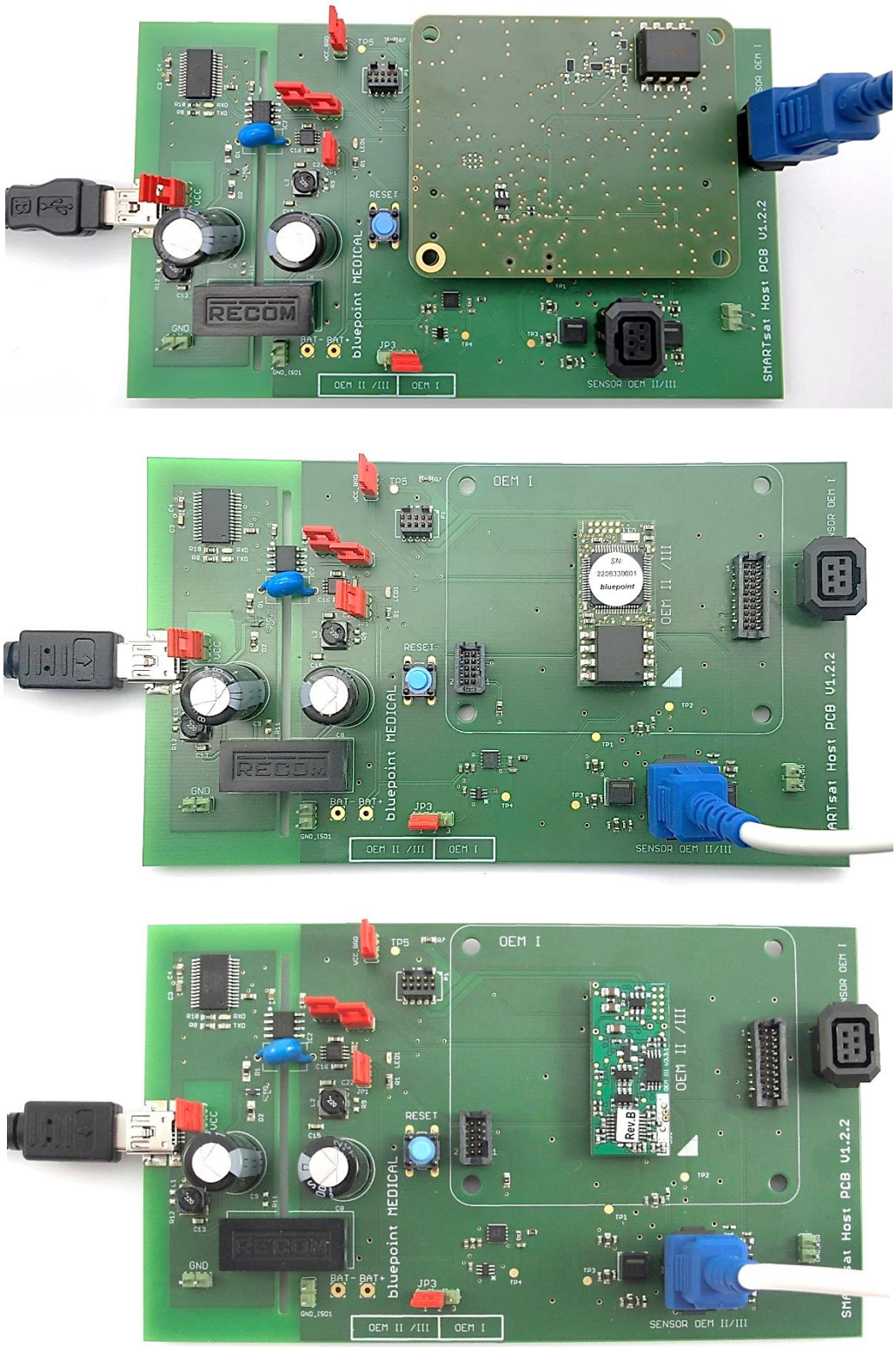


Fig. 6-3: Orientation of SMARTsat®, connection of jumpers and SpO_2 sensor on the development board v1.2.2

NOTE: The SMARTsat® development board is supplied via the USB connection to a PC. Depending on the PC and its configuration the supply can be very noisy.

This can have significant influence on the signal quality as the power supply specifications (ripple <10 mV) are not met. Such distortion becomes clearly visible e.g. during charging of the laptop battery during data acquisition.

Supply the development board using a battery (OEM I: 4.9 V – 5.5 V; OEM II/III: 3.7 V – 5.5 V) to eliminate the USB voltage noise. This is done by removing the JP1 and connecting the battery to BAT-/BAT+ connector.

2) Connect the development board via USB to a PC and install the USB drivers (provided on the USB stick)

The SMARTsat® development board is using an FTDI UART bridge. After connecting the board with the Desktop PC the UART latency of the virtual COM port has to be set to 4 msec to avoid loss of data and ensure good runtime performance (see figure below).

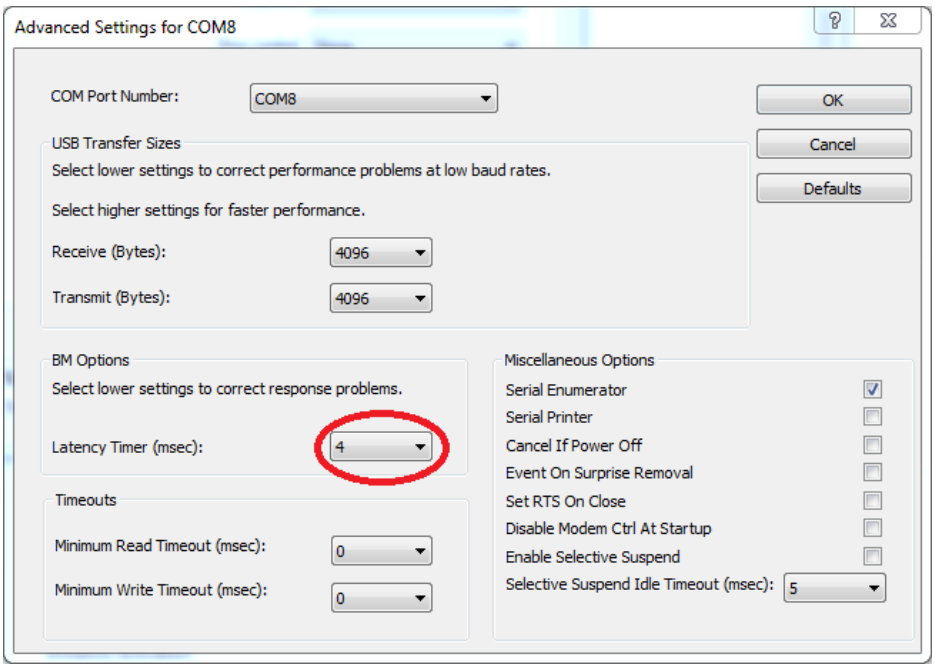


Fig. 6-4: Virtual COM port UART settings

6.2 SMARTsat® Protocol Viewer and Emulator

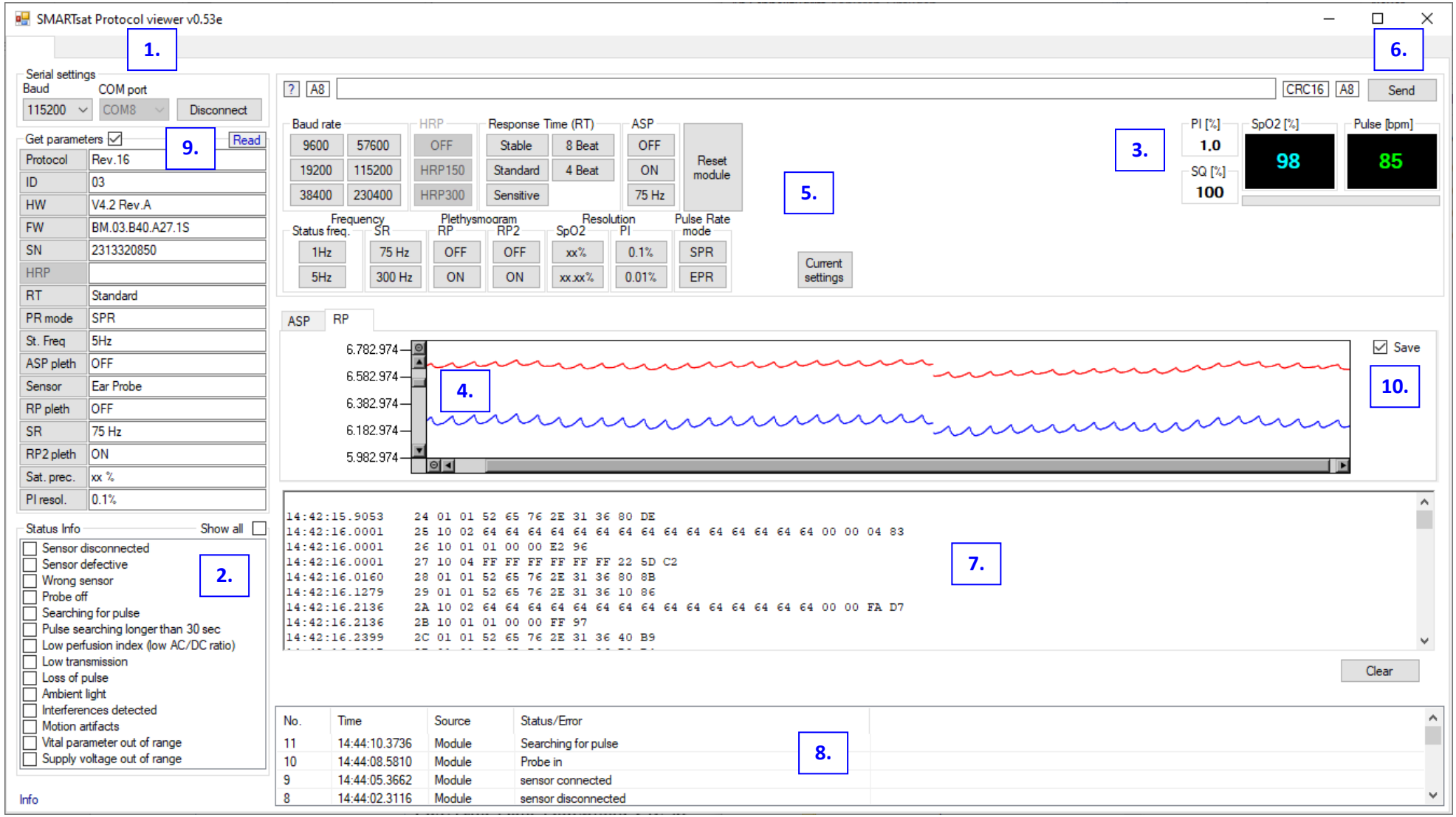


Fig. 6-5: SMARTsat® ProtocolViewer

To view and store data sent by the SMARTsat® module open the SMARTsat® Protocol Viewer (SMARTsat®ProtocViewer.exe provided on USB stick).

Functions available are described in the table below and in Figure 6-5.

Nr.	Description
1.	Select Baud and COM port and start the communication using the CONNECT button
2.	Continuous display of transmitted SMARTsat® status information
3.	Continuous display of transmitted measurement values SpO_2 and pulse rate, perfusion index (PI) and signal quality (SQ).
4.	Display of IR transmission plethysmogram, if the Raw Plethysmogram RP is activated and display of IR and RED transmission plethysmogram, if the Raw Plethysmogram RP2 is activated. The display switches to the RP (Raw Pleth) tab and displays the absorption plethysmogram.
5.	Selected commands can be send to the SMARTsat® module by using the buttons e.g. Set response time, activate RP etc.
6.	Possibility to send commands to SMARTsat® according to the SMARTsat® Communication Protocol [1]. Send the command (e.g. enter ***10 31 73*** to set baud 115200) to the module by pressing the SEND button or ENTER **NOTE:** The PC-SW automatically links the Identifier with the attribute ***0x80 OR***, adds the Start flag (0xA8), End flag (0xA8) and the correct CRC before sending the command to the SMARTsat®.
7.	Transmitted SMARTsat® data in HEX format. Start flag (0xA8) and End flag (0xA8) have been removed. Data has been destuffed. Data can be exported using the right mouse context menu.
8.	List of status and errors send by SMARTsat® including frame errors which occurred during communication between SMARTsat® and the Protocol Viewer application. The log entries can be exported using the right mouse context menu.
9.	Current module settings. These are first updated upon pressing the *connect* button. Thereafter they are updated if the setting is changed, or if the *Get parameter quick button* is pressed.
10	Start store of RP, RP2 data (or HRP for Protocol rev.8 and smaller) and results by activating the SAVE check box and entering a file name. Stop data acquisition by deactivating the check box. The file is also closed if the application is closed or if the port is disconnected (1.). The RP data is stored in the .txt including the start time and module settings. Each second the SpO2, pulse rate (PR), perfusion index (PI) and signal quality (SQ) is plotted next to the RP, separated by a semicolon (e.g. 4508517;99;73;7.0;100 // HRP; SpO2; PR; PI; SQ)

6.3 SMARTsat® Protocol Emulator

Verify the host system using the SMARTsat® Emulator provided on the USB stick. This tool sends data in the SMARTsat® protocol format (see Figure below).

Use the development kit (or a level shifter like FTDI_TTL-232R) to connect the host system (Rx, Tx, GND) via USB to the PC. The SMARTsat® is simulated by the Emulator. Status and measurement results sent can be changed and errors generated by the emulator to verify the host system behavior.

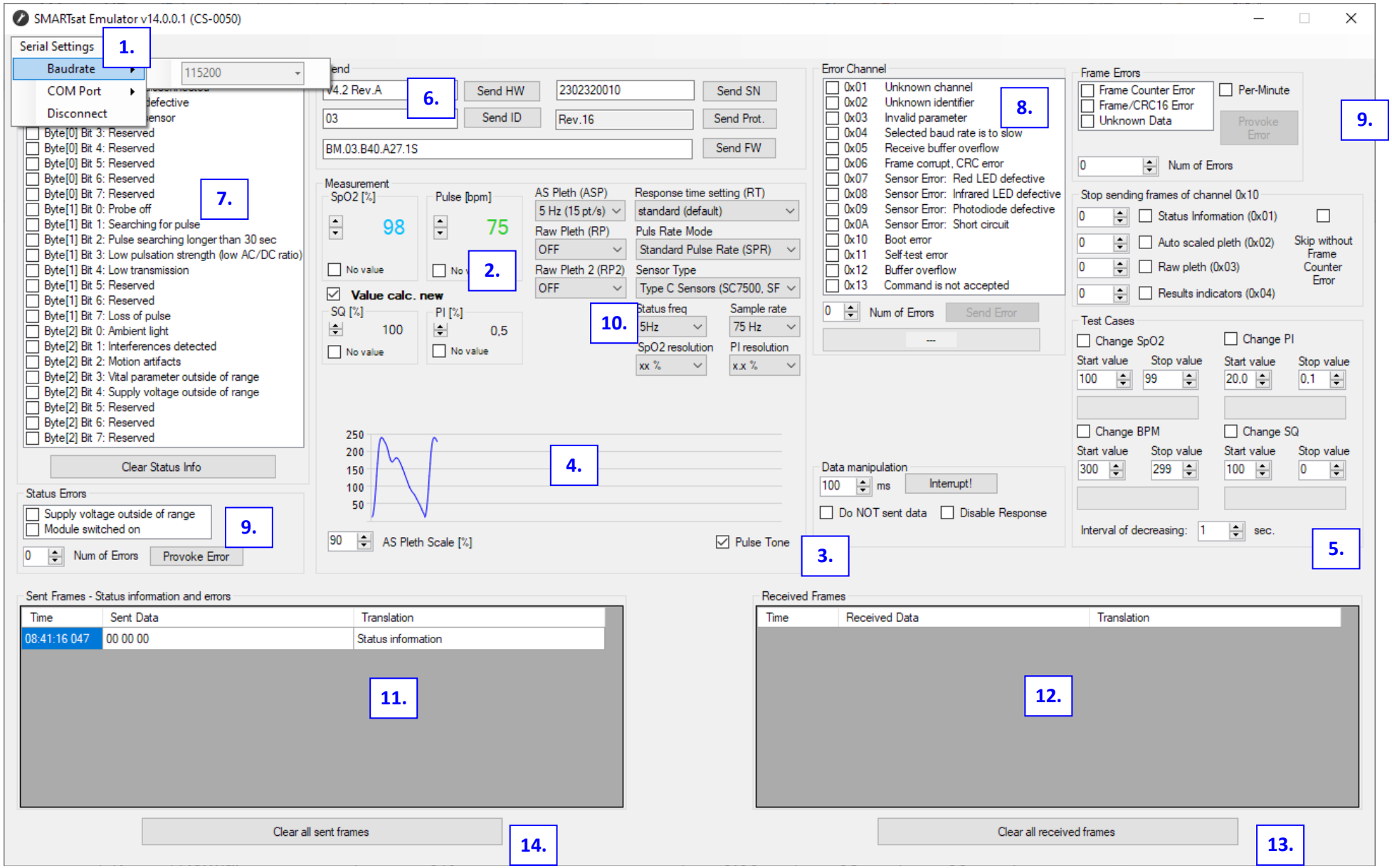


Fig. 6-6: SMARTsat® Emulator

Nr.	Description
1.	Select COM port and baud rate to open the serial connection using the Serial Settings button.
2.	Current measurement values transmitted to the host
3.	Adjustment of the measurement values. The *Pulse Tone* checkbox enables/disables the pulse beep indicator
4.	Normalized Plethysmogram transmitted to the host. The same waveform is used for the AS (auto scaled) and RP (raw) plethysmogram.
5.	Generation of test cases. Enter a start and stop value for a measurement value and start the test case using the *change …* Checkbox. The value is changed automatically. The change interval can be set at box *Interval of decreasing*.
6.	Hardware and firmware information of the simulated SMARTsat® module. This information can be requested by the host or is sent by the emulator using the buttons next to the entered strings.
7.	By activating the checkboxes the appropriate flags in the status information frame are set and sent continuously to the host.
8.	Generation of error channel messages. Activate a checkbox and enter the number of errors transmitted to the host. The errors are sent using the Send Error button.
9.	Generation communication errors. Activate a checkbox and enter the number of errors transmitted to the host. The errors are sent using the Provoke Error button.
10	Settings configuration of the simulated SMARTsat® module and sensor type. Use the drop down menus to change the settings.
11	All data received from the host. The information is not filtered or post-processed. The valid data frames are already de-stuffed.
12	Description of the valid data frames received from the host.
13	Use this buttons to clear the received data.
14	Use this buttons to clear sent data.

7 Technical data

Functional measurement range:

Parameter	OEM I/II	OEM III
SpO_2	0 – 100 %	
Pulse Rate	Standard Mode: 30 – 240 bpm; Enhanced Pulse Rate Mode (EPR): 20 – 300 bpm	
Perfusion Index	0.02 – 20 % (no motion)	0.1 – 20 % (no motion)

Accuracy:

Parameter	Measurement range	Accuracy
SpO_2 [6]	0 – 100 %	70 – 100 %: A_{rms} ≤ 2% (no motion, incl. low perfusion[3])[1, 4]
		60 – 80% : A_{rms} ≤ 2.5% (no motion, incl. low perfusion[3]) [1, 4]
		70 – 100 %: A_{rms} ≤ 3% (motion condition)[2]
		<60%: unspecified
Pulse Rate	Standard Mode: 30 – 240 bpm	A_{rms} ≤ 2bpm (no motion, incl. low perfusion[3]) [5] A_{rms} ≤ 3bpm (motion condition[2])
	Enhanced Pulse Rate Mode (EPR): 20 – 300 bpm	

1) Pulse oximeter measurements are statistically distributed. A_{rms} accuracy is a statistical calculation of the differences between device measurements and reference measurements. Approximately two-thirds of device measurements are expected to fall within ± A_{rms} of the reference measurements.

2) Tested with all Fluke Index II Oximeter tester motion patterns with pattern specific motion frequency of 0.5Hz to 6Hz at perfusion PI: 0.65% to 5% including non-repetitive motion and motion repeating every 0.5Hz.

3) Tested with Fluke ProSim 8 Oximeter tester at infrared percentage modulation PI: 0.7% to 0.1%

4) Applies to reusable SMARTsat® sensors, refer to sensor instructions for use for sensor specific accuracy claims. SpO_2 accuracy is validated by clinical accuracy studies on healthy adult male and female test subjects of age 21 to 32 with skin pigmentation ranging from light to dark over the specified functional oxygen saturation range.

5) Pulse rate accuracy was verified by simulated bench tests with Fluke ProSim 8 Oximeter tester to ensure that the entire range was verified.

6) Arterial functional oxygen saturation

Response time:

Parameter	Specification
Display of first value	The time until the first value is displayed after application is depending on the measurement conditions (perfusion, motion artefacts) and is in the following range: SpO_2: 3 to 7 s; Pulse Rate: 5 to 8 s.
Response time modes	Refer to section 2.2.2
Data update period	Typically, the displayed data update period is 1s. The data update is delayed in case no new valid data is available, e.g. due to excessive signal distortion. The longest data update period is 28 s.

Power requirements:

	OEM I	OEM II	OEM III	EB (OEM III)
Input voltage range [VDC] (Ripple <10mV)	3.8 – 5.5	3.3 – 4.0	3.2 – 3.6	4.5 – 5.25

Parameter	OEM I [1)]		OEM II [1)]		OEM III		EB (OEM III)	
Supply voltage [VDC]	5		3.3		3.3		5	
Sample Rate [Hz]	75	300	75	300	75	300	75	300
Typical power consumption	96mW (19mA)	187mW (37mA)	65mW (20mA)	125mW (38mA)	33mW (10mA)	53mW (16mA)	50mW (10 mA)	80mW (16mA)
Maximum power consumption	140mW (28mA)	230mW (46mA)	96mW (29mA)	155mW (47 mA)	43mW (13mA)	102mW (31mA)	65mW (13 mA)	145mW (29mA)

[1)] The maximum power consumption was determined under extreme ambient light conditions; the typical value is significantly lower.

NOTE: The baud rate and sampling rate has significant influence on the total power consumption of the SMARTsat® OEM I and II modules (see Chapter 4.1 for more detail). Here listed specifications are valid for baud rate 230400 Bd and raw plethysmogram (RP, RP2) switched off.

Environmental specifications:

Parameter	OEM I OEM II OEM III EB
Operating temperature	-20°C to 60°C
Storage temperature	-40 °C to +70 °C
Relative humidity	15 % to 95 % (operation, non-condensing) 10 % to 95 % (storage, non-condensing)
Altitude [1)]	620 [1)] to 1060 hPa (620 hPa corresponding to an altitude of 4000m)

[1)] May differ depending on host specification and validation tests

Serial communication and data:

Parameter	OEM I/II/ III
Time until the first command is accepted after switch-on	1.5 sec
Baud Rate	9600 Bd up to 230400 Bd (min. rate for Raw Plethysmogram: 115200 Bd)
Sampling rate adjustable to	75 Hz, 300 Hz

Dimension:

Parameter	OEM I	OEM II	OEM III
Dimensions (L x W x H)	63.5mm x 50.8mm x 11.0mm	31.0mm x 14.7mm x 8.7mm	31.0mm x 14.0mm x 5.2mm

Classification:

Requirement	Classification
According to the degree of protection against harmful ingress of water according to EN 60601-1	Applicable to SpO2 sensors. Refer to respective sensors instructions for use.
Sterility according to EN 60601-1	The SMARTsat® module, sensors and cable are not sterile
Mode of operation according to EN 60601-1	Continuous mode
the degree of protection against electric shock according to EN 60601-1	The SMARTsat® pulse oximeter sensors together with the SMARTsat® module are classified as TYPE BF applied part
Medical Electrical System (ME System)	The SMARTsat® module integrated in a host system shall be considered as a ME system
Classification according to MDD, Annex IX	**Integrated SMARTsat® Module:** **IIa**[1] (Rule 10 of MDD Annex IX applies) [1] NOTE: In case of alarm monitoring of SpO_2 and pulse rate, the nature of variations is such that it could result in immediate danger to the patient. Therefore in case the host device in which the SMARTsat® module is integrated has an alarm function, the host device is classified as IIb. **SMARTsat® SpO2 sensors:** **IIb** (Rule 10 of MDD Annex IX applies) NOTE: As part of the transition to MDR the SpO2 sensors in future will be classified as IIa according to Rule 10 of MDR Annex VIII. **SMARTsat® SpO2 cables:** **I** (Rule 1 of MDD Annex IX applies)

8 Order numbers

8.1 Development kits, modules and connectors

Product	REF
SMARTsat® I development kit SMARTsat® OEM I module; Development platform (incl. USB cable and PC software); SoftFlap SpO_2 sensor SF7500	8110140009
SMARTsat® II development kit SMARTsat® OEM II module; Development platform (incl. USB cable and PC software); SoftFlap SpO_2 sensor SF7500	8110140010
SMARTsat® III development kit SMARTsat® OEM III module; Development platform (incl. USB cable and PC software); SoftFlap SpO2 sensor SF7500	8110140012
SMARTsat® OEM I module	8110502001**xx**
SMARTsat® OEM II module	9110100001**xx**
SMARTsat® OEM III module	8110140011**xx**
SMARTsat® 6 pin sensor plug	5020660002
SMARTsat® sensor plug - PCB mounting version	10020660002
SMARTsat® sensor basic flex cable	9020522001
SMARTsat® OEM I sensor low noise flex cable	12110140001
SMARTsat® EB with OEM III module	on request
SMARTsat® EB 4 PIN female host plug	205012004

xx: Indicates customized FW versions (e.g. customized start-up settings/ Sensor ID)

8.2 Sensors and accessories

Product	Type	REF
SoftCap® SpO_2 sensor – Large	SC7500	6020132004
SoftCap® SpO_2 sensor – Medium	SCM7500	6020132010
SoftCap® SpO_2 sensor – Small	SCP7500	6020132300
SoftFlap® SpO_2 sensor	SF7500	6020132002
SoftWrap® SpO_2 sensor	W7500	6020132006
Adult Plaster Disposable SpO_2 Sensor	10-AP	6020131194
Paediatric Plaster Disposable SpO_2 Sensor	10-PP	6020131197
Infant Plaster Disposable SpO_2 Sensor	10-IP	6020131199
Neonatal Plaster Disposable SpO_2 Sensor	10-NP	6020131201

Product	Type	REF
Ear Probe SpO_2 sensor	EP7500	6020132254
Y- SpO_2 Sensor for Single Patient Use	Y7500	12020132001
Baby Foot Spotcheck Sensor	BF7500	14020132001
SMARTsat® Hydrogel pads	HGP7500	12020121002
SMARTsat® Hydrogel stripes	HGS7500	12020121001
Sensor extension cable 1.2m	XT6500	1020132275
Sensor extension cable 2.4m	XT6501	1020122058
Wrap Tape 12cm	Wrap Tapes, Box of 12 pcs	15020621001
Wrap Tape 15cm	Wrap Tapes XL, Box of 12 pcs	17020621001
Ear probe cable support for Earprobe	Cable support (CS)	13020663004

Customized sensors (e.g. sensor ID or connector) available depending on order quantity. Contact your SMARTsat® implementation support at bluepoint for more detail.

9 Reporting of serious incidents

Report any serious incident that occurs in connection with the use of this product to the competent authority in your country and to the manufacturer. Serious incidents associated with the use of this product are low oxygen saturation, high oxygen saturation, electric shock and death.

Contact manufacturer bluepoint medical directly, or send an email to the following address: prrc@bluepoint-medical.com.

For reporting always provide the following information:

- Order number and model as indicated on the product
- Serial number/batch number
- Date and description of the serious incident, including its impact on the patient or any injury
- Your contact details (name and title, institution, address and phone number)

10 Revision History

Rev	Effective Date	Change description
12	2024-Jan-24	Update referenced to Communication Protocol; Update section 4.3 (reset behavior of SMARTsat® OEM III): last user settable parameters are preserved after pin reset.
11	2023-Oct-16	Update SMARTsat® OEM III to HW V4.2 Rev.A; Update Terms (1.3) and Symbols (1.4) Remove redundant data (former table 1 and former table 6) also listed in section 7 (technical data) Update Table 2 (add Arms at 60-80% SaO2) and Table 3 (update and add motion amplitude) Add RP2 description (implemented in host protocol rev.16) Add Fig. 3-7 (recommended fixation of module) Update SpO2 sensor basic flag dimension, section 3.4.2 Update drawing Spo2 sensor low noise flex- OEM I , section 3.4.3 (remove REF: 8110140014) Update power consumption OEM III (Table 5 and section 7) Update section 4.3 reset behavior Add explanation to section 6.1 (1). Add section 4.9 Validation of host systems which replaces section 6.4 Update to ProtocolViewer v53.0.0.0 (6.2) and Emulator v14.0.0.1 (6.3) Update description to accuracy specifications (7) Update section 9 (remove SMARTsat EB with OEM II option, Add Wrap tapes and earprobe cable support)
10	2022-March-17	Update images, dimension and power consumption specifications for OEM I & OEM II with AAC; OEM III SpO2 accuracy validation results updated; Table 4 SMARTsat® performance under motions tested with FLUKE Index II SpO2 simulator updated; Product Standards section 4.8 updated; Add typical results for power consumption depending on baud and sample rate (4.1.2) Added “Response time”, “Classification” and method detail for validation of low perfusion and motion performance and heart rate accuracy validation (section 7).
9	2020-Mai-20	Update according to communication protocol rev.11 [2] Update power consumption, response time and motion performance based on new FW Update images and features for Development brd, Protocol viewer and Emulator Move Host validation checklist to a separate document Correct typos and rework of complete format and chapters Move description of “wake up byte” to the Communication protocol rev.11 [2] Add: sensor BF7500, add drawings of connectors
8 to 0	2018-Apr-11 to 2014-Dez-15	Refer to SMARTsat® OEM I/ II / III - Integration Guide |Doc. No. O-07-00-001 | rev. 8

ANNEX 1

Before submitting the host system for validation at bluepoint medical, send the checklist below to ensure that all requirement categories were addressed during integration (refer to section 4.9). Provide a detailed explanation in case a test is not applicable or accepted as fail.

CATEGORY	RESULT
Measurement Values and Waveform	
- Results and indicators are fully implemented (ch 0x10; id 0x04/ 0x05)	☐ PASS ☐ FAIL ☐ N/A
- At least one waveform presentation is implemented (ch 0x10; id 0x02/ 0x03/ 0x07)	☐ PASS ☐ FAIL ☐ N/A
- Design of display scales compliant with MDR (2017/745) Annex I, clause 14.6.	☐ PASS ☐ FAIL ☐ N/A
Status and Error information	
- Status information is adequately implemented (ch 0x10; id 0x01)	☐ PASS ☐ FAIL ☐ N/A
- Error information is fully implemented (ch 0x02)	☐ PASS ☐ FAIL ☐ N/A
- Data transmission errors are detected (CRC/ Frame error, no-data)	☐ PASS ☐ FAIL ☐ N/A
- At unintended module reset (ch 0x01; id 0x06 is sent at each start-up) the host will check the user adjustable configuration and readjust if applicable.	☐ PASS ☐ FAIL ☐ N/A
- The host device is compliant with MDR (2017/745) Annex I, clause 18.4	☐ PASS ☐ FAIL ☐ N/A
Electrical aspects	
- Circuit connecting SMARTsat® with the host device is separated from live parts and complies with two MOPP according to IEC 60601-1 (circuit diagram part of sensor and module is attached).	☐ PASS ☐ FAIL ☐ N/A
- Input voltage supplied by the host complies with the specified range (see section 7)	☐ PASS ☐ FAIL ☐ N/A
- Ripple in the input voltage are <10mV (has influence on low perfusion performance)	☐ PASS ☐ FAIL ☐ N/A
Mechanical aspects	
Module is mechanically fixed if integrated into mobile host devices (see Fig. 3-7)	☐ PASS ☐ FAIL ☐ N/A
Host internal connection between sensor and module considers aspects listed in section 4.4 (Shielding/ Crosstalk)	☐ PASS ☐ FAIL ☐ N/A
User documentation	
- Instructions for sensor application and cleaning are adequately implemented	☐ PASS ☐ FAIL ☐ N/A
- Safety information (section 1.5) is included	☐ PASS ☐ FAIL ☐ N/A
- Technical specifications referenced correspond to section 7.	☐ PASS ☐ FAIL ☐ N/A

Name:	**Company:**
Signature:	*Date:*