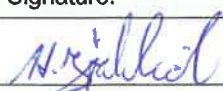
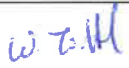
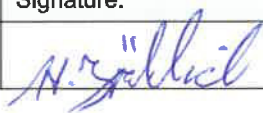


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Document number:	LI-07-03-004
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“SMARTsat® OEM III VM - Product History”

Authored by:	Title/Position/ Function:	Date (YYYY-MM-DD):	Signature:
H. Fröhlich	PLV SMARTsat	2020-04-03	
Reviewed by:	Title/Position/Function:	Date (YYYY-MM-DD):	Signature:
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H. Fröhlich	PLV SMARTsat	2020-04-03	

Valid from: 2020-04-03

File: LI-07-03-004 SMARTsat oem3 - Product History VM rev.4
Template: FBT-07-00-003_rev1 Product History Log Template

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File: LI-07-03-004_SMARTsat_oem3 - Product_History_VM_rev.4

Template: FBT-07-00-003_rev1_Product_History_Log_Template

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1 CONTACT INFORMATION

<i>Project:</i>	SMARTsat® OEM III
<i>Product Name:</i>	SMARTsat OEM III - VM
<i>Customer:</i>	Viamed Ltd. 15 Station Road Cross Hills Keighley West Yorkshire BD20 7DT United Kingdom
<i>Contact - Customer:</i>	Steve Nixon steve.nixon@viamed.co.uk, Tel: +44 (0)1535 634 542
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<i>Contact - Distributor:</i>	D. Wigger d.wigger@bluepoint-medical.com; +49 (0) 38823 / 5488-11

2 PRODUCT DESCRIPTION

bluepoint Order number (REF):	8110140011VM	
Hardware (HW):	V3.3.1 Rev. B	
Firmware (FW):	VM.03.B36.A24.1B / VM2.03.B36.A24.1B	
Bootloader version:	V2	
Status:	☒ released product	☐ Evaluation sample, not for clinical use

SMARTsat@OEM III with customized HW and FW:

HW customization:	none
SW customization:	Module accepts only sensors with Viamed sensor ID as specified in document O-07-00-002. - VM: Standard version - VM2. EPR ON (20 to 300 bpm), as required for use in VM-2160

Module is integrated in the following products:

REF: 8110140011VM with VM2.03.B33.A22.1S.1__RevB:
integrated in VM-2160 (REF: 12020112001).

File: LI-07-03-004_SMARTsat_oem3 - Product_History_VM_rev.4
Template: FBT-07-00-003_rev1_Product_History_Log_Template

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3 MODULE START-UP SETTINGS

ID	Description	Default start-up setting
S1	Host Protocol	rev. 8
S2	SpO2 and Pulse Rate Response time mode (RTM)	standard
S3	High Resolution Plethysmogram(HRP) send frequency	OFF (0 Hz)
S4	Enhanced Pulse Rate Mode (EPR)	VM.xx.xxx.xxx.xx.x: OFF (30 to 240 bpm) VM2.xx.xxx.xxx.xx.x: ON (20 to 300 bpm)
S5	Status send frequency	5 Hz
S6	Auto scaled plethysmogram (ASP)	ON (5 Hz)
S7	Baud rate setting	115200 Bd

4 SENSOR COMPATIBILITY

ID	Description	Parameter
C1	Sensor type	Closed sensors (ID-10): SC7500VM, SCM7500VM, SCP7500VM, SF7500VM Open sensors (ID-40): W7500VM, 10-AP_VM, 10-PP_VM, 10-IP_VM Ear sensor (ID-50): EP7500VM -1 Ear sensor (ID-51): EP7500VM -2 Neonatal sensor (ID-91): 10-NP VM Development versions: SCP7500VM (ID-20); SF7500VM (ID-30);10-AP_VM (ID-61);10-PP_VM (ID-71);10-IP_VM (ID-81)
C2	R-Curve	SMART - -12 (ID-10, 40, 91), SMART-E13 (ID-50, ID-51)

File: LI-07-03-004_SMARTsat_oem3 - Product_History_VM_rev.4

Template: FBT-07-00-003_rev1_Product_History_Log_Template

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5 PRODUCT HISTORY LOG

<i>Product version</i>	<i>FW</i>	<i>HW</i>	<i>Host Protocol</i>	<i>Summary of HW changes</i>	<i>Summary of FW changes</i>	<i>HW comp.</i>	<i>Impact of changes (none¹ /list)</i>	<i>Release</i>
1	VM.03.B33.A22.1S/ VM2.03.B33.A22.1S	V3.3.1 Rev. A	Rev.8	initial version	initial version	V3.3.1 Rev.A	initial version	18.05.2018
2	VM.03.B33.A22.1S.1 / VM2.03.B33.A22.1S.1	V3.3.1 Rev. A	Rev.8	none	Small bug fixes in verifying signal quality of pulse rate.	V3.3.1 Rev.A	none	16.01.2019
3	VM.03.B33.A22.1S.1 / VM2.03.B33.A22.1S.1	V3.3.1 Rev. B	Rev.8	replaced MOSFET by proven equivalence (SMART_N_01_Module_HW)	none	V3.3.1 Rev.A/ B	none	29.08.2019 CL-07-03-003_004
4	VM.03.B36.A24.1B / VM2.03.B36.A24.1B	V3.3.1 Rev. B	Rev.8	none	- enhanced signal noise rejection during analysis of ear sensor signals (small AC signal with large DC part and large amplitude motion artefacts during head movement) resulting in improved performance in displaying valid readings during distortion (less drop-outs). - enhanced reaction on bad sensor signal /or potential cardiac arrest: before instantly "loss of pulse" flag resulting in high priority alarm. Often however only bad sensor positioning etc. and no cardiac arrest. Improved reaction by analyzing the signal difference resulting in down count of SpO2 before "loss of pulse" flag in some cases. - small bug fixes (faster ADC calibration, PI output limited to specified range 0,1 – 20,0%) - Reviewed limits for power supply flag (set flag if <3,1V or >3,6V during LED on of R and IR, before only IR) - Add bootloader functionality for updating code at bluepoint via UART	V3.3.1 Rev.A/ B	none	03.04.2020 CL-07-03-008/ CL-07-03-009

¹ None: These changes will in no way affect the function or performance of existing HOST devices

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Document revision history:

Rev.	Effective Date	Author	Changes	Reviewed
0	18.05.2018	H. Fröhlich	Initial version for integration in VM-2160 handheld pulseoximeter	UT, PK, HG
1	16.01.2019	H. Fröhlich	Update to product version 2: Bugfix: B-195	UT, PK, AKM
2	29.08.2019	H. Fröhlich	Update to product version 3: update HW to v3.3.1_B (new Mosfet, see SMART_N_01_Module_HW)	UT, PK, AKM
3	10.12.2019	H. Fröhlich	- No Changes to Product (HW or FW), only update to structure of document, add sections with product information (FB-07-00-003). - add product version to Product History log	UT, PK, AKM
4	03.04.2020	H. Fröhlich	- Update to product version 4. - Add information of implemented Host protocol in Product History Log table.	UT, PK, AKM, WT, JPB