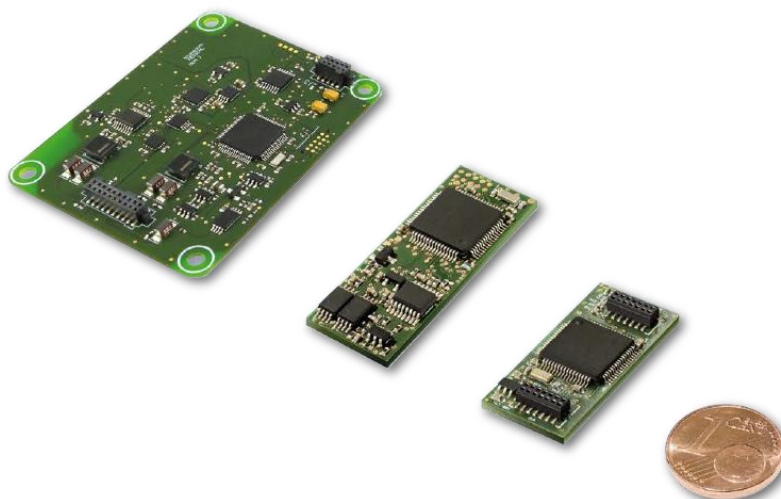


SMARTsat® OEM I/ II/ III

Host Validation Checklist



CHECKLIST FOR INTEGRATION OF THE COMMUNICATION PROTOCOL

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SMARTsat® Host Validation Checklist

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1 Purpose and scope

The Host Validation Checklist verifies the implementation of the SMARTsat communication protocol (Doc. No. O-07-00-002 rev.8 and rev.11) at the equipment under test (*EUT*).

For more information see the SMARTsat® OEM I/ II / III - Integration Guide (Doc. No. O-07-00-001 rev. 9)

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.

2 Revision History

Doc. Rev.	Effective Date	Prot. Rev.	Change description
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

3 Host Validation Checklist

1) Common device channel 0x01

ID	Item	Description and suggested Host action	Suggested Host Message	min. priority at Host Alarm	Typical Appl.	Mandatory	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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA

2) Error channel 0x02

ID	Item	Description and suggested Host action	Suggested Host Message	min. priority at Host Alarm	Typical Appl.	Mandatory	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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA
0x04	Selected baud rate is too slow	Raw Pleth (RP) /HRP150 and HRP300 need a minimum baud rate of 115200 Bd. Increase baud rate if RP /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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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 receive buffer overflow at the emulator and send to the EUT – verify that an appropriate HOST action follows.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA

ID	Item	Description and suggested Host action	Suggested Host Message	min. priority at Host Alarm	Typical Appl.	Mandatory	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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA

ID	Item	Description and suggested Host action	Suggested Host Message	min. priority at Host Alarm	Typical Appl.	Mandatory	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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	Mandatory	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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA

Flag	Status information	Description and suggested Host action	Suggested Host Message	min. priority at Host Alarm	Typical Appl.	Mandatory	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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA

Flag	Status information	Description and suggested Host action	Suggested Host Message	min. priority at Host Alarm	Typical Appl.	Mandatory	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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA

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

ID	Feature	Description and suggested Host action	Typical Appl.	Mandatory	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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA
0x03	High Resolution Plethysmogram (HRP)	NOTE: only available until protocol rev.8 For prot. 11 use Raw Pleth (RP) and Set Sampling Rate.	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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA

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

Flag	Results and indicators	Description and suggested Host action	Typical Appl.	Mandatory	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 it takes less than two seconds to display all values (after value is changed at the PC)	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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 it 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	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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 it takes less than two seconds to display all values (after value is changed at the PC)	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA

Flag	Results and indicators	Description and suggested Host action	Typical Appl.	Mandatory	Test	IMPL	Result
Byte[5]	Signal quality [1...100 %], 0xFF = no value	<p>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 %.</p> <p>If possible it is recommended to implement a bar graph representing the plethysmogram movement (based on channel 0x10, identifier 0x02).</p> <p>The color of the bar graph can be used as indicator for signal quality and measurement performance.</p> <p>100 - 61% - Green: good signal quality, very accurate measurement</p> <p>60 - 31% - Yellow: average signal quality, measurement may be inaccurate</p> <p>30 - 1% - Red: poor signal quality, unreliable measurement</p>	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 it takes less than two seconds to display all values (after value is changed at the PC)	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA
Byte[6]	Measurement settings (active if respective bit is set to 1)						
Bit 0	Response time: stable	<p>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.</p> <p>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.</p> <p>See also: Common device channel 0x01, 0x06 to identify a module restart.</p>	AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA
Bit 1	Response time: standard		AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA
Bit 2	Response time: sensitive		AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA
Bit 3	Response time: 8-Beat averaging		AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA

Flag	Results and indicators	Description and suggested Host action	Typical Appl.	Mandatory	Test	IMPL	Result
Bit 4	Response time: 4-Beat averaging		AM, CM, PTT	NO	Change the mode at the emulator and verify the host action	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA
Bit 7	New measurement (SpO ₂ and pulse rate value new. The longest Data Update Period is 28 sec)	<p>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)</p> <p>NOTE: if the distortion period exceeds 28sec, measurement values are set to no value “-”</p>	AM, CM, PTT	NO	Uncheck the Value calc. new checkbox. Verify host action and IFU.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA

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

Description and suggested Host action	Typical Appl.	Mandatory	Test	IMPL	Result
<p>SMARTsat® identifier which sensor type is connected.</p> <p><u>The standard SMARTsat® sensors are listed below:</u></p> <p>0x00FF /255= undefined sensor type</p> <p>(see status information in identifier 0x01for detailed reason e.g. sensor disconnected or wrong)</p> <p>0x000A /10 = Type C Sensors (closed sensors):</p> <p>SC7500 SoftCap; SCM7500 SoftCap medium; SCP7500 SoftCap pediatric; SF7500 SoftFlap</p> <p>0x0028 /40 = Type O Sensors (open sensors):</p> <p>W7500 SoftWrap; 10-AP Disposable adult; 10-PP Disposable pediatric; 10-IP Disposable infant</p> <p>0x0032 /50 = Type E Sensors (ear sensors): EP7500 Ear Probe</p> <p>0x005B /91 = Type N Sensors (neonatal sensors): 10-NP Disposable neonatal</p> <p>NOTE: Customer specific firmware with customized Sensor Type Codes are listed in a separate document</p>	All	NO	<p>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</p>	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	Mandatory	Test	IMPL	Result
0x10	Response Time setting	<p>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).</p> <p>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.</p>	All	NO	<p>Request the response time setting on the EUT and verify that the data received equals the setting in the emulator</p> <p>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</p>	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA
0x11	High Resolution Plethysmogram (HRP)	See APPENDIX 1 section 3.2	All	NO	<p>Request the high resolution plethysmogram mode on the EUT and verify that the data received equals the setting in the emulator</p> <p>Switch the high resolution plethysmogram to OFF at the EUT and verify that no waveform is displayed</p> <p>Switch the high resolution plethysmogram to ON at the EUT and verify that the waveform is displayed</p>	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA

ID	Feature	Description and suggested Host action	Typical Appl.	Mandatory	Test	IMPL	Result
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	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA
0x17	Set Send Frequency of status information	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	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA
0x18	Set Auto scaled plethysmogram	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	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA
0x19	Switch RP pleth	Possibility to switch Raw Pleth on/off independent of sampling rate. Only available in OEM I and II (for OEM III use HRP mode, 0x11 (protocol rev.8))	All	NO	Switch the RP (raw Pleth) on and off and verify that EUT behaves as specified.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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.	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA
0x30	Software reset	See APPENDIX 1 section 2	All	YES	See APPENDIX 1 section 2	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> 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	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> NA