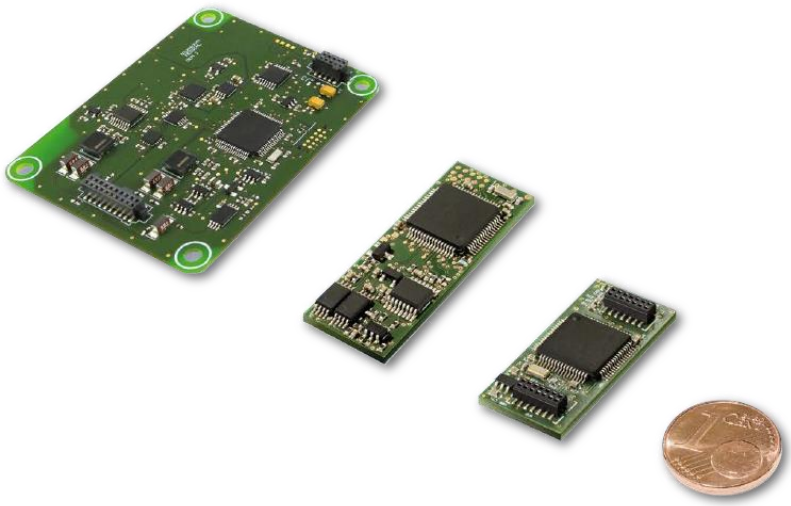
SMARTsat® OEM I / II / III
Integration Guide



MODULE SPECIFICATION AND TECHNICAL INFORMATION

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SMARTsat® Integration Guide

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SMARTsat®, Rubber boot®, SoftCap®, SoftFlap® and SoftWrap®

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1 Introduction

1.1 Revision History

Rev	Date	**Name**	Change description
0	2014-Dez-15	UT	Initial version
0_B	2014-Dez-19	HF	*Add:* Test Method pulse rate (2.2); SpO2 Flex cable in supplied in development kit (3.3.2); Power consumption spec depending on BAUD (4.1); Footnote 4 (power at baud) (7) *Change:* standard pulse rate range 30-240bpm (2.2.1); rem unify product names and correct order number paediatric disposable sensor syntax correction throughout document (8.2) *Remove:* REF at Order numbers in chapter 8 (3.3.1), Interboard flex cable (8.1)
1	2015-Mar-31	PK	*Changed:* Pin 3, Layout BU2 Table "Host Connector Pin Assignments (BU1 and BU2)" (3.2); Power supply requirements Table "Operating Parameters SMARTsat®" (4.1) *Add:* Fig. Power vs. baud (4.1); Host transmission start-up sequence(5.3); picture overview and jumper description at SMARTsat® Host PCB (6.1)
2	2015-May-19	PK	*Add:* Reset (4.3) *Change:* SMARTsat® Protocol Viewer updated to current version of PC-software (Figure 6-5)
3	2015-Dec-09	PK	*Add:* Specifications of SMARTsat® OEM I and II module throughout document; One integration guide for all versions; Earprobe, SMARTsat® OEM II available Q1/2016, SQ indicator (2.1); Baud rate configuration (5.5); Warning to avoid undue bending of cable (2.3); summary of SpO2 / PR accuracy and detailed results based on clinical study 7/2015; add accuracy under motion (3.1); description of Protocol Viewer (7.2); *Changed:* Power consumption (4.1, 7); picture first page; Figure 6-5 (SMARTsat® Protocol Viewer); maximal Data Update Period to 28sec (3.2.2); part numbers (9); Description of figure 3-4: OEM I and II to OEM II and III
4	2016-Mar-03	HF	Add: Basic sensor flex cable and drawings (4.3.2, 9.2), Power consumption at different sampling rates (5.1), Safety note (4.3) *Change:* Specifications and name of wake-up sequence (6.3), description of Protocol Viewer (7.2), "normal time response mode to standard time response mode, Update to A_{rms} results of last Study UCSF (2.1).
5	2016-Apr-04	HF	*Add:* Emulator Tool (6.2) *Corrected:* FTM-107-03-L-DV instead of FTM-107-03-L-DV-S (p.22) *Update:* Protocol Viewer with store function (6.2)
6	2016-Nov-29	HG, UT, HF	*Update:* Response time behavior (Figure 2-1 Table 6 p.14); Various symbols replaced by vector graphics; power specs and accuracy study *Add:* Status Flags (2.3): Loss of Pulse; SMARTsat Emulator description; Communication Protocol Verification Procedure; Appendix (recommended Host actions and Protocol Verification Check List); IEC 62471 to list of standards; Parts REF 10020660002 and 6020132010; Terms and definitions, circuit example at section 4.6 *Remove*: OEM I
7	2018-Mar-01	UT, HF	*OEM I added, source OEM_I_supplement_Sheet.pdf 2/2017; added: OEM I Flex , Y Sensor , Hydrogel Pads+Stripes, update to communication protocol rev.9*
8	2018-Apr-11	UT,WT	*SMARTsat EB added*

1.2 References

ID.	Description / Title	Rev.
[1]	SMARTsat® Communication Protocol	rev. 9

1.3 Terms and definitions

Item	**Description**
AM	Alarm monitor
Appl.	Application
ASP	Auto scaled plethysmogram
BPM	Beats per minute
CM	Continues measurement

Item	Description
CO	Carbon monoxide
COHb	Carboxyhemoglobin
EMC	Electro magnetical compatibility
ESD	Electrostatic discharge
EUT	Equipment under test
HI	Host interface
IFU	Instructions for Use
IMPL	Implemented
MetHb	Methemoglobin
PI	Perfusion index
PR	Pulse rate
PTT	Pulse Transit Time
SpC	Spot check measurement
SpO2	Oxygen saturation

1.4 Overview and intended use

The bluepoint MEDICAL SMARTsat® pulse oximetry module is a small printed circuit board assembly that provides the new SMARTsat® technology for the 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; taking safety instructions into account (see section 8.2, for more detail on sensors and field of application):

- **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 platform, designed for OEM use and support the full range of bluepoint MEDICAL SMARTsat® oximeter sensors as SoftCap®, SoftWrap®, Earprobe and Disposable. Available SMARTsat® boards are listed in the table below.

Module	Part Number (REF)	Description
SMARTsat® OEM I	8110502001	Low perfusion performance and motion tolerant, active ambient light compensation, equipped with EMI filter for optional direct sensor connection
SMARTsat® OEM II	9110100001	compact, low perfusion performance and motion tolerant, active ambient light compensation
SMARTsat® OEM III	8110140011	compact, motion tolerant and low power
SMARTsat® EB	On request	external housing with SMARTsat® OEM II or OEM III

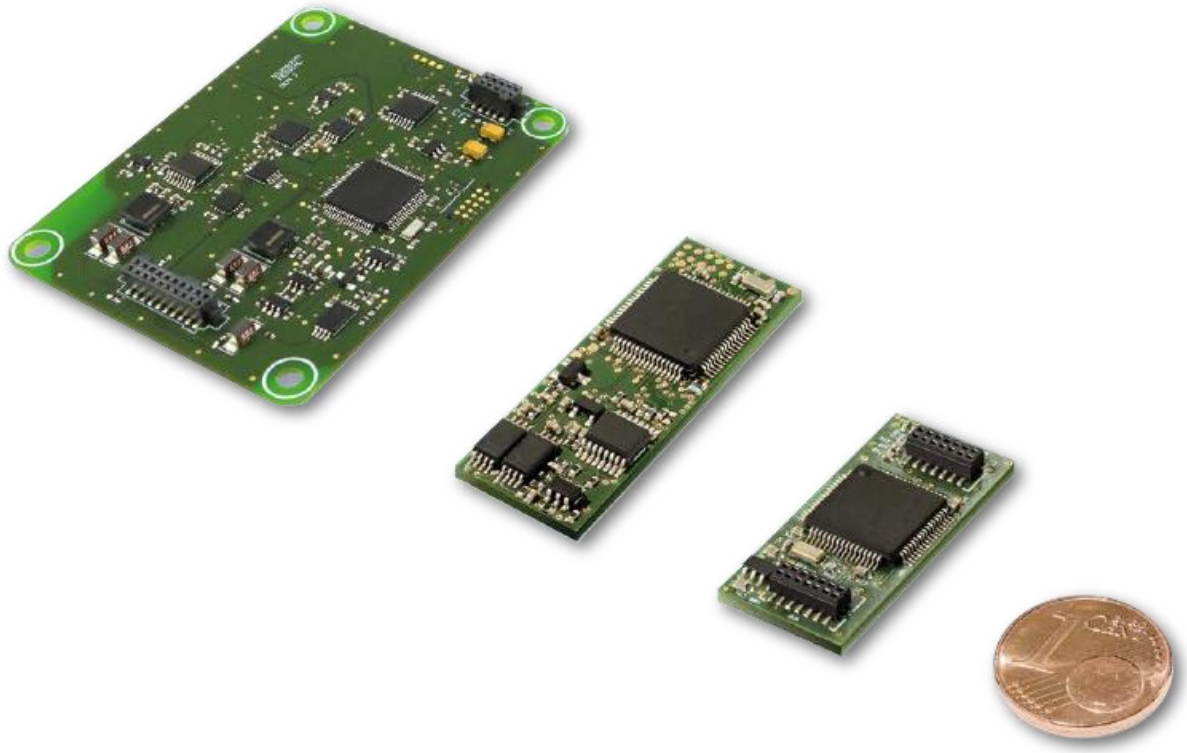


Figure 1-1: SMARTsat® OEM I (left), OEM II (middle) OEM III (right)

The SMARTsat® technology provides a motion tolerant algorithm to measure SpO_2 and PR 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).

The following parameters are available via the Host Interface:

- Functional oxygen saturation
- Pulse rate
- Pulse waveform and perfusion index (based on 905 nm)
- Signal quality indicator
- Pulse search indicator
- Interference Indicator
- Sensor disconnect indicator
- Probe off patient indicator

In **standard mode** the normalized and **A**uto **S**caled **P**lethysmogram (ASP) is available sampled at 75 Hz.

By selecting the **H**igh **R**esolution **P**lethysmogram mode (HRP) a waveform is available at 150 Hz or 300 Hz. This mode is typically used by a host to calculate the PTT (Pulse Transit Time) based on additional designated host signals. In addition the low perfusion performance is increased at sampling rate 150 Hz in case of the SMARTsat® OEM I/II.

Note*:* Due to the high sampling rate the HRP mode requires a minimum baud rate of 115200 Bd and the total power consumption of the board is increased.

SMARTsat® OEM modules are capable of communicating 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.

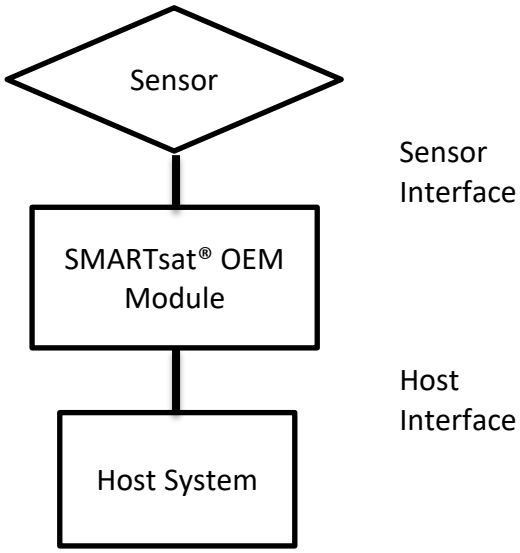


Figure 1-2: SMARTsat® integration into a host system

As an alternative to an internal module the external SMARTsat® EB can be chosen which can carry the OEM II or OEM III. It allows a fast an easy connection to a host system via USB or UART.

Figure 1-3: External SMARTsat® EB

1.5 Symbols

	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
	Date of manufacture
	Type BF applied part
	Catalogue number
	Serial number
	Temperature limitation
	Humidity limitation
	Fragile, handle with care
	Do not dispose in the consumer waste. Electrical and electronic equipment shall be collected and recycled in accordance with (Directive 2002/96/EC)
CE 000	European Union approval (complies with 93/42/EEC Medical Device Directive)

1.6 Safety information

SMARTsat® has been developed to meet the requirements of the standards listed in section 4.8. 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:
Any radio frequency transmitting equipment or other nearby sources of electrical noise may result in disruption of the monitoring system.

Warning:
Only the sensors and accessories offered by bluepoint Medical and listed in the SMARTsat® compatibility list may be used. Sensors and accessories must be in undamaged condition. If other sensors and accessories are used, it could lead to malfunctions and problems with biocompatibility.

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

Warning:
The use of accessories, sensors, and cables other than those specified may result in increased electromagnetic emission and/or create invalid readings of the monitor.

Warning:
If there should be any reason to doubt the exactness of the measurement, then the vital functions of the patient should first be investigated by alternate means. Afterwards, the functionality of SMARTsat® should be checked.

Warning:
Pulse oximeter equipment measurements are statistically distributed. Only about two-thirds of measurements can be expected to fall within ± A_{rms} of the value measured values by a CO-Oximeter. To verify the function of pulse oximeter probes a functional tester like Index II SpO_2 simulator or equivalent can be used.

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

2 Features and performance

2.1 SpO2 and pulse rate measurement accuracy

The SMARTsat® boards and SMARTsat® SpO_2 sensors are designed to meet the accuracy requirements in accordance with ISO 80601-2-61:2011.

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 SMARTsat®

The SMARTsat® pulse rate range and low perfusion capability was validated with the Fluke Prosim 8 vital sign simulator.

The pulse rate und saturation accuracy under motion (standard response time mode and standard pulse rate mode) was tested with the Index II SpO_2 simulator.

A summary of the accuracy specifications is listed in the table below, detailed results are found further below.

Table 1: Summary of accuracy specifications SMARTsat® OEM I/ II / III

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

[1] As inherent to their functional principle, pulse oximetry measurements are statistically distributed; therefore only about two-thirds of the measurement data are expected to fall within ± A_{rms} of the value measured by a CO-oximeter

[2] Tested with all motion patterns Fluke Index II SpO_2 simulator at standard response time mode setting

[3] Tested with Fluke Prosim 8 vital sign simulator

[4] Applies to SC7500, refer to sensor specific results (table 2)

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 18 years and older.

All subjects were healthy, non-smoking, light-to-dark-skinned and without anemia. 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 verify that the bluepoint MEDICAL SMARTsat® Pulse Oximeter Technology in combination with the SMARTsat® SpO_2 sensors: SoftCap® (SC7500), SoftFlap® (SF7500), SoftWrap® (W7500), Disposable Adult® (10-AP) and Ear Probe (EP7500), demonstrated clinical accuracy performance consistent with the requirements of the applicable international standard criteria for accuracy.

The study results are summarized in the tables below.

Table 2: **SMARTsat® OEM I/II** SpO_2 accuracy validation results

	A_{RMS} in the SaO_2 ranges					
Sensor type	**60 - 100 %**	**70 - 100 %**	**90 - 100 %**	**80 - 90 %**	**70- 80 %**	**60 - 70 %**
10-AP	2,1	2,1	2,2	1,9	2,0	2,2
EP7500	2,2	2,1	1,0	1,7	2,8	3,5
SC7500 [1)]	1,6	1,6	1,1	1,7	1,8	1,9
SF7500	1,6	1,5	1,4	1,3	1,7	2,3
W7500	1,6	1,4	1,0	1,2	1,8	2,8

Table 3: **SMARTsat® OEM III** SpO_2 accuracy validation results

	A_{RMS} in the SaO_2 ranges					
Sensor type	**60 - 100 %**	**70 - 100 %**	**90 - 100 %**	**80 - 90 %**	**70- 80 %**	**60 - 70 %**
10-AP	2,5	2,4	2,1	2,3	2,6	3,4
EP7500	2,4	2,3	1,4	1,6	3,2	3,3
SC7500 [1)]	1,7	1,6	1,5	1,8	1,7	2,4
SF7500	1,6	1,5	1,4	1,4	1,7	2,0
W7500	1,7	1,6	1,3	1,5	1,9	2,4

[1)] Accuracy statement applies to SC7500, SCM7500 and SCP7500

Table 4 presents the detailed motion performance results of the SMARTsat® at standard response time mode and standard pulse rate mode.

Table 4: SMARTsat® performance under motions tested with FLUKE Index II SpO_2 simulator

Fluke Index II SpO2 simulator					**SMARTsat® (standard pulse range mode, standard response time mode*)**			
Motion pattern	**PI [%]**	**Motion Freq. [Hz]**	**SpO_2 Index II [%]**	**Pulse Index II [bpm]**	**measured SpO_2 [%]**	**abs error SpO_2 [digit]**	**measured Pulse [bpm]**	**abs error Pulse [bpm]**
Normal	5,00	-	98	55	98	0	55	0
Weak	0,65	-	90	95	90	0	95	0
Bradycardia	5,00	-	88	45	87	-1	45	0
Hypoxic	2,00	-	70	95	71	1	95	0
Neonate	1,00	-	90	180	90	0	180	0
Tachycardia	1,20	-	85	130	86	1	130	0
Geriatric	2,40	-	92	95	92	0	95	0
Obese	3,00	-	93	90	93	0	90	0
Normal/Tap	5,00	2,5	98	55	97	-1	56	1
Normal/Shiver	5,00	6,0	98	55	98	0	56	1
Weak/Tap	0,65	4,3	90	95	90	0	95	0
Weak/Shiver	0,65	6,0	90	95	90	0	95	0
Brachy/Shiver	5,00	6,0	88	45	88	0	44	-1
Hypoxic/Tap	2,00	4,3	70	95	72	2	95	0
Hypoxic/Shiver	2,00	6,0	70	95	71	1	95	0
Neonate/Shiver	1,00	6,0	90	180	90	0	180	0
BradyTap#2	5,00	3,9	88	45	88	0	44	-1
HypoxTap#2	2,00	4,3	70	95	69	-1	93	-2
WeakTap#2	0,90	1,0	80	95	83	3	93	-2
NormalTap#2	5,00	2,5	93	55	90	-3	54	-1
Asystole	2,00	1,1	0	0	0	0	0	0
LowFreq1	1,00	0,5	80	75	81	1	76	1
LowFreq2	1,00	0,5	70	75	73	3	75	0
SlowTap	1,00	2,0	80	75	82	2	75	0
|abs. error| >		**6**	**|abs. error| >**		**4**	**|abs. error| <=**		4

* Changing the Response Time Settings has significant influence on motion tolerance performance (see section 2.2.2, table 6).

2.2 Additional measurement modes

2.2.1 Enhanced Pulse Rate Mode (EPR)

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

The *standard pulse rate mode* offers a pulse rate range of 30 – 240 bpm (beats per minute) with high motion tolerance performance depending on the response time mode setting.

By selecting the *enhanced pulse rate mode* (EPR) the pulse rate measurement range is significantly increased to 300 bpm, however the motion tolerance performance is reduced. See the table below for more detail.

NOTE: Changing the *Response Time Settings* has significant influence on motion tolerance performance (see section 2.2.2, table 6).

Table 5: Pulse rate modes

Pulse rate mode	Measurement range	Accuracy	
Standard Pulse Rate	30 – 240 bpm	*No motion:* *motion:*	± 2 bpm ± 3 bpm*
Enhanced Pulse Rate (EPR)	20 – 300 bpm	*No motion:* *motion:*	± 2 bpm unspecified

* Tested in standard response time mode with all motion patterns of Fluke Index II SpO_2 simulator (see **Table 4**)

2.2.2 Response Time Setting

Five different response time settings are available for selection depending on the application. 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.

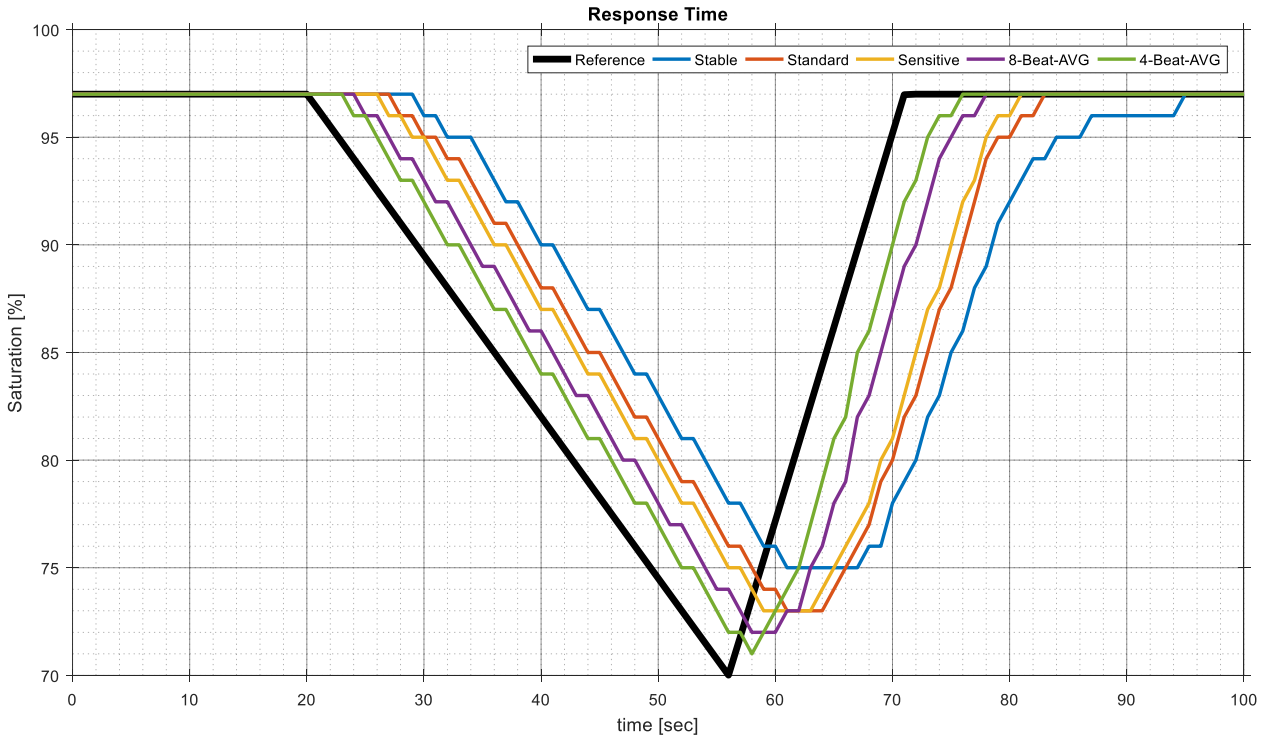


Figure 2-1: SMARTsat® SpO_2 response time diagram

Changing the response time mode has influence on the time delay of displayed SpO_2 and pulse rate measurement values. Note however that the motion tolerance performance is significantly

reduced for modes with short response time. Table 6 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.

Table 6: Average response time for each response time mode

Response Time Mode	Motion tolerance performance	Average response time	
		SpO_2 (see Fig 2-1)	Pulse rate (@75bpm)
Stable	highly motion resistant	11 sec	12 sec
Standard (default)	motion resistant	8 sec	11 sec
Sensitive	reduced motion resistance	7 sec	9 sec
8-Beat averaging	no motion resistance	5 sec	4 sec
4-Beat averaging	no motion resistance	3 sec	3 sec

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

2.2.3 High Resolution Plethysmogram Mode (HRP)

The **HRP** Mode is an optional feature which can be activated at all Response Time Settings and allows the output of a high resolution plethysmogram.

This mode is typically used by a host to calculate the PTT (Pulse Transit Time) based on additional designated host signals. In addition the low perfusion performance is increased at sampling rate 150 Hz in case of the SMARTsat® OEM II.

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

In case the actual used baud rate is below 115200 Bd the HRP mode is blocked and the host has to increase the baud rate to enable the feature. The HRP mode is available at two different samples rates: 150 Hz (HRP150) and 300 Hz (HRP300). For switching between modes 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 finger
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 during patient shock conditions, cold hands etc.
Low transmission	The sensor signal is very small. Low signal transmission can occur if the medium 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, moving the finger inside the sensor head etc.
Vital parameter out of range	Measurement values are invalid because they are outside the specified measurement range du to e.g. intravascular dyes etc.
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.
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 SpO2 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:

- Externally applied coloring agents such as nail polish or artificial nails,
- Blood flow restrictors (arterial catheters, blood pressure cuffs, infusing lines, etc.),
- Low perfusion, venous pulsations, anemia or low hemoglobin concentrations,
- Electromagnetic interference or electrosurgical interference

3 Guidelines for integration

3.1 Physical dimensions

The SMARTsat® 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.

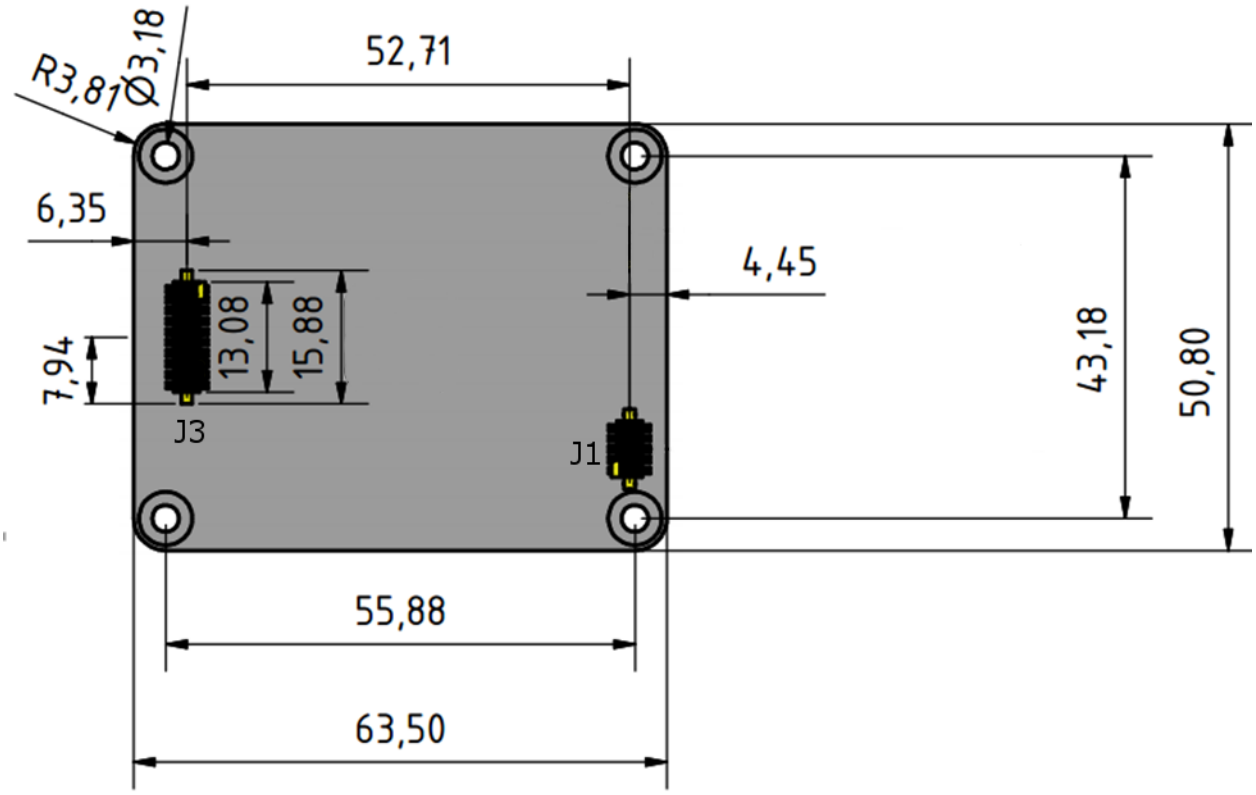


Figure 3-1: SMARTsat® OEM I Board Physical Dimensions, TOP View (in mm)

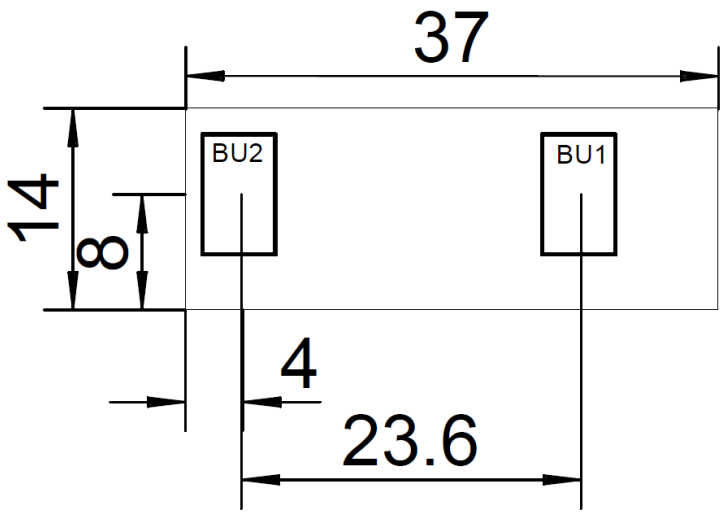


Figure 3-2: SMARTsat® OEM II Board Physical Dimensions, Bottom View (in mm)

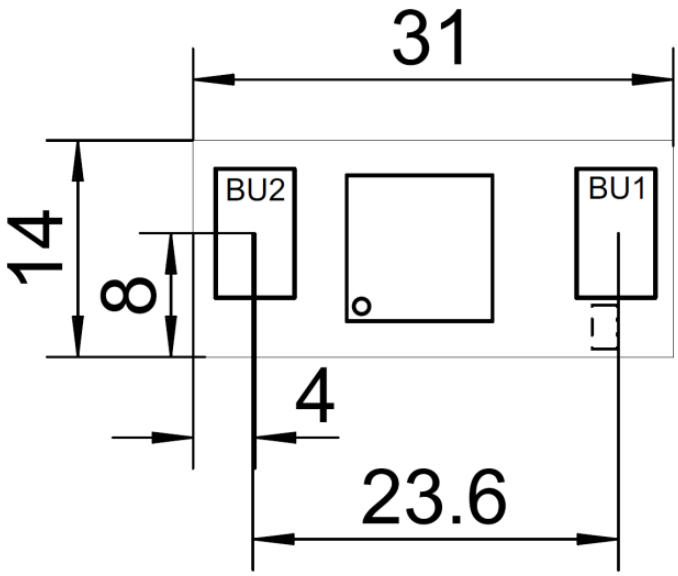


Figure 3-3: SMARTsat® OEM III Board Physical Dimensions, Bottom View (in mm)

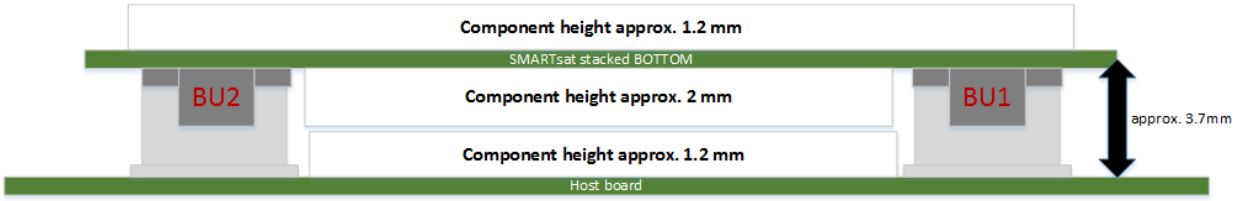


Figure 3-4: SMARTsat® OEM II and III Board Physical Dimensions; Side View (in mm)

3.1.1 External SMARTsat EB

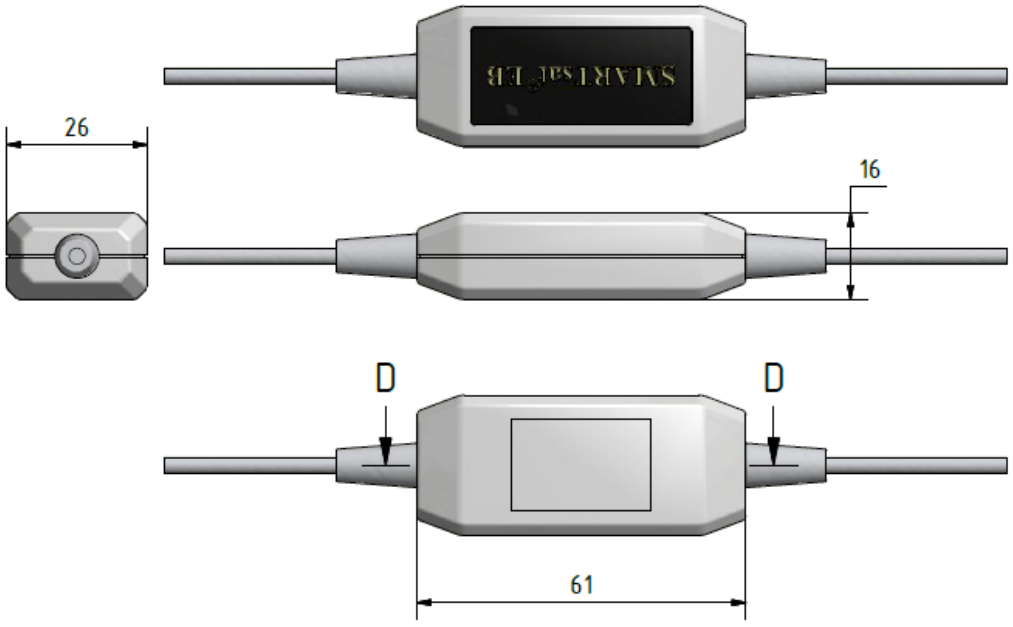


Figure 3-5: SMARTsat® EB Physical Dimensions in mm

The cable length from the module to the host connector is 30cm and the overall length from host connector to sensor connector is 175cm. As standard host connector a 4 PIN SMARTsat® EB host connector (3.3.5) is used but custom versions are available on request. The standard SMARTsat® sensor plug (3.3.1) is used for the sensor connection.

3.2 Electrical interface

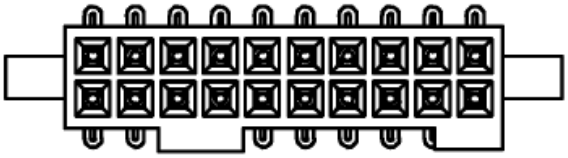
The SMARTsat® OEM Boards are multi-layer PCBs with surface mount (SMT) components.

The OEM I have two standard host connectors (J1, J3).

The OEM II and OEM III have two standard host connectors (BU1, BU2).

OEM I Sensor Connector (J1) and Power /Communication Connector (J3):

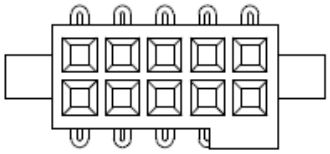
Sensor Connector J1



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)

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)

OEM II and OEM III Host Connector (BU1, BU2):

The Host Interface Connectors (BU1, BU2) provide power, communication and the sensor connection. The Host Interface Connectors are 14 pin dual row connectors with a pitch of 1 mm (Samtec part number CLM-107-02-L-D). The header connector at the host is for example the Samtec connector with part number FTM-107-03-L-DV.

Figure 3-6: BU1 and BU2 PIN OUT (OEM II and OEM III), Bottom View

Host Interface Connector Pin Assignments (BU1 and BU2)

PIN	BU1 Signal Description	PIN	BU2 Signal Description
1.	+3.3 V 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

3.3 Connectors and cables

3.3.1 SMARTsat® sensor plug

The 6-pole female connector is the standard *SMARTsat® sensor plug* (REF: 5020660002). Note that also a PCB mounting version is available (REF: 10020660002).

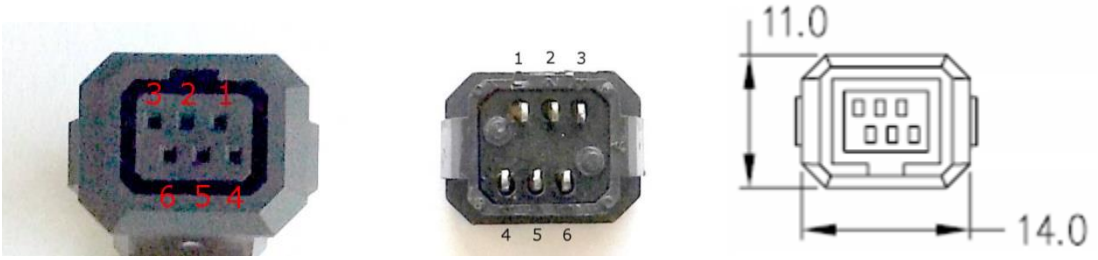


Figure 3-7: 6-pole female connector front view (left), rear view (middle), dimensions (right)

Sensor Plug 6-pole female connector Pin Assignments

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

3.3.2 SMARTsat® OEM I low noise flex cable

Directly connect the SpO_2 sensor to the SMARTsat® OEM I module with the SMARTsat® OEM I low noise flex cable (OEM I sensor connector J1 to SMARTsat® sensor plug)

Figure 3-8: SMARTsat® OEM I low noise sensor flex cable (REF: 12110140001)

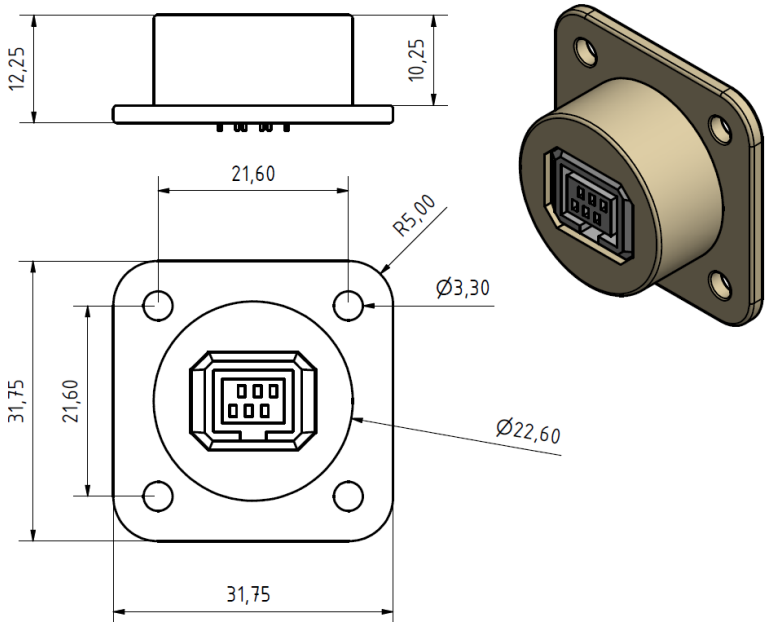


Figure 3-9: SMARTsat® OEM I low noise sensor flex connector - dimensions in mm

3.3.3 SMARTsat® sensor low noise flex cable

The *SMARTsat® sensor low noise flex cable* connects to the SMARTsat® development platform (see section 6.1).

Figure 3-10: SMARTsat® sensor low noise flex cable (REF: 8110140014)

The 4 layer flexible connection has a length of 90 mm. The shielded flex is ideal for use with the SMARTsat® OEM II to support the low perfusion performance of the module.

3.3.4 SMARTsat® sensor basic flex cable

The *SMARTsat® sensor basic flex cable* connects to a PCB flex connector (e.g. FPC1.0mm Atom®)

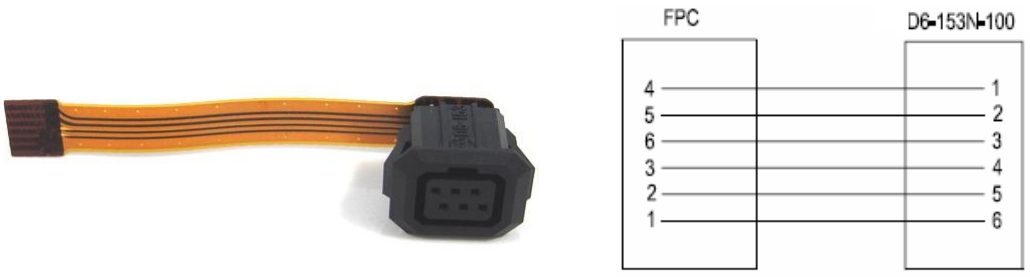


Figure 3-11: SMARTsat® sensor basic flex cable with pin connector drawing (REF: 9020522001)

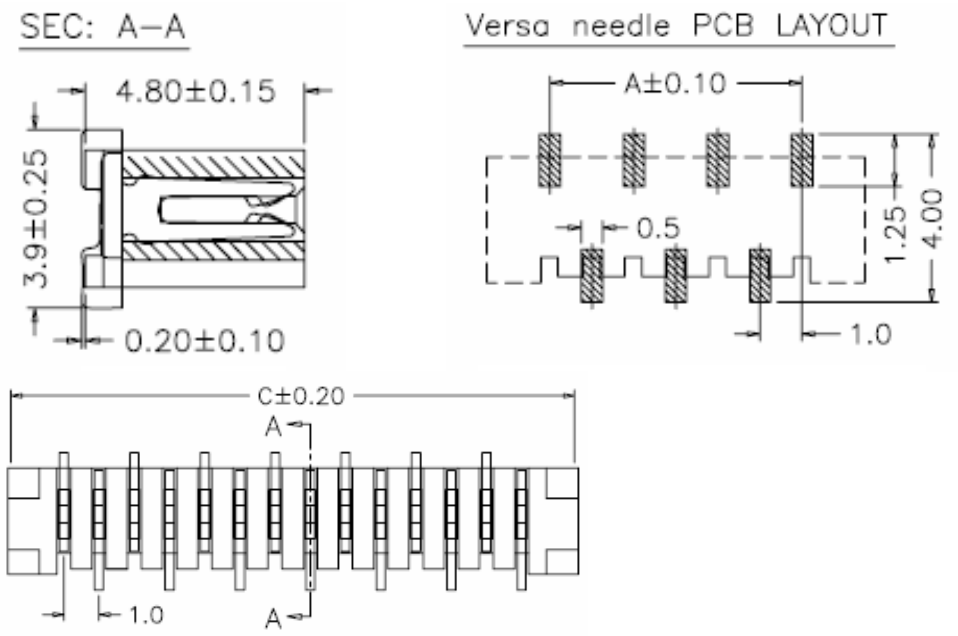


Figure 3-12: PCB flex connector FPC1.0mm (company: Atom®) dimensions

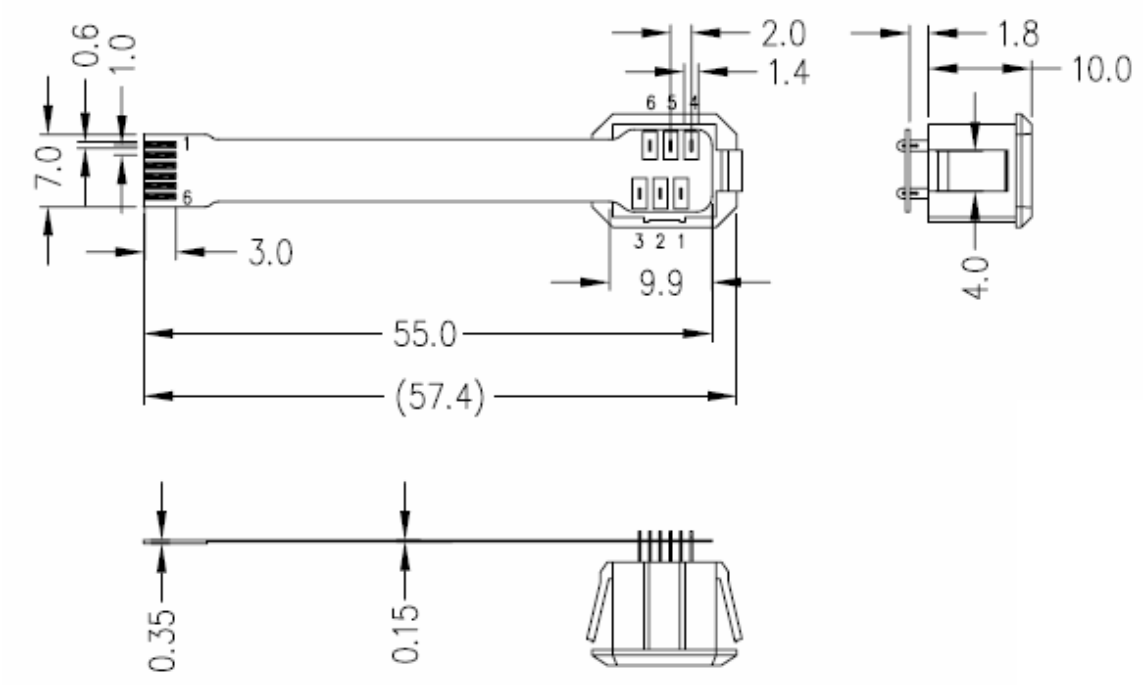


Figure 3-13: SMARTsat® sensor basic flex cable dimensions

3.3.5 SMARTsat® EB host connector

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

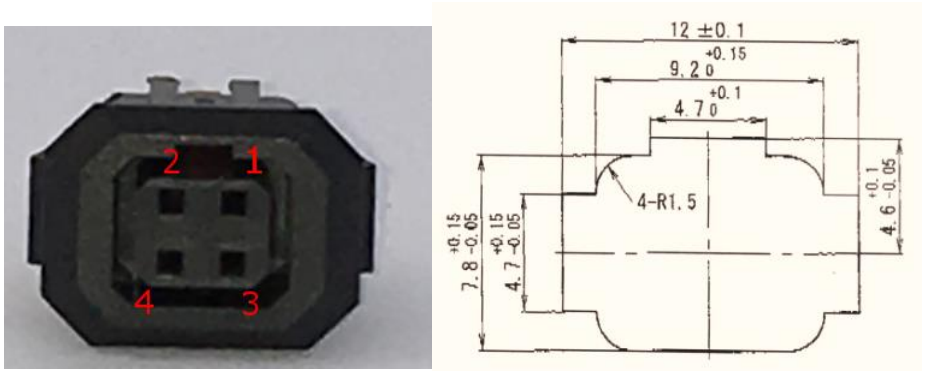


Figure 3-14: 4-pole female connector front view (left), dimensions mounting hole (right)

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

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 to stabilize 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.

Table 7: SMARTsat® Power requirements

	OEM I [a]	OEM II [a]	OEM III [a]	EB [a]
Input voltage (Ripple <10mV)	4.5 – 5.5 VDC	3.2 – 3.6 VDC	3.1 – 3.6 VDC	4.5 – 5.25 VDC
Average power consumption	110 mW @5V [b]	70 mW @3.3V [b]	24 mW @3.3V [b]	106 mW @5V [b][c] 47 mW @5V [b][d]
Maximum power consumption	131 mW @5V [b]	83 mW @3.3V [b]	29 mW @3.3V [b]	125 mW @5V [b] [c] 55 mW @5V [b][d]

[a] The baud rate has significant influence on the total power consumption of the SMARTsat® OEM I, OEM II and OEM III modules. [b] 75 Hz, 230400 Bd [c] EB with OEM II [d] EB with OEM III

Dependence of total power consumption on baud rate at 75 Hz sampling rate is presented in the graph below.

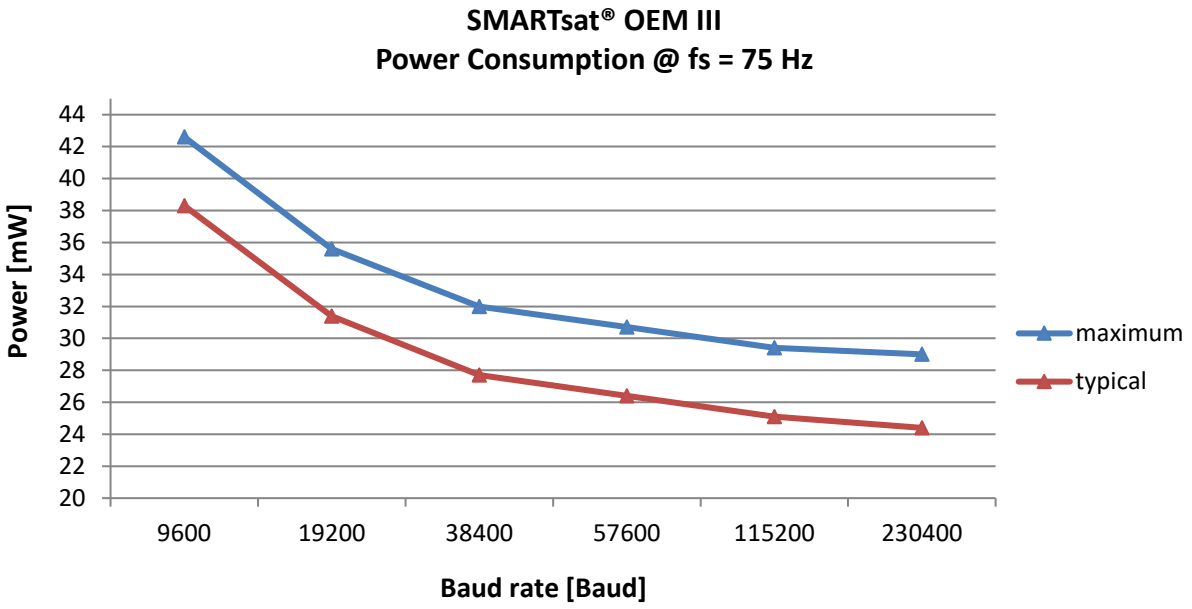


Figure 4-1: Power consumption vs. baud rate in SMARTsat® OEM III (@ 75 Hz sampling rate)

Higher sampling rates (150 Hz, 300 Hz) also increase the power consumption. The dependency of power consumption on sampling rate is summarized in the table below.

Power Consumption SMARTsat® OEM III (@3,3V)

	sample rate	**I [mA]** (baud 230400)	**P [mW]** (baud 230400)
Typical	*75Hz*	7	24
	150Hz	13	44
	300Hz	24	80
Maximum	*75Hz*	9	29
	150Hz	16	52
	300Hz	29	96

Power Consumption SMARTsat® OEM II (@3.3V)

	sample rate	**I [mA]** (baud 230400)	**P [mW]** (baud 230400)
Typical	*75Hz*	21	69
	150Hz	31	102
Maximum	*75Hz*	25	83
	150Hz	37	122

Power Consumption SMARTsat® OEM I (@5V)

	sample rate	**I [mA]** (baud 230400)	**P [mW]** (baud 230400)
Typical	*75Hz*	21	105
	150Hz	32	160
Maximum	*75Hz*	25	125
	150Hz	37	185

Power Consumption SMARTsat® EB with OEM III (@5V)

	sample rate	**I [mA]** (baud 230400)	**P [mW]** (baud 230400)
Typical	*75Hz*	9	45
	150Hz	8	40
	300Hz	27	135
Maximum	*75Hz*	11	55
	150Hz	18	90
	300Hz	31	155

Power Consumption SMARTsat® EB with OEM II (@5V)

	sample rate	**I [mA]** (baud 230400)	**P [mW]** (baud 230400)
Typical	*75Hz*	21	105
	150Hz	31	157
Maximum	*75Hz*	25	125
	150Hz	37	185

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

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) will be performed.

NOTE: For safety reasons the host is recommended to perform a reset, if measurement data is not continuously receive latest 2 seconds after module power on and during operation. Switch off the supply of the module if after the reset still no measurement data is received. 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

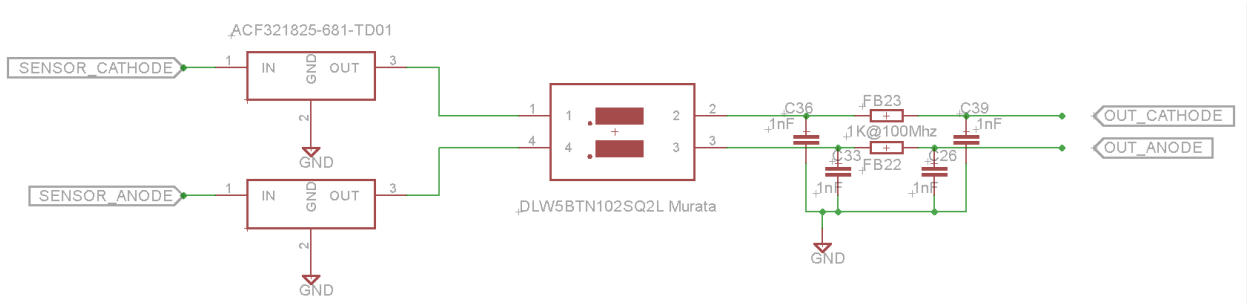
4.5 Electrostatic discharge (ESD) protection

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

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.



The networks consist of three sections:

1. T-Filter „TDK - ACF321825-681-TD01“
2. Common mode choke “Murata - DLW5BTN102SQ2L”
3. Discrete PI-Filter with a ferrite bead and an impedance of 1K Ohm at 100Mhz

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 60601-1:2005 (3rd Ed); IEC 60601-1 (2nd Ed) IEC 60601-1-2:2014 (4th Ed); IEC 60601-1-2 (3rd Ed); EN ISO 80601-2-61:2011; EN ISO 9919:2009 ISO 14971:2007; IEC 60601-1-6:2010; IEC 60601-1-11:2010 IEC 62471:2006
SMARTsat® sensors	ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-10:2010

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.

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.

Electrical properties RX/TX

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

5.2 Data packet structure

Each data packet received from SMARTsat® or command sent to the SMARTsat® has the following structure:

Packet			
Start Flag	Frame		End Flag
Start Flag	Data	CRC16	End Flag

Name	Description	Size
Start flag	Indicates the beginning of a frame: 0xA8	1 byte
Data	Data field	variable
CRC16	CRC16 data verification as below from all characters in the field 'Data'. Send: High byte first	2 bytes
End flag	Indicates the end of a frame: 0xA8	1 byte

For more information and detailed description on the data send by SMARTsat® please refer to the enclosed SMARTsat® Communication Protocol [1].

5.3 Host transmission wake-up sequence

Each command send from host to SMARTsat® OEM III must be initiated by a **Wake-Up byte**.

This Wake-Up byte is necessary to ensure that no data is lost while the module is in a power save mode. The impressive low power consumption of the SMARTsat® OEM III is achieved due to this feature.

At the beginning of each command the host therefore needs to send one byte of data as Wake-Up byte to SMARTsat®(for example 0x77).

The Wake-Up byte is followed by a delay time of 1 up to 10 milliseconds (± 0.5 msec). Do not send data during this delay time. In embedded applications using a delay time of 1 msec is recommended. For PC-applications e.g. written in C# a stopwatch timer is required to ensure the delay time stays within specifications (thread sleep methods are inaccurate).

After the delay time the transmission is completed by sending the data frame based on the structure given in section 5.2.

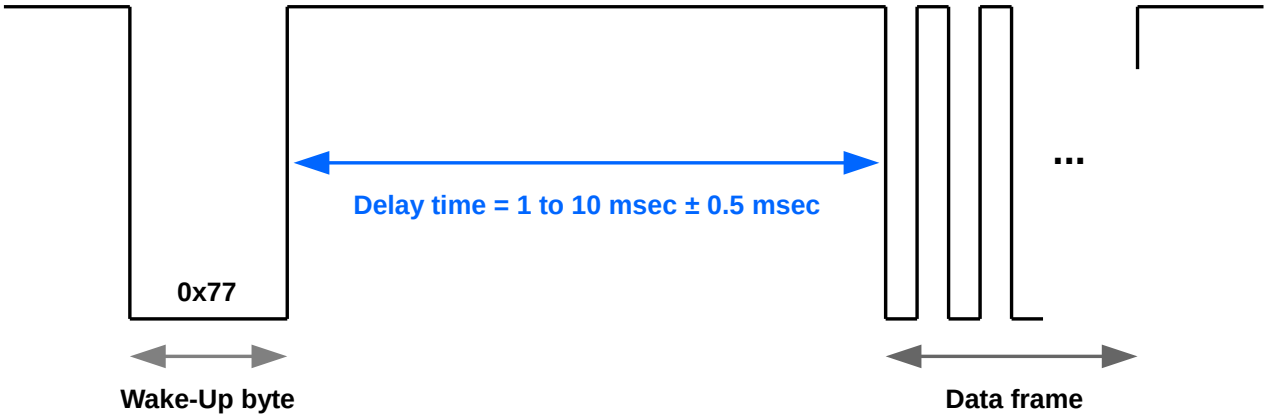


Figure 5-1: Timing of wake-up sequence

Example on how to activate the HRP 150Hz Mode:

```
UART_Send(0x77);          // Send Wake-up byte
WaitUs(1);           // Wait 1-10 ms
UART_Send(0xA8);          // Send command
UART_Send(0x10);          //
UART_Send(0x11|0x80);     //
UART_Send(0x02);          //
UART_Send(0x54);          //
UART_Send(0x9C);          //
UART_Send(0xA8);          //
```

NOTE: Depending on baud rate a limited number of commands send by the host can be evaluated each second (at 9600 Bd smallest number). The *receive buffer overflow flag* is send, if this limit is reached.

5.4 Host Protocol

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

5.5 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® OEM module
- Development platform with SMARTsat® sensor low noise flex cable
- USB cable
- SoftFlap® SpO_2 sensor SF7500
- CD with the SMARTsat® Protocol Viewer PC-Software, SMARTsat® Emulator PC-Software, Integration guide (this document) and Communication Protocol Specification [1].

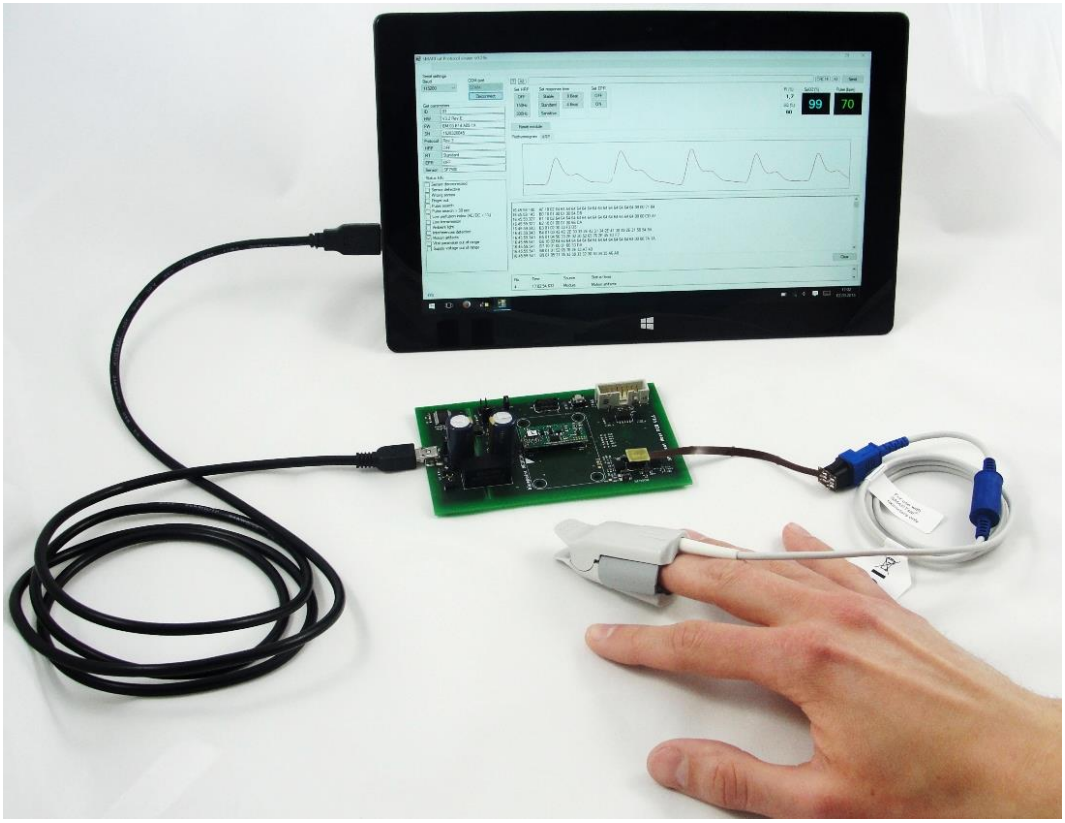


Figure 6-1: SMARTsat® OEM III Development kit (tablet PC not part of delivery scope)

6.1 SMARTsat® Host PCB

1) **Connect the SMARTsat® module (BU2, BU1) and SpO_2 sensor (SENSOR) to the development board.**

In addition some jumpers and a reset button are available for analyzing purposes (see figure below).

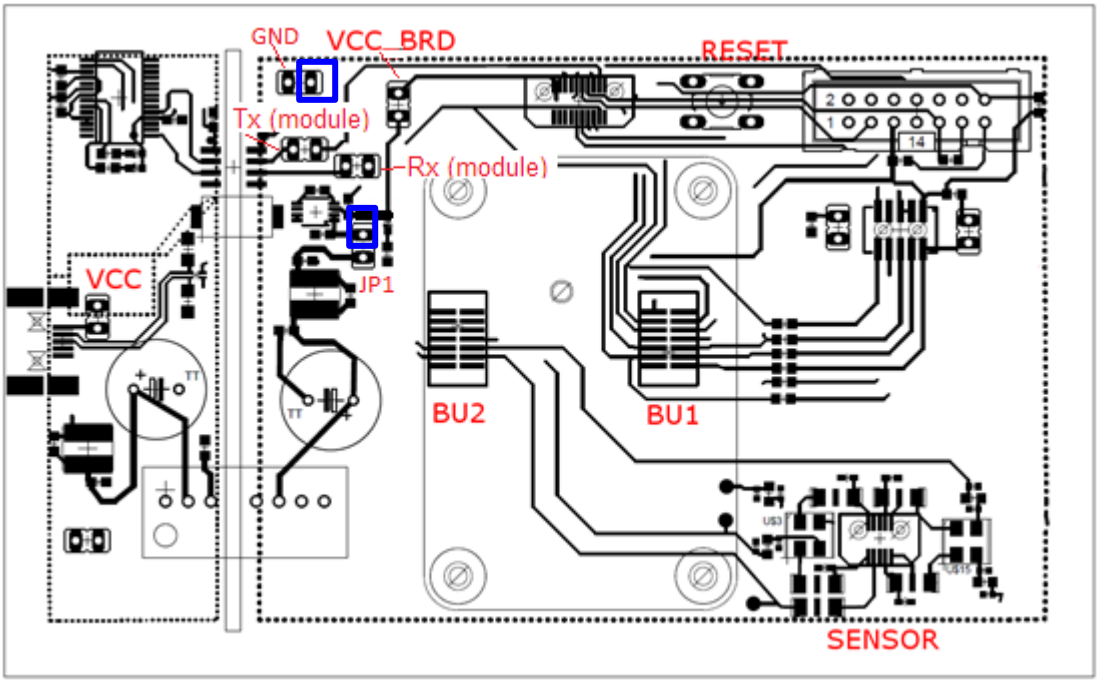


Figure 6-2: Overview of SMARTsat® Host PCB V1.1

Function	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)
Sensor	Connection to SpO2 sensor using *SMARTsat® sensor flex cable*
Reset	Perform hardware reset

All jumpers have to be connected. Furthermore check the orientation of the SMARTsat® module.

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 (3,7 V – 10 V) to eliminate the USB voltage noise. This is done by removing the JP1 and connecting the positive terminal of the battery to the upper JP1 connector. The negative terminal is connected to GND (see blue indicators in Figure 6-2).

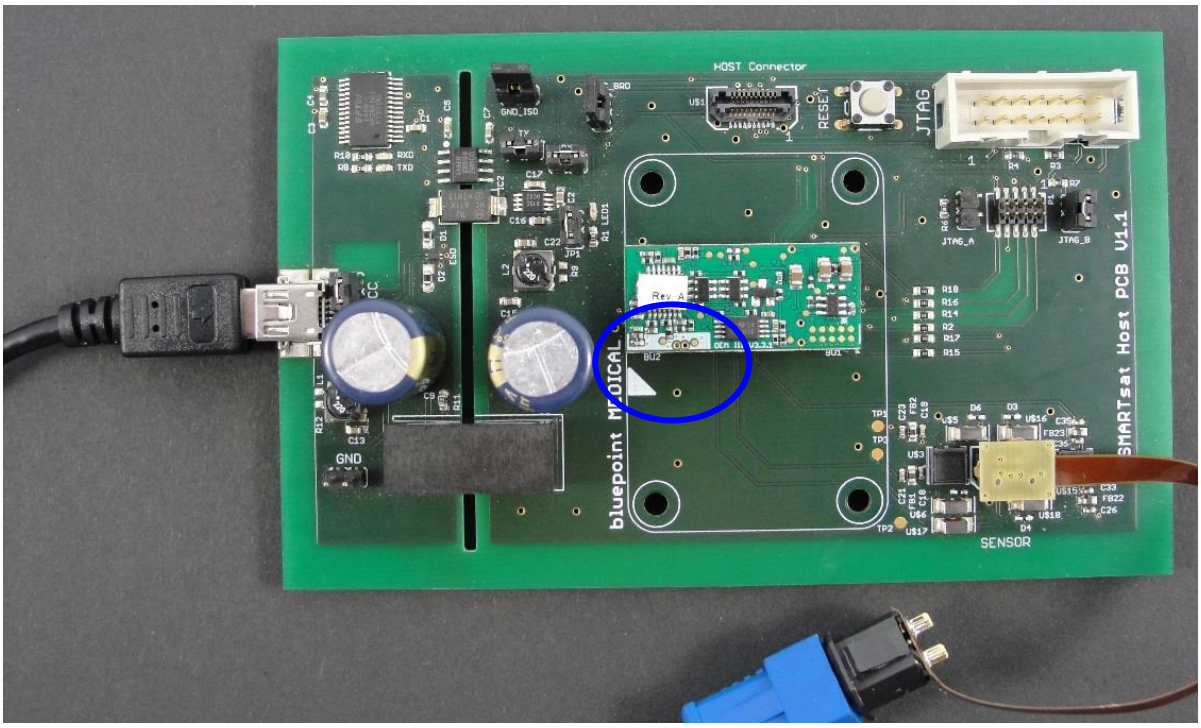


Figure 6-3: Orientation of SMARTsat® OEM III on the development board (REF: 8110140012)

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

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).

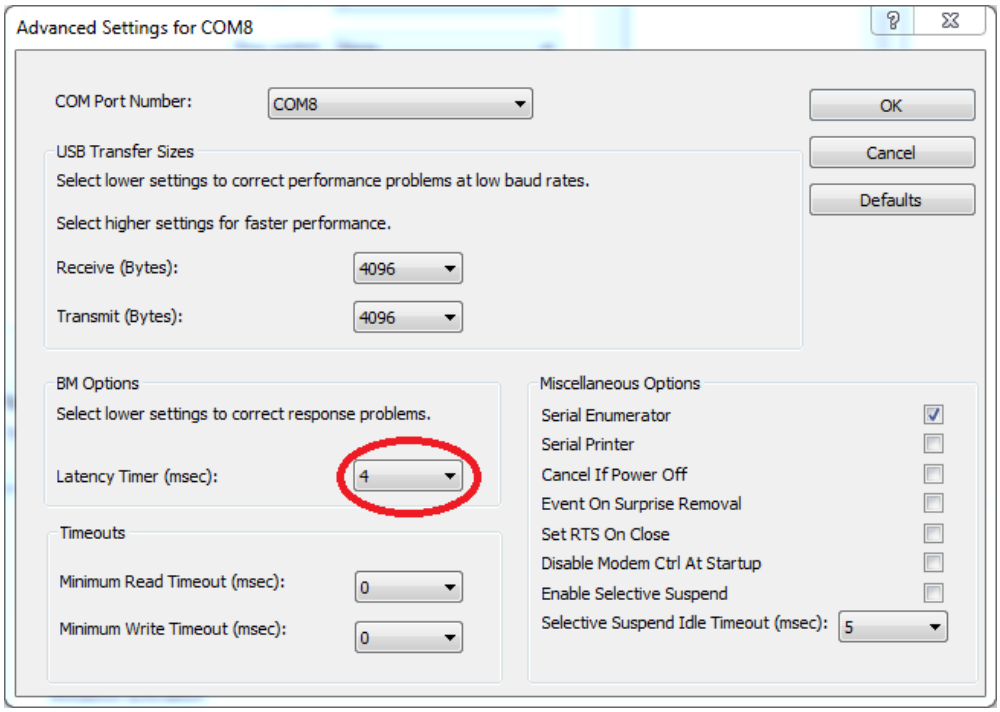


Figure 6-4: Virtual COM port UART settings

6.2 Verification PC-Tools (Protocol Viewer and Emulator)

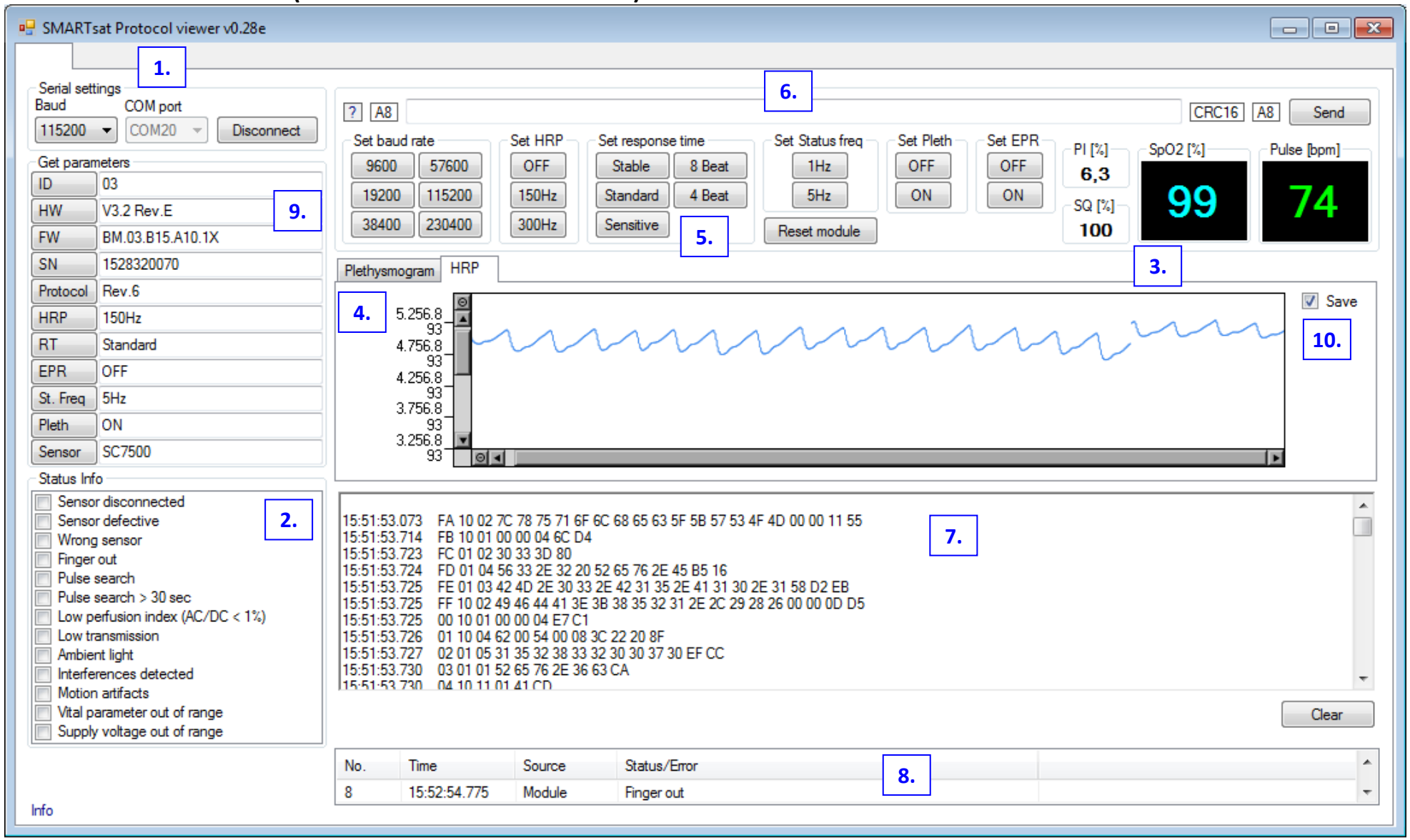


Figure 6-5: SMARTsat® Protocol Viewer

SMARTsat® Protocol Viewer:

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

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 High Resolution Plethysmogram is activated, the display switches to the HRP 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 HRP 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 HRP data 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 HRP 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 HRP, separated by a semicolon (e.g. 4508517;99;73;7.0;100 // HRP; SpO2; PR; PI; SQ)

SMARTsat®Emulator:

Verify the host system using the SMARTsat® Emulator provided on the CD. This tool sends data in the SMARTsat® protocol format (see Figure 6-6).

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.

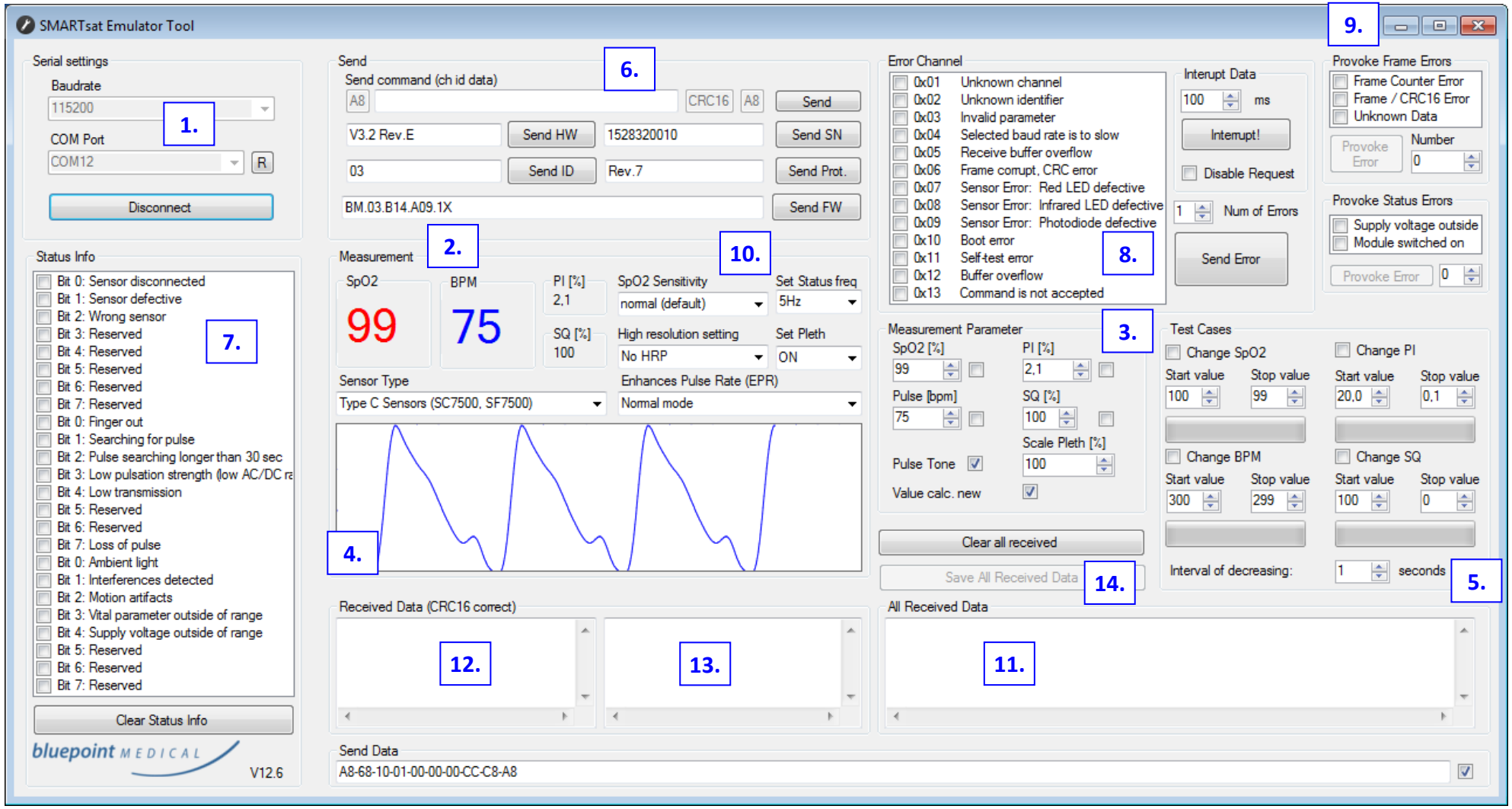


Figure 6-6: SMARTsat® Emulator

Nr.	Description
1.	Select COM port and baud rate to open the serial connection using the Connect/Disconnect 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.	Plethysmogram transmitted to the host. The same waveform is used for the auto scaled and high resolution 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.	In this section the hardware and firmware information of the simulated SMARTsat module is set. 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	In this section the settings of the simulated SMARTsat module are configured. Furthermore the sensor type connected to the SMARTsat module is set. Use the drop down menus to change the settings.
11	This message box displays all data received from the host. The information is not filtered or post-processed.
12	This messages box displays the valid data frames extracted from the received data. The data frames are already de-stuffed.
13	This message box displays the description of the valid data frames received from the host.
14	Use this buttons to clear the received data or save the data. The saving operation is possible only if the COM port is disconnected.

6.3 Communication Protocol Verification Procedure

To prevent communication errors a proper validation of the communication protocol in the host system is mandatory. Depending on the intended use of the host system not every part of the protocol must be implemented (see section APPENDIX 1).

The host validation is passed, if all the mandatory sections in the checklist are implemented and none of the implemented sections failed.

The communication protocol verification checklist is attached in the appendix of this document together with the list of recommended host actions. Based on the Risk Analysis of the host system, the implemented actions may differ from the suggestion, provided the risk has been addressed appropriately.

7 Technical data

Measurement range:

	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:

	OEM I	OEM II	OEM III
SpO_2	60 – 100 % ± 2 A_{rms} (no motion)[1, 4] 70 – 100 % ± 3 A_{rms} (motion condition)[2] 60 – 100 % ± 2 A_{rms} (low perfusion, no motion)[3]		
Pulse Rate	20 – 300 bpm ± 2 bpm (no motion)		

[1] As inherent to their functional principle, pulse oximetry measurements are statistically distributed; therefore only about two-thirds of the measurement data are expected to fall within ± A_{rms} of the value measured by a CO-oximeter

[2] Tested with all motion patterns Fluke Index II SpO_2 simulator at standard response time mode setting

[3] Tested with Fluke Prosim 8 vital sign simulator

[4] Applies to SC7500, refer to sensor specific results (table 2)

Power requirements:

	OEM I*	OEM II *	OEM III *	EB *
Input voltage	4.5 – 5.5 VDC	3.2 – 3.6 VDC	3.1 – 3.6 VDC	4.5 – 5.25 VDC
Average power consumption	110 mW **a)**	70 mW **a)**	24 mW **a)**	106 mW @5V **a) b)** 47 mW @5V **a) c)**
Maximum power consumption	131 mW **a)**	83 mW **a)**	29 mW **a)**	125 mW @5V **a) b)** 55 mW @5V **a) c)**

* The baud rate and sampling rate has significant influence on the total power consumption of the SMARTsat® OEM modules. Reduced data transfer rates and / or higher sampling rates (150Hz, 300Hz) increase the power consumption (see Chapter 4.1) **a)** 75 Hz, 230400 Bd **b)** EB with OEM II **c)** EB with OEM III

Environmental specifications:

	OEM I OEM II OEM III EB
Operating temperature	-25 °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)

Serial communication and data:

	OEM I/II	OEM III
Time until the first command is accepted after switch-on	1,5 sec	
Baud Rate	9600 Bd up to 230400 Bd	
Sampling rate adjustable to	75 Hz, 150 Hz	75 Hz, 150 Hz, 300 Hz

Miscellaneous:

	OEM I	OEM II	OEM III
Dimensions (L x W x H)	63,5mm x 50.8mm x 6.3mm	37,0 mm x 14 mm x 5,0 mm	31,0 mm x 14 mm x 5,0 mm

8 Order numbers

8.1 Development kits, modules and connectors

Product	REF
SMARTsat® II development kit SMARTsat® OEM II module; Development platform (incl. sensor flex cable, USB cable and PC software); SoftFlap SpO_2 sensor SF7500	8110140010
SMARTsat® III development kit SMARTsat® OEM III module; Development platform (incl. sensor flex cable, USB cable and PC software); SoftFlap SpO2 sensor SF7500	8110140012
SMARTsat® OEM I module	8110502001
SMARTsat® OEM II module	9110100001
SMARTsat® OEM III module	8110140011
SMARTsat® sensor plug	5020660002
SMARTsat® sensor plug - PCB mounting version	10020660002
SMARTsat® sensor basic flex cable	9020522001
SMARTsat® sensor low noise flex cable	8110140014
SMARTsat® OEM I sensor low noise flex cable	12110140001
SMARTsat® EB with OEM II module	on request
SMARTsat® EB with OEM III module	on request

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 [b)]	10-AP	6020131194
Paediatric Plaster Disposable SpO_2 Sensor [b)]	10-PP	6020131197
Infant Plaster Disposable SpO_2 Sensor [b)]	10-IP	6020131199
Neonatal Plaster Disposable SpO_2 Sensor [b)]	10-NP	6020131201
Ear Probe SpO_2 sensor	EP7500	6020132254
Y- SpO_2 Sensor for Single Patient Use	Y7500	12020132001
SMARTsat Hydrogel pads	HGP7500	12020121002
SMARTsat Hydrogel stripes	HGS7500	12020121001
Sensor extension cable 1.2m [b)]	XT6500	1020132275
Sensor extension cable 2.4m [b)]	XT6501	1020122058

b) Accessories and Replacement Parts only for use inside Healthcare Facilities

For additional information, please visit www.bluepoint-medical.com

9 APPENDIX 1: Host Validation Checklist

The Host Validation Checklist verifies the implementation of the SMARTsat communication protocol [1] at the equipment under test (*EUT*).

All implemented features have to be tested. Mandatory features must be implemented.

Optional features are implemented depending on the intended use of the host system and the host system risk analysis.

Typical applications are:

- Alarm monitor (*AM*)
- Continues measurement (*CM*)
- Spot check measurement (*SpC*)
- Sleep diagnostic/ PTT measurement (*PTT*)
- All applications listed here (*All*)

The host validation is passed, if all the mandatory sections in the checklist are implemented (*IMPL)* and none of the implemented sections failed the verification.

Tests are performed with the SMARTsat® Emulator (see section 6.2).

NOTE: The table below lists suggested host actions. Based on the Risk Analysis of the host system, the implemented actions may differ from the suggestion, provided the risk has been addressed appropriately. The listed minimal alarm priorities only apply to host systems with implemented alarm system.

NOTE: It is recommended to store all errors send by the SMARTsat® in the service section of the host system to enable efficient root cause analysis in case of device errors. Read out and analyze the errors on an annual base within the recommended service intervals of the host system.

1) Common device channel 0x01

ID	Item	Description and suggested Host action	Suggested Host Message	min. priority at Host Alarm	Typical Appl.	Manda-tory	Test	IMPL	Result
0x01	Protocol version	Information for service staff. Display version e.g. at the start-up screen or in the service menu.	N/A	N/A	All	NO	Request the ***protocol version*** at the EUT and verify that the received string equals the one set at the emulator.	□ yes □ no	□ pass □ fail □ NA
0x02	Device identification	Information for service staff. Display version e.g. at the start-up screen or in the service menu.	N/A	N/A	All	NO	Request the ***device identification*** at the EUT and verify that the received string equals the one set at the emulator.	□ yes □ no	□ pass □ fail □ NA
0x03	Firmware version	Information for service staff. Display version e.g. at the start-up screen or in the service menu.	N/A	N/A	All	NO	Request the ***firmware version*** at the EUT and verify that the received string equals the one set at the emulator.	□ yes □ no	□ pass □ fail □ NA
0x04	Hardware version	Information for service staff. Display version e.g. at the start-up screen or in the service menu.	N/A	N/A	All	NO	Request the ***hardware version*** at the EUT and verify that the received string equals the one set at the emulator.	□ yes □ no	□ pass □ fail □ NA
0x05	Serial number	Information for service staff. Display version e.g. at the start-up screen or in the service menu.	N/A	N/A	All	NO	Request the ***serial number*** at the EUT and verify that the received string equals the one set at the emulator.	□ yes □ no	□ pass □ fail □ NA
0x06	Identifier sent once at device start-up	Repeated sending of this identifier indicates a repeated reset of the module. In this case display a technical message. A typical reason for reset of the module is an unstable or fluctuating supply voltage	SpO_2 Module defective / Device defective	low	All	**YES**	Set ***module switched on*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA

2) Error channel 0x02

ID	Item	Description and suggested Host action	Suggested Host Message	min. priority at Host Alarm	Typical Appl.	Manda-tory	Test	IMPL	Result
0x01	Unknown channel	HOST should retry to send his request. Display a technical error message for at least 1 sec upon occurrence, if the error continues. In addition check if the changed setting has been implemented (Ch=0x10: ID=0x04 Byte[6]). Also display the message, if the error occurs, independent of requests sent by the HOST.	SpO2 Module defective / Device defective	low	All	**YES**	Set ***unknown channel*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
0x02	Unknown identifier	HOST should retry to send his request. Display a technical error message for at least 1 sec upon occurrence, if the error continues. In addition check if the changed setting has been implemented (Ch=0x10: ID=0x04 Byte[6]). Also display the message, if the error occurs, independent of requests sent by the HOST.	SpO2 Module defective / Device defective	low	All	**YES**	Set ***unknown identifier*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
0x03	Invalid parameter	HOST should retry to send his request. Display a technical error message for at least 1 sec upon occurrence, if the error continues. In addition check if the changed setting has been implemented (Ch=0x10: ID=0x04 Byte[6]). Also display the message, if the error occurs, independent of requests sent by the HOST.	SpO2 Module defective / Device defective	low	All	**YES**	Set ***invalid parameter*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
0x04	Selected baud rate is too slow	HRP150 and HRP300 need a minimum baud rate of 115200 Bd. Increase baud rate if HRP150 or HRP300 is selected. Display a technical error message for at least 1 sec upon occurrence, if the error continues.	SpO2 Module defective / Device defective	low	All	**YES**	Set ***selected baud rate is too slow*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
0x05	Receive buffer overflow	Too much input data to module. Reset module upon repeated sending of the error. Display a technical error message for at least 1 sec upon occurrence, if the error continues.	SpO2 Module defective / Device defective	low	All	**YES**	Set r***eceive buffer overflow*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
0x06	Frame corrupt, CRC error	HOST should retry to send his request. Display a technical error message for at least 1 sec upon occurrence, if the error continues. In addition check if the changed setting has been implemented (Ch=0x10: ID=0x04 Byte[6]). Also display the message, if the error occurs, independent of requests sent by the HOST.	SpO2 Module defective / Device defective	low	All	**YES**	Set ***frame corrupt, CRC error*** at the emulator error channel and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA

ID	Item	Description and suggested Host action	Suggested Host Message	min. priority at Host Alarm	Typical Appl.	Manda-tory	Test	IMPL	Result
0x07	Sensor Error: Red LED defective	The red LED at the sensor is defective. **NOTE**: status information 'Sensor defective' (Byte[0] Bit: 1 in channel 0x10, identifier 0x01) is sent at the same time .	Replace sensor/ Sensor fault	low	All	NO	Set ***Red LED defective*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
0x08	Sensor Error: Infrared LED defective	The infrared LED at the sensor is defective. **NOTE**: status information 'Sensor defective' (Byte[0] Bit: 1 in channel 0x10, identifier 0x01) is sent at the same time .	Replace sensor/ Sensor fault	low	All	NO	Set ***Infrared LED defective*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
0x09	Sensor Error: Photodiode defective	The detector at the sensor is defective. **NOTE**: status information 'Sensor defective' (Byte[0] Bit: 1 in channel 0x10, identifier 0x01) is sent at the same time . Display error message for at least 1 sec upon occurrence of the error	Replace sensor/ Sensor fault	low	All	NO	Set ***Photodiode defective*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
0x0A	Sensor Error: Short circuit	Short circuit occurred in the sensor cable or connector. Measurement is interrupted. Disconnect sensor to reset the error.	SpO2 Module defective / Device defective	low	All	NO	Set ***Short circuit*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
0x10	Boot error	The boot-test during module switch-on failed. Display a technical error message for at least 1 sec upon occurrence, thereafter reset the module.	SpO2 Module defective / Device defective	low	All	**YES**	Set ***Boot error*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
0x11	Self-test error	The self-test during module switch-on failed. Display a technical error message for at least 1 sec upon occurrence, thereafter reset the module.	SpO2 Module defective / Device defective	low	All	**YES**	Set ***Self-test error*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
0x12	Buffer overflow	An internal buffer overflow error occurred. Display a technical error message for at least 1 sec, thereafter reset the module.	SpO2 Module defective / Device defective	low	All	**YES**	Set ***Buffer overflow*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
0x13	Command to switch on auto scaled plethysmogram is not accepted	Auto scaled plethysmogram (ASP) and HRP cannot be switched on simultaneously. In HRP mode the ASP is not available to ensure minimal time jitter between sending of samples. The error code will show up, if the host enables ASP in HRP mode. Switch of HRP before switching on the ASP.	SpO2 Module communication error	N/A	PTT	**YES**	Set ***Command is not accepted*** at the emulator and send to the EUT – verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA

ID	Item	Description and suggested Host action	Suggested Host Message	min. priority at Host Alarm	Typical Appl.	Manda-tory	Test	IMPL	Result
n/a	Error log	It is recommended that the host stores all errors in an internal service error log to simplify root cause analysis in case of defects	store in the service menu of the host	N/A	All	NO	Read out the Error Log stored within the Host system and verify that all errors generated before were stored in the log.	□ yes □ no	□ pass □ fail □ NA

3) SMARTsat® channel 0x10

3.1) Status information (Ch=0x10: *ID=0x01*)**:**

Flag	Status information	Description and suggested Host action	Suggested Host Message	min. priority at Host Alarm	Typical Appl.	Manda-tory	Test	IMPL	Result
Byte[0] Bit 0:	Sensor disconnected	Inform user that no sensor is connected.	Connect sensor / Sensor disconnected	low	All	**YES**	Set status flags at the emulator and verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
Byte[0] Bit 1:	Sensor defective	Inform user that the connected sensor is defective	Replace defective sensor / Sensor defective	low	All	**YES**	Set status flags at the emulator and verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
Byte[0] Bit 2:	Wrong sensor	Inform user that the connected sensor is not compatible with the SpO2 module	Replace incompatible sensor/ Sensor incompatible	low	All	**YES**	Set status flags at the emulator and verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
Byte[1] Bit 0:	Finger out	Inform user that the sensor is no longer at the measurement site	Sensor off patient	low	All	**YES**	Set status flags at the emulator and verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA
Byte[1] Bit 1:	Searching for pulse	Inform user that if the condition continues, the user should check the sensor application site and patient vital signs	Pulse search, no values (- -) displayed	N/A	All	NO	Set status flags at the emulator and verify that an appropriate HOST action follows. Verify IFU.	□ yes □ no	□ pass □ fail □ NA
Byte[1] Bit 2:	Pulse searching longer than 30sec	Inform user that pulse search continues for a duration longer than 30 sec. User should check sensor application site and patient vital signs	Pulse search longer than 30sec	message mandatory (80601-2-61 clause 201.12.4.101)	AM, CM	**YES**	Set status flags at the emulator and verify that an appropriate HOST action follows. Verify IFU.	□ yes □ no	□ pass □ fail □ NA
Byte[1] Bit 3:	Low pulsation strength (low AC/DC ratio)	Inform user that the perfusion index (PI) is low. User should check the sensor application site and patient vital signs. Warming the application site improves perfusion.	Low perfusion	N/A	All	NO	Set status flags at the emulator and verify that an appropriate HOST action follows. Verify IFU.	□ yes □ no	□ pass □ fail □ NA

Flag	Status information	Description and suggested Host action	Suggested Host Message	min. priority at Host Alarm	Typical Appl.	Manda-tory	Test	IMPL	Result
Byte[1] Bit 4:	Low transmission	Inform user that the transmission signal at the sensor is low. Suggest to reposition the sensor, e.g. to a thinner finger	Low transmission, reposition sensor	N/A	All	NO	Set status flags at the emulator and verify that an appropriate HOST action follows. Verify IFU.	□ yes □ no	□ pass □ fail □ NA
Byte[1] Bit 7:	Loss of pulse	Inform the user that no pulse signal is identified and suggest checking sensor application site and patient vital signs. This condition occurs during prolonged bad signal quality at the sensor site.	Loss of pulse/ Bad signal quality (No value is displayed (- -))	Alarm monitors should give at least medium priority alarm	AM, CM	**YES**	Set status flags at the emulator and verify that an appropriate HOST action follows. Verify IFU.	□ yes □ no	□ pass □ fail □ NA
Byte[2] Bit 0:	Ambient light	Inform the user that ambient light is distorting the measurement. Suggest covering sensor site.	Too much ambient light	low	All	**YES**	Set status flags at the emulator and verify that an appropriate HOST action follows. Verify IFU.	□ yes □ no	□ pass □ fail □ NA
Byte[2] Bit 1:	Interferences detected	Inform the user that the sensor signal is disturbed by interferences (e.g. EMI). These affects the measurement - locate and isolate interference source	Signal interferences	N/A	All	NO	Set status flags at the emulator and verify that an appropriate HOST action follows. Verify IFU.	□ yes □ no	□ pass □ fail □ NA
Byte[2] Bit 2:	Motion artifacts	Inform the user that the sensor signal is disturbed by motion artifacts. Reduce motion at the sensor application site to increase measurement performance.	Motion artifacts	N/A	All	NO	Set status flags at the emulator and verify that an appropriate HOST action follows. Verify IFU.	□ yes □ no	□ pass □ fail □ NA
Byte[2] Bit 3:	Vital parameter out of range	Inform the user that the measurement is invalid due to abnormal signal properties e.g. intravascular dyes etc.	Parameter out of range	N/A	All	**YES**	Set status flags at the emulator and verify that an appropriate HOST action follows. Verify IFU.	□ yes □ no	□ pass □ fail □ NA
Byte[2] Bit 4:	Supply voltage out of range	Inform the user that the measurement accuracy is affected because the module supply voltage is out of range. Display a technical alarm message for at least 1 second upon occurrence.	Device defective, send device to service department	medium	All	**YES**	Set status flags at the emulator and verify that an appropriate HOST action follows.	□ yes □ no	□ pass □ fail □ NA

3.2) Auto scaled and High Resolution Plethysmogram (Ch=0x10: *ID=0x02, ID=0x03*)*:*

ID	Feature	Description and suggested Host action	Typical Appl.	Mand a-tory	Test	IMPL	Result
0x02	Auto scaled Plethysmogram (ASP)	The auto scaled plethysmogram is derived from the Infrared LED transmission signal. Display the plethysmogram at the host to visualize the signal quality and heart pulsation activity to the clinical staff. The plethysmogram may be switched off to extend battery life in case of low power host applications (see Ch=0x10: ID=0x18).	All	NO	**Set Pleth ON** at the emulator. Verify the correct display of the simulated emulator plethysmogram waveform at the EUT.	□ yes □ no	□ pass □ fail □ NA
	Pulse beep indicator	The pulse beep indicator can be used to emit a sound at the host correlating with the pulse rate frequency. It tags each detected pulse. In case no pulse tone sounds, the signal quality is not sufficient to reliably detect the single pulse as typically found under signal interference conditions (EMI, motion conditions)	All	NO	Activation the **Pulse Tone** checkbox at the emulator. Verify that the EUT emits a periodic audible tone at the frequency of the pulse rate. Deactivate the **Pulse Tone** checkbox. Verify that the EUT does not emit a periodic audible tone.	□ yes □ no	□ pass □ fail □ NA
0x03	High Resolution Plethysmogram (HRP)	The HRP is typically used to calculate the PTT (Pulse Transit Time) based on additional designated host signals (ECG). The minimum baud rate for using HRP is 115200 Bd. The power consumption of the board is significantly increased at 150 Hz (HRP150) and even more at 300Hz (HRP300). The ASP is automatically switched off upon activation of HRP to ensure that data samples are sent at a constant delay as required for PTT measurement.	PTT	NO	**Set HRP** at the emulator (150 Hz and 300 Hz, if implemented at host). Verify the correct display of the simulated HRP plethysmogram waveform at the EUT.	□ yes □ no	□ pass □ fail □ NA

3.3) Results and indicators (Ch=0x10: *ID=0x04*)*:*

Flag	Results and indicators	Description and suggested Host action	Typical Appl.	Manda-tory	Test	IMPL	Result
Byte[0]	SpO2 Value [1…100 %], 0xFF = no value	Continuously display the SpO2 value, if no value is transmitted display "- -". In case of single spot-check measurement, display value after 5 -10 seconds of measurement (also refer to response time modes identifier 0x10).	All	**YES**	Cycle through valid SpO2 values (e.g. 100 to 0 %) using the decrease SpO2 functionality in the emulator and verify that is takes less than two seconds to display all values (after value is changed at the PC)	□ yes □ no	□ pass □ fail □ NA
Byte[1-2]	Pulse rate [1…300 bpm], 0xFFFF = no value, (Hi+Lo)	Continuously display the pulse rate value, if no value is transmitted display "- -". In case of single spot-check measurement, display value after 5 -10 seconds of measurement (also refer to response time modes identifier 0x10).	All	**YES**	Cycle through valid pulse rate values (e.g. 300 to 20 BPM) using the decrease BPM functionality in the emulator and verify that is takes less than two seconds to display all values (after value is changed at the PC) – additionally verify that the frequency of the plethysmogram is changed accordingly during the test	□ yes □ no	□ pass □ fail □ NA
Byte[3-4]	Perfusion Index PI= I_{AC}/I_{DC} [1...200 ‰] 0xFFFF = no value, (1 ‰ = 0.1 %)	If a bar graph is implemented the perfusion index can be used to continuously define the bar graph amplitude during measurement. Due to the nature of the PI a logarithmic correlation is suggested (also refer to Byte [5] below)	All	NO	Cycle through valid pulsation strength values (e.g. 20.0 to 0.1 %) using the decrease pulsation strength functionality in the emulator and verify that is takes less than two seconds to display all values (after value is changed at the PC)	□ yes □ no	□ pass □ fail □ NA

Flag	Results and indicators	Description and suggested Host action	Typical Appl.	Manda-tory	Test	IMPL	Result
Byte[5]	Signal quality [1...100 %], 0xFF = no value	It is mandatory to implement an indicator to show signal inadequacy when applicable (IEC 80601-2-61 (201.12.4.102)). Use at least symbol ISO 7000-0435 if signal quality below 61 %. If possible it is recommended to implement a bar graph representing the plethysmogram movement (based on channel 0x10, identifier 0x02). The color of the bar graph can be used as indicator for signal quality and measurement performance. 100 - 61% - Green: good signal quality, very accurate measurement 60 - 31% - Yellow: average signal quality, measurement may be inaccurate 30 - 1% - Red: poor signal quality, unreliable measurement	All	**YES**	Cycle through valid signal quality values (e.g. 100 to 1 %) using the decrease signal quality functionality in the emulator and verify that is takes less than two seconds to display all values (after value is changed at the PC)	□ yes □ no	□ pass □ fail □ NA
Byte[6]	Measurement settings (active if respective bit is set to 1)						
Bit 0	Response time: stable	Check continuously the settings of SMARTsat® by the host especially in case of continuous monitoring applications in which the HOST changes at start-up the default settings at the SMARTsat® module. ***Reason:*** In case SMARTsat® resets (e.g. fluctuating supply voltage), the setting returns to default. The HOST must set the HOST specific settings again if the module was reset.	AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	□ yes □ no	□ pass □ fail □ NA
Bit 1	Response time: standard		AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	□ yes □ no	□ pass □ fail □ NA
Bit 2	Response time: sensitive		AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	□ yes □ no	□ pass □ fail □ NA
Bit 3	Response time: 8-Beat averaging		AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	□ yes □ no	□ pass □ fail □ NA

Flag	Results and indicators	Description and suggested Host action	Typical Appl.	Manda-tory	Test	IMPL	Result
Bit 4	Response time: 4-Beat averaging	See also: Common device channel 0x01, 0x06 to identify a module restart.	AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	□ yes □ no	□ pass □ fail □ NA
Bit 5	Pulse Rate mode: Standard mode (30 – 240 bpm)		AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	□ yes □ no	□ pass □ fail □ NA
Bit 6	Pulse Rate mode: EPR Mode (20 – 300 bpm)		AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	□ yes □ no	□ pass □ fail □ NA
Bit 7	New measurement (SpO_2 and pulse rate value new. The longest Data Update Period is 28 sec)	This feature is useful during continuous monitoring to indicate periods in which the measurement value is not updated due to signal distortion. An indicator may be set at the host to show the user that data are not updated (e.g. circle element is filled proportional to fraction of 28sec) NOTE: if the distortion period exceeds 28sec, measurement values are set to no value "- -"	AM, CM, PTT	NO	Uncheck the **Value calc. new** checkbox. Verify host action and IFU.	□ yes □ no	□ pass □ fail □ NA

3.4) Sensor type (Ch=0x10: *ID=0x06*):

Description and suggested Host action	Typical Appl.	Manda-tory	Test	IMPL	Result
SMARTsat® identifier which sensor type is connected. The standard SMARTsat® sensors are listed below: 0x00FF /255= undefined sensor type (see status information in identifier 0x01for detailed reason e.g. sensor disconnected or wrong) 0x000A /10 = Type C Sensors (closed sensors): SC7500 SoftCap; SCM7500 SoftCap medium; SCP7500 SoftCap pediatric; SF7500 SoftFlap 0x0028 /40 = Type O Sensors (open sensors): W7500 SoftWrap; 10-AP Disposable adult; 10-PP Disposable pediatric; 10-IP Disposable infant 0x0032 /50 = Type E Sensors (ear sensors): EP7500 Ear Probe 0x005B /91 = Type N Sensors (neonatal sensors): 10-NP Disposable neonatal **NOTE:** Customer specific firmware with customized Sensor Type Codes are listed in a separate document	All	NO	Cycle through all available sensor types in the emulator and request the sensor type on the EUT – verify that the correct sensor type is identified by the EUT	□ yes □ no	□ pass □ fail □ NA

3.5) Set Modes: Response time, HRP, Pulse rate, Status freq., Auto scaled plethysmogram, Reset, Baud (Ch=0x10):

ID	Feature	Description and suggested Host action	Typical Appl.	Manda-tory	Test	IMPL	Result
0x10	Response Time setting	The selected response time setting has influence on the motion resistance performance and the response time of SpO2 and PR measurement (see section 2.2.2 for more detail). Depending on the intended use of the host a selection or all response time modes may be implemented. For sleep diagnostic 4-beat averaging is typically used, during continuous monitoring during daily activity the standard or stable mode is recommended.	All	NO	Request the response time setting on the EUT and verify that the data received equals the setting in the emulator Cycle through and set all available response time settings on the EUT – verify that the received message in the emulator equals the setting on the EUT	□ yes □ no	□ pass □ fail □ NA
0x11	High Resolution Plethysmo	See APPENDIX 1 section 3.2	All	NO	Request the high resolution plethysmogram mode on the EUT and verify that the data received equals the setting in the emulator	□ yes □ no	□ pass □ fail

ID	Feature	Description and suggested Host action	Typical Appl.	Manda-tory	Test	IMPL	Result
	gram (HRP)				Switch the high resolution plethysmogram to OFF at the EUT and verify that no waveform is displayed Switch the high resolution plethysmogram to ON at the EUT and verify that the waveform is displayed		□ NA
0x12	Pulse rate mode	The standard pulse rate mode covers the typical pulse rate measurement range in humans (30 - 240bpm). In case of veterinary applications it can be suitable to activate the enhanced pulse rate mode (20 - 300bpm).	All	NO	Request the pulse rate mode on the EUT and verify that the result received equals the setting in the emulator Cycle through and set all available pulse rate modes on the EUT– verify that the received message in the emulator equals the setting on the EUT	□ yes □ no	□ pass □ fail □ NA
0x17	Set Send Frequency of status informatio n	Typically the status information is sent at 5Hz. For low power handheld host applications the battery life is extended by reducing the data sent by SMARTsat®. This is mainly achieved by deactivating the HRP; in addition data rates can be reduced by reducing the send frequency of the status to 1 Hz. This has to be considered in the risk analysis depending on the intended use of the host application.	All	NO	Request the status information send frequency on the EUT and verify that the result received equals the setting in the emulator Cycle through and set all available status information send frequencies on the EUT – verify that the received message in the emulator equals the setting on the EUT Verify that the status information frames are received with the correct frequency by the EUT	□ yes □ no	□ pass □ fail □ NA
0x18	Set Auto scaled plethysmo gram	See APPENDIX 1 section 3.2	All	NO	Request the auto scaled plethysmogram setting on the EUT and verify that the result received equals the setting in the emulator Switch the auto scaled plethysmogram to OFF in the EUT and verify that no waveform is displayed Switch the auto scaled plethysmogram to ON in the EUT and verify that the waveform is displayed	□ yes □ no	□ pass □ fail □ NA
0x19	Switch HR pleth	Possibility to switch High Resolution Pleth on/off independent of sampling rate. Only available in OEM I and II (for OEM III use HRP mode, 0x11)	All	NO	Switch the HR Pleth on and off and verify that EUT behaves as specified.	□ yes □ no	□ pass □ fail □ NA
0x1A	Set sampling rate	Possibility to select sampling rate independent of High Resolution Pleth. Only available in OEM I and II (for OEM III use HRP mode, 0x11)	All	NO	Cycle through all settable sampling rates at the EUT and verify that EUT behaves as specified.	□ yes □ no	□ pass □ fail □ NA
0x30	Software reset	See APPENDIX 1 section 2	All	**YES**	See APPENDIX 1 section 2	□ yes □ no	□ pass □ fail □ NA
0x31	Baud rate setting	For low power handheld host applications the battery life is extended by selecting the highest baud rate available at the SMARTsat®. Note that lower baud is also available for host systems with limited baud rate. Note that the selected baud rate is stored in the permanent flash. At each restart the last selected baud is valid. The baud can be **changed maximal 1000 times**. After this the baud rate cannot be changed again.	All	NO	Request the baud rate setting on the EUT and verify that the result received equals the setting in the emulator Cycle through the available baud rates on the EUT and verify that valid data is received (e.g. auto scaled plethysmogram is displayed properly) after the baud rate change	□ yes □ no	□ pass □ fail □ NA

3.6) Communication errors

The SMARTsat® protocol offers three different methods to detect transmission errors and the implementation in the EUT is mandatory.

Item	Description and suggested Host action	Typical Appl.	Mand a-tory	Test	IMPL	Result
Frame counter error	Each frame has a continuously incremented number. By verifying the incrimination lost frames are detected. In case too many frames are lost the display and update of the measurement results is no longer guaranteed. Display a technical alarm message (e.g. Device defective).	All	**YES**	Provoke **frame counter errors** using the emulator – verify that an appropriate message or action is seen on the EUT	□ yes □ no	□ pass □ fail □ NA
Frame error	Communication and timing errors, including distortion by EMI, can result in partially received frames. These can potentially transport faulty data. Analyze the structure of each received data frame to ensure complete data transmission. Do not display or store data sent in a corrupted frame or frame with CRC error. Display a technical alarm condition upon frame errors (e.g. Device defective).	All	**YES**	Provoke **frame / CRC errors** using the emulator – verify that an appropriate message or action is seen on the EUT	□ yes □ no	□ pass □ fail □ NA
Unknown data	Display a technical alarm condition to make the user aware that a communication error occurred (e.g. Device defective).	All	**YES**	Provoke **unknown data** using the emulator – verify that an appropriate message or action is seen on the EUT	□ yes □ no	□ pass □ fail □ NA