Doc. No.: O-07-00-011
Titel: SMARTsat_Host_Integration_End-User_Documentation
rev. 0

Source: **O-07-00-001_rev12_SMARTsat_I-III_Integration_Guide**

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Review: U. Timm
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"**yes**": Applicable "**no**": Not applicable

All warnings which need to be added to the IFU of the host device shall be verified during Host Validation. The respective sensor IFU's (IFU-01-02-0001/ IFU-01-02-0002) must always be delivered with the Host product/ each replacement sensor.

			Applicable to End User			
Integration Guide Warning ID (Source)	**Warning Text**	**Applicable to Integrator**	**Also part of sensor IFU**	**Adding to the Host System IFU is mandatory**	**Proposed End-User IFU Text** (Host warnings with equivalent content are accepted)	**Justification**
IW-1	These user instructions are a component of SMARTsat®. SMARTsat® should only be used for the purpose and in the manner described in this manual.	yes	no	no	N/A	The intended use within the host device is defined by the integrator.
IW-2	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.	yes	no	no	N/A	The operating parameters are controlled by the integrator. For e.g.: Power supply
IW-3	SMARTsat® and all accessories may only be used by persons with sufficient expertise	yes	no	yes	Add information regarding needed experience of users to the IFU e.g. "The home caregiver may use the equipment in the home environment after instruction by, or under supervision of, a healthcare professional. "	Integration of the module is done by the integrator. Use of the accessories is done by the end user.
IW-4	SMARTsat® is only to be integrated in a host system and operated by qualified personnel	yes	no	no	N/A	The integration of the SMARTsat module should be done by the integrator and verified by bluepoint medicals.
IW-5	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	yes	no	no	N/A	The integrator is responsible to provide ESD protection in the host system and validate the effectiveness with a IEC 60601-1-2 report.
IW-6	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	yes	no	no	N/A	The integrator is responsible to provide electrical patient insulation. Implementation is verified by the Host Validation testing.
IW-7	For the SpO2 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.	no	yes	no	N/A, part of sensor IFU (RW-7, DW-7)	The end user must be aware of the wavelengths of light used because it may have influence on other devices used at the same time.
IW-8	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).	no	yes	no	N/A, part of sensor IFU (RW-12, DW-11)	The user must be aware of possible interference which may affect accuracy of the measurement result.
IW-9	SMARTsat® can show faulty measurements or can be damaged if it will be used outside the specification or environmental conditions	no	no	yes	**Host IFU:** Only operate the device at the specified environmental conditions to prevent wrong measurement results, patient injury or damage to the device.	ISO 80601-2-61 (2019) cl. 201.7.9.2.9.101 (d)
IW-10	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.	yes	no	no	N/A	The integrator is responsible for water protection in the monitor housing. At least water protection IPX2 for mobile host devices (according to ISO ISO 80601-2-61 (2019), cl. 201.7.2.9.101)
IW-11	Do not apply excessive tension to any of the monitor cables.	yes	no	no	N/A	Integrator needs to verify that no tension is on the internal cables leading to SMARTsat e.g. sensor cable. Validated during host integration.
IW-12	Any radio frequency transmitting equipment or other nearby sources of electrical noise may result in disruption of the monitoring system.	yes	yes	no	N/A, part of sensor IFU (RW-19, DW-18)	The integrator should add EMC measures and test according to 60601-1-2. The end user should be aware, that other devices nearby may disrupt the function of the device.
IW-13	To prevent damage, avoid undue bending of the sensor cable.	no	no	yes	Host IFU: To prevent damage, avoid undue bending of the**SpO2** sensor cable.	Optional warning to potentially extend the service life of the sensor. No risk to patient if not added, as RW-12 and DW-11 warn to not use damaged sensors. Will be added to the sensor IFU in the next update.
IW-14	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.	no	yes	yes	- **Host IFU:** No change to "Warning Text" in column B - Sensor IFU: Partially part of sensor IFU (RW-12, DW-11)	The integrator should add EMC measures and test according to 60601-1-2. The end user should be aware, that other devices nearby may disrupt the function of the device or the other devices.
IW-15	Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the host monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.	no	no	yes	**Host IFU:** Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the **equipment**, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.	The integrator should add EMC measures and test according to 60601-1-2. The end user should be aware, that other devices nearby may disrupt the function of the device or the other devices.
IW-16	The use of accessories, sensors, and cables other than those specified or provided by bluepoint Medical could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.	no	yes	no	N/A, part of sensor IFU (RW-1, DW-1)	ISO 80601-2-61 (2019), cl. 201.7.9.2.2.101 (a) Similar to IW-17. May be removed in future.
IW-17	Only pulse oximeter accessories, sensors, and cables offered by bluepoint Medical and listed in the SMARTsat® compatibility list may be used together with SMARTsat® integrated in a host monitor. Sensors and accessories must be in undamaged condition. If other sensors and accessories are used, it could lead to malfunctions, problems with biocompatibility and create invalid readings. The operator is responsible for checking compatibility prior to use.	no	yes	yes	- **Host IFU:** " Only use the compatible SpO2 sensors listed in this document to prevent patient injury." - Sensor IFU (RW-1, DW-1/ RW-11, DW-10)	ISO 80601-2-61 (2019), cl. 201.7.9.2.1.101 g) ; cl. 201.4.103; cl. 201.7.9.2.14.101 (a), (b) - monitor cl. 201.7.9.2.2.101 a) - sensor
IW-18	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.	no	yes	no	N/A, part of sensor IFU (RW-11, DW-10)	Never use damaged equipment
IW-19	Always disconnect the monitor and probes from the patient during magnetic resonance imaging (MRI) scanning. An induced current could potentially cause burns.	no	yes	no	N/A, part of sensor IFU (RW-17, DW-16)	Applicable to user applying the sensor.
IW-20	Disconnect the sensor from the patient throughout computed tomography, as during the active irradiation period, the reading might be inaccurate.	no	yes	no	N/A, part of sensor IFU (RW-8, DW-8)	Applicable to user applying the sensor.
IW-21	Do not autoclave or steam sterilize the SMARTsat® or its accessories. Refer to the specific 'Instructions for Use' of the used SpO2 sensor for correct cleaning and/or sterilization	no	yes	no	N/A, part of sensor IFU (RW-10, DW-9)	Applicable to user cleaning the sensor.
IW-22	If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternative means, then ensure that the SMARTsat® is functioning correctly.	no	yes	yes	- **Host IFU:** "If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternative means, then ensure that the device is functioning correctly." - Sensor IFU: Partialy part of sensor IFU (RW-19, DW-18)	Responsibility of the doctor to check the patient in case measurement results seem uncertain
IW-23	A functional tester (like Index II or equivalent) may not be used to validate SpO2 accuracy. A functional tester can be used to verify the function of pulse oximeter probes.	no	yes	no	N/A, part of sensor IFU (RW-2, DW-2)	ISO 80601-2-61 (2019), cl. 201.7.9.3.1.101 Responsibility of the service staff performing the maintenance and functional checks.

Source: **[1] O-07-00-001_rev12_SMARTsat_I-III_Integration_Guide**
[2] IFU-01-02-0001_rev6
[3] IFU-01-02-0002_rev5

"**yes**": Applicable "**no**": Not applicable

Integration Guide Specification ID	**Doc - Section, page**	**Category**	**Specification according to "Source"**	**Applicable to Integrator**	**Applicable to End-User**	**Adding to the End User Documentation mandatory**	**Justification**
IS-1-1	[1] - Ch 7, p39	Functional measurement range	SpO2 range	yes	yes	yes	ISO 80601-2-61, cl. 201.7.9.2.1.101 (e)
IS-1-2	[1] - Ch 7, p39	Functional measurement range	Pulse rate range	yes	yes	yes	ISO 80601-2-61, cl. 201.7.9.2.1.101 (e)
IS-1-3	[1] - Ch 7, p39	Functional measurement range	Perfusion Index range	yes	yes	no	Mandatory if host displays the perfusion index
IS-1-4	[1] - Ch 7, p39	Functional measurement range	Calibrated to functional oxygen saturation	yes	yes	yes	ISO 80601-2-61, cl. 201.7.9.2.1.101 (b)
IS-2-1	[1] - Ch 7, p39	Accuracy	SpO2 accuracy including conditions	yes	yes	yes	ISO 80601-2-61, cl. 201.12.1.101.1
IS-2-2	[1] - Ch 7, p39	Accuracy	Pulse rate accuracy including conditions	yes	yes	yes	ISO 80601-2-61, cl. 201.12.1.104
IS-3-1	[1] - Ch 7, p39	Response time	Display of first value	yes	yes	no	Recommended for Spot-Check devices
IS-3-2	[1] - Ch 7, p39	Response time	Response time modes	yes	yes	yes	ISO 80601-2-61, cl. 201.7.9.2.1.101 (d)
IS-3-3	[1] - Ch 7, p39	Response time	Data update period	yes	yes	yes	ISO 80601-2-61, cl. 201.7.9.2.1.101 (d)
IS-4-1	[1] - Ch 7, p40	Power requirements	Supply voltage [VDC]	yes	no	no	Needed by the integrator during host design
IS-4-2	[1] - Ch 7, p40	Power requirements	Sample Rate [Hz]	yes	no	no	Needed by the integrator during host design
IS-4-3	[1] - Ch 7, p40	Power requirements	Typical power consumption	yes	no	no	Needed by the integrator during host design
IS-4-4	[1] - Ch 7, p40	Power requirements	Maximum power consumption	yes	no	no	Needed by the integrator during host design
IS-5-1	[1] - Ch 7, p40	Environmental conditions	Operating temperature	yes	yes	yes	ISO 80601-2-61 (2019) cl. 201.7.9.2.9.101 (d)
IS-5-2	[1] - Ch 7, p40	Environmental conditions	Storage temperature	yes	yes	yes	ISO 80601-2-61 (2019) cl. 201.7.9.2.9.101 (d)
IS-5-3	[1] - Ch 7, p40	Environmental conditions	Relative humidity	yes	yes	yes	ISO 80601-2-61 (2019) cl. 201.7.9.2.9.101 (d)
IS-5-4	[1] - Ch 7, p40	Environmental conditions	Altitude	yes	yes	yes	ISO 80601-2-61 (2019) cl. 201.7.9.2.9.101 (d)
IS-6-1	[1] - Ch 7, p40	Serial communication and data	Time until the first command is accepted after switch-on	yes	no	no	Needed by the integrator during host design
IS-6-2	[1] - Ch 7, p40	Serial communication and data	Baud Rate	yes	yes	no	Mandatory if host allows change of baud
IS-6-3	[1] - Ch 7, p40	Serial communication and data	Sampling rate	yes	yes	no	Mandatory if host allows change of sampling rate
IS-7-1	[1] - Ch 7, p40	Dimension	Dimensions (L x W x H)	yes	no	no	Needed by the integrator during host design
IS-8-1	[1] - Ch 8.1/ 8.2/ 8.3, p 42	Compatible sensors	Sensor List with part number	yes	yes	yes	ISO 80601-2-61, cl. 201.7.9.2.1.101 (g)
IS-9-1	[2] - Ch 4.2/ [3] - Ch 3.2	Emitter	Wavelength and Power	yes	yes	no	Part of sensor IFT, ISO 80601-2-61, cl. 201.7.9.2.1.101 (c)
IS-10-1	[1] - Ch 2.3, p16	Operating instructions	signal inadequacy description	yes	yes	yes	ISO 80601-2-61, cl. 201.7.9.2.9.101 (a)
IS-10-2	[1] - ch 1.1 (ASP), p7 [1] - ch 2.2.3 (RP, RP2), p15	Operating instructions	normalized waveform	yes	yes	yes	ISO 80601-2-61, cl. 201.7.9.2.9.101 (a)
IS-11-1	[1] - Ch 1.5.1, p11	Maintenance	Model of functional tester	yes	yes	yes	In the technical description: ISO 80601-2-61, cl. 201.7.9.3.1.101 (b)

Source: **IFU-01-02-0001_rev6_SMARTsat_Reusable_Sensors_IFU_BPM**
IFU-01-02-0002_rev5_SMARTsat_Disposable_Sensors_IFU_BPM

Reusable Sensor Warning ID (Source)	**Reusable Sensors Warning**	**Equivalent Disposable Sensor** Warning ID (Source)	**Level of equivalence**	**Remark**
RW-1	Pulse oximeter probes and extension cables are designed for use with specific monitoring systems. Incompatible components can result in degraded performance and electromagnetic incompatibility, or patient injury. The operator is responsible for checking compatibility prior to use.	DW-1	Identical	Identical to the reusable sensors (RW-1)
RW-2	A functional tester cannot be used to assess the accuracy of pulse oximeter probes.	DW-2	Identical	Identical to the reusable sensors (RW-2)
RW-3	To prevent skin erosion and pressure necrosis, check the patient skin condition at least every **6 hours** and reposition to an alternative location if skin integrity changes. Check the measurement site more frequently with patients which may have low tissue perfusion or edema at the measurement site.	DW-3	Equivalent	(RW-3) Equivalent warning: Reposition every **4h for disposable** sensors and **6h for reusable** sensors
RW-4	Misapplication of a pulse oximeter probe with excessive pressure (e.g. sensor too small or applied too tight) and for prolonged periods can cause pressure injury and inaccurate readings.	DW-6	Equivalent	(RW-4) Equivalent warning: "**Do not strap the sensor tape, wrap or the medical tape too tight to prevent blood flow restriction, inaccurate readings and pressure injuries to the skin beneath the sensor.**"
RW-5	Do not apply the sensors to areas with poor skin integrity to prevent damage to the skin.	DW-4	Identical	Identical to the reusable sensors (RW-5)
RW-6	Routinely clean the sensor according to the instructions and before attaching it to a new patient to prevent cross infection.	DW-5	Equivalent	Instead of cleaning warning, the disposable sensors have this (RW-6) equivalent warning **"Do not reuse disposable sensors as this can cause cross infection, risk of electric shock and inaccurate readings."**
RW-7	During measurement, the sensor generates red and infrared light with specific fixed wavelengths as listed in the specifications below. Consider that these wavelengths might influence diagnostic parameters of other optical applications.	DW-7	Identical	Identical to the reusable sensors (RW-7)
RW-8	Keep the SpO2 sensor out of the radiation field during computed tomography or full-body radiation to avoid possible inaccurate readings for the duration of the active irradiation period.	DW-8	Identical	Identical to the reusable sensors (RW-8)
RW-9	Do not clean the device or sensors whilst in use or connected to a patient.	n/a	n/a	Disposable sensors are not cleaned
RW-10	Do not sterilize by irradiation, steam, or ethylene oxide – refer to cleaning and disinfection instructions. Use of agents other than specified may damage the sensor.	DW-9	Equivalent	(RW-10) Equivalent warning: "**Do not sterilize, clean, disinfect or immerse in liquid of any kind to prevent product damage which may result in patient injury.**"
RW-11	Do not use the sensor or extension cable if it is damaged. Use of a damaged sensor or extension cable could cause patient injury or equipment failure.	DW-10	Identical	Identical to the reusable sensors (RW-11)
RW-12	Excessive patient motion, excessive ambient light, electromagnetic interference (e.g. stacking and location to other medical equipment), blood pressure cuff on sensor site, venous congestion, abnormal venous pulsations, abnormal pulse rhythms due to physiological conditions or nduced through external factors, dysfunctional haemoglobin, intravascular dyes, fingernail polish and artificial fingernails may affect the sensor performance and the accuracy of the measurement.	DW-11	Identical	Identical to the reusable sensors (RW-12)
RW-13	Route all cables carefully to reduce the possibility of patient entanglement or strangulation.	DW-12	Identical	Identical to the reusable sensors (RW-13)
RW-14	Do not alter or modify the sensor or extension cable. Alterations or modifications may affect performance or accuracy.	DW-13	Identical	Identical to the reusable sensors (RW-14)
RW-15	Properly apply sensors according to sensor's directions for use. If the sensor is not applied properly or partially gets loose, this may cause no or inaccurate readings	DW-14	Identical	Identical to the reusable sensors (RW-15)
RW-16	Select a well perfused site for monitoring, very low perfusion at the monitored site may result in no or inaccurate readings.	DW-15	Identical	Identical to the reusable sensors (RW-16)
RW-17	Remove the SMARTsat® sensor, extension cable or other oximetry sensors from the patient during magnetic resonance imaging (MRI). Conducted current may cause burns. Note: Excluded from this warning are W7501 sensors, which are validated for use during MRI and are labelled as such.	DW-16	Equivalent	(RW-17) Equivalent warning: Identical, only the "**NOTE: Excluded from this warning are W7501 sensors, which are validated for use during MRI and are labelled as such."** is not included because there is no MRI compatible disposable sensor currently available.
RW-18	If SpO2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.	DW-17	Identical	Identical to the reusable sensors (RW-18)
RW-19	Avoid possible interference from sources of electromagnetic interference such as, but not limited to: Cellular phones, radio transmitters, motors, telephones, lamps, electrosurgical units, defibrillators, and other devices. Interference may cause accurate measurements. If you are unsure if your device is working properly, contact your clinician.	DW-18	Identical	Identical to the reusable sensors (RW-19)

O-07-00-011 (SMARTsat_Host_Integration_End-User_Documentation)

Rev.	Effective Date	Author	Description of Change
0	2024-07-29	C. George, H. Fröhlich	Initial version listing all warnings and technical specifications of the integration guide which need to be implemented at the host device IFU