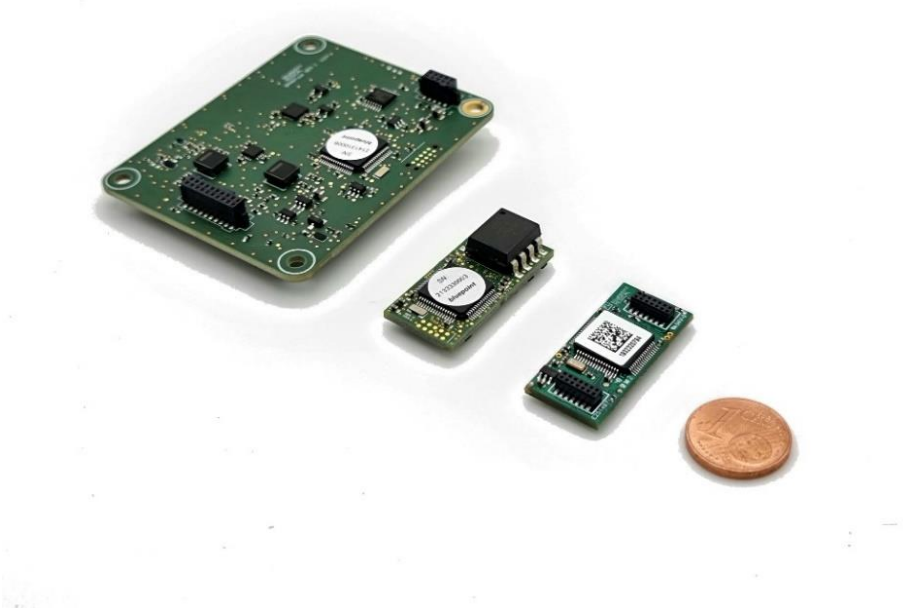
SMARTsat® OEM I/ II/ III

Protocol Implementation Checklist



CHECKLIST FOR INTEGRATION OF THE COMMUNICATION PROTOCOL

COMPANY CONFIDENTIAL

SMARTsat® Protocol Implementation Checklist

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Contact information

bluepoint MEDICAL GmbH & Co. KG
An der Trave 15
23923 Selmsdorf
Germany

Phone: +49-(0)-38823-5488-0
Fax: +49-(0)-38823-5488-29
E-mail: info@bluepoint-medical.com
Web: www.bluepoint-medical.com

1 Purpose and scope

The Protocol Implementation Checklist verifies the implementation of the SMARTsat® communication protocol [1] at the equipment under test (*EUT*). For more information refer to section 4.9 of [2].

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*)

Verify that your host system fulfils communication requirements according to this checklist and send the results to bluepoint medical before, submitting at least one fully integrated host system to bluepoint medical for the final host validation.

The tests in the checklist are performed with the SMARTsat® Emulator (refer to section 6.3 of the Integration Guide [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.

2 Reference

ID	Doc. Number	Name	Rev
[1]	O-07-00-002	SMARTsat® Communication Protocol – SMARTsat® OEM III	16
[2]	O-07-00-001	SMARTsat® OEM I/ II / III - Integration Guide	11

3 Definitions

Definition	Description
ALL	All applications listed here
AM	Alarm monitor
Appl.	Application

Definition	Description
ASP	Auto scaled plethysmogram
bd	baud rate
CM	Continues measurement
EUT	equipment under test
HRP	High Resolution Pleth NOTE: This feature is only available up to host protocol rev.8. For Protocol revisions larger than rev8 it is possible to switch the raw pleth (RP) and sampling rate (SR) independantly.
ID	Channel Identified according to host protocol [1]
IMPL	implemented
LED	Light emitting diode
min.	Minimal
N/A	Not applicable
PI	Perfusion index
PTT	Sleep diagnostic/ PTT measurement
RP	Raw plethysmogram
SpC	Spot check measurement
SpO2	Arterial oxygen saturation
SR	Sampling rate

4 Protocol Implementation Checklist

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	Raw Pleth (RP)/ (RP2) need a minimum baud rate of 115200 Bd. Increase baud rate if RP /RP2 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 RP/PR2 cannot be switched on simultaneously. In RP/RP2 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 RP/RP2 mode. Switch of RP/RP2 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:	Probe off	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

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 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 (IR AC/DC ratio <1%)	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
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

Flag	Status information	Description and suggested Host action	Suggested Host Message	min. priority at Host Alarm	Typical Appl.	Manda-tory	Test	IMPL	Result
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 (15 points @ 5 Hz Or 1 point @ 75 Hz)	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 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 which clinically do not require display of a plethysmogram (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	Monitor with sound functionality: 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	Raw Plethysmogram (RP)	Select RP or RP2 depending on monitor function.	PTT	NO	**Set RP/ RP2 and sample Rate (SR)** at the emulator. Verify the correct display of the simulated RP/ RP2 plethysmogram waveform at the EUT and implemented calculations (e.g. PTT).	□ yes □ no	□ pass □ fail □ NA

3.3) Results and indicators - Ch=0x10, ID=0x04 (SpO_2 Integer Representation):

Flag	Results and indicators	Description and suggested Host action	Typical Appl.	Manda-tory	Test	IMPL	Result
Byte[0]	ID 0x04 : (integer) 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 [x…y bpm], 0xFFFF = no value, (Hi+Lo) x = 20 bpm, EPR on x= 30 bpm, EPR off y = 300 bpm, EPR on y= 240 bpm, EPR off	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, **a)** Format with identifier 0x1D → 0x01 = resolution of PI is 0.1% **b)** Format with identifier 0x1D → 0x02 = resolution of PI is 0.01%	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. It is recommended to change the bar graph amplitude with changing signal quality (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 - Green: Good signal quality resulting in accurate measurement values. 60 %- Yellow: Reduced signal quality, which may reduce measurement accuracy. Also applies if following flags are set:"Supply voltage out of range" - "Vital parameter out of range 30 %- Red: Poor signal quality, measurement values may be inaccurate 1% - Red: No SpO2 and PR measurement values available	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]	Each second the active settings for externally adjustable parameter are send in Byte 6. If a setting is active, the respective bit is set to 1.						
Byte[6] Bit 0	Response time: stable	Continuously check the settings of SMARTsat® 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	AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	□ yes □ no	□ pass □ fail □ NA
Byte[6] 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

Flag	Results and indicators	Description and suggested Host action	Typical Appl.	Manda-tory	Test	IMPL	Result
Byte[6] Bit 2	Response time: sensitive	must set the HOST specific settings again, if the module was reset. Also see: 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
Byte[6] 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
Byte[6] Bit 4	Response time: 4-Beat averaging		AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	□ yes □ no	□ pass □ fail □ NA
Byte[6] 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
Byte[6] 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
Byte[6] 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, the 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) Results and indicators - Ch=0x10, ID=0x05 (SpO_2 Float Representation – 2 decimal digits):

Flag	Results and indicators	Description and suggested Host action	Typical Appl.	Manda-tory	Test	IMPL	Result
Byte[0-1]	ID 0x05 : (2 decimal digits) SpO2 Value [0.01…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 0.01 %) 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[2-3]	Pulse rate [x…y bpm], 0xFFFF = no value, (Hi+Lo) x = 20 bpm, EPR on x= 30 bpm, EPR off y = 300 bpm, EPR on y= 240 bpm, EPR off	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[4-5]	Perfusion Index PI= I_{AC}/I_{DC} [1...200 ‰] 0xFFFF = no value, **a)** Format with identifier 0x1D → 0x01 = resolution of PI is 0.1% **b)** Format with identifier 0x1D → 0x02 = resolution of PI is 0.01%	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. It is recommended to change the bar graph amplitude with changing signal quality (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[6]	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 - Green: Good signal quality resulting in accurate measurement values. 60 %- Yellow: Reduced signal quality, which may reduce measurement accuracy. Also applies if following flags are set:"Supply voltage out of range" - "Vital parameter out of range 30 %- Red: Poor signal quality, measurement values may be inaccurate 1% - Red: No SpO2 and PR measurement values available	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[7]	Each second the active settings for externally adjustable parameter are send in Byte 6. If a setting is active, the respective bit is set to 1.						
Byte[7] Bit 0	Response time: stable	Continuously check the settings of SMARTsat® 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	AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	□ yes □ no	□ pass □ fail □ NA
Byte[7] 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

Flag	Results and indicators	Description and suggested Host action	Typical Appl.	Manda-tory	Test	IMPL	Result
Byte[7] Bit 2	Response time: sensitive	must set the HOST specific settings again, if the module was reset. Also see: 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
Byte[7] 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
Byte[7] Bit 4	Response time: 4-Beat averaging		AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	□ yes □ no	□ pass □ fail □ NA
Byte[7] 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
Byte[7] 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
Byte[7] 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, the 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. ***Byte*[0-1]:** sensor type value = Byte[0]*0x100 + Byte[1] The standard SMARTsat® sensors are listed below: 0xFFFF /65535= 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, BF7500 Baby Foot Spotcheck Sensor 0x0028 /40 = Type O Sensors (open sensors): W7500 SoftWrap; 10-AP Disposable adult; 10-PP Disposable pediatric; 10-IP Disposable infant, Y7500 Disposable Multisite Y Sensor 0x0033 /51 = 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, RP/ RP2, 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 (refer to section 2.2.2 of [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
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

ID	Feature	Description and suggested Host action	Typical Appl.	Manda-tory	Test	IMPL	Result
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 RP/ RP2; 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	Refer to section 3.2 of the Integration Guide [2] for more information.	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 RP pleth	Possibility to switch Raw Pleth on/off independent of sampling rate. Refer to section 2.2.3 of the Integration Guide [2] and the host protocol [1] for more information. NOTE: for host protocol rev.8 and smaller use the HRP function	All	NO	Verify correct implementation of the protocol and verify that an error is send in case the PR/ PR2 is switched off at the emulator during use. Note: Functionality of Host specific PTT calculations is not part of this verification.	□ yes □ no	□ pass □ fail □ NA
0x1A	Set sampling rate	Possibility to select the desired sampling rate. The measurement accuracy is increased with higher sampling rates, but also the power consumption is increased. The raw plethysmogram (RP/RP2) is transmitted in the selected sampling rate.	All	NO	Cycle through all settable sampling rates at the EUT and verify that EUT behaves as specified.	□ yes □ no	□ pass □ fail □ NA
0x1B	Raw Plethysmo gram (RP2)	Refer to section 2.2.3 of the Integration Guide [2] and the host protocol [1] for more information.	PTT	NO	Functionality of the PTT feature is not part of this verification. Verify correct implementation of the protocol and verify that an error is send in case the PR/ PR2 is switched off at the emulator during use.	□ yes □ no	□ pass □ fail □ NA
0x1C	Set SpO2 results Resolution	0x01 = send results with identifier 0x04 each second. (integer representation: SpO2 results without decimal digits) 0x02 = send results with identifier 0x05 each second (float representation: SpO2 results with 2 decimal digits)	All	NO	Set desired resolution and verify displayed data	□ yes □ no	□ pass □ fail □ NA
0x1D	Set perfusion index (PI) Resolution	0x01 = resolution of PI is 0.1% 0x02 = resolution of PI is 0.01% (default setting since protocol rev.12). Used for OEM I and II which perform at lower perfusion (down to 0.02%)	All	NO	Set desired resolution and verify displayed data	□ yes □ no	□ pass □ fail □ NA

ID	Feature	Description and suggested Host action	Typical Appl.	Manda-tory	Test	IMPL	Result
0x1F	Request current module settings	Used to verify that the correct setting is set at the SMARTsat module. Result may be used to show setting at the host system or to check if send command was accepted in case the SMARTsat® response was not received upon change of setting.	All	NO	Change externally adjustable parameter at the emulator. Request current setting in the host and verify that the host requests change of parameter to the correct initial settings before manipulation.	□ yes □ no	□ pass □ fail □ NA
0x30	Software reset	The host may reset the SMARTsat by sending a SW command, through the reset pin or by switching the power supply. Consider that upon restart the SMARTsat returns to the default settings. The settings selected by the user after power on should therefore be preserved after reset initiated by the host system without user action. Refer to section 4.3 of the Integration Guide [2] for more information.	All	**YES**	Verify that the implemented HW reset (power on) and SW reset (command send by host and/ or reset pin) are functional. Ensure that selected user settings (externally adjustable parameter) are restored after reset by reset pin or software host command.	□ yes □ no	□ pass □ fail □ NA
0x31	Baud rate setting	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.	Manda-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

5 Revision History

Doc. Rev.	Effective Date	Prot. Rev.	Change description
4	2023-10-04	16	Add section Reference (2) Rename to “Protocol Implementation Checklist” (before Host Validation Checklist) Update to Protocol rev.16 [1]: --identifier 0x05 (Float SpO2 results) - identifier 0x07 (Raw Plethysmogram output of two wave length) - identifier 0x1B (Switch Raw Plethysmogram output of two wave length (RP2) ON/OFF) - identifier 0x1C (Result output switch between identifier 0x04 and 0x05) - ASP with 1 data point at 75 Hz, (see Ch 10, Id 0x02, 2) - identifier 0x1D (resolution of perfusion index in results identifier 0x04)
3	2020-05-20	11	- Add RP (Raw Pleth)
2	2018-03-01	9	- Add Identifier 0x19 (Switch High Resolution Plethysmogram ON/OFF) - Add Identifier 0x1A (Set sample rate)
1	2017-02-20	8	Add Identifier 0x0A (Sensor Error: Short circuit) to Error channel (TN-2.15)
0	2016-12-05	7	Initial version based on documents: - SMARTsat_I-III_Integration_Guide_rev6; - SMARTsat_Communication_Protocol_rev7-A