Software Delivery Note

Customer Details

To:	Smith & Nephew Wound Management
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Bitwise Project / Contact Detail

Project Code:	BIT_SO
Project Title:	PICO Protect : Formal Development Phase
Project Manager:	Grant Sharp
Account Manager:	Gavin Edgar
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Bitwise Delivery Record

Released To	Delivery Method	Carried Out By	Date
Roberto Rodrigues	S&N Teams "Prj_pico_onboard"	Allan Morton	31.Mar.2021

Release Authorisation

Prepared By	Signature
Allan Morton	

Verified By	Signature
Pavel Ivan	

Approved By	Signature
Grant Sharp	

Comments

This delivery note confirms the formal release of the PICO Protect Firmware Application software image, identified by the revision 2.1.1 with respect to Smith and Nephew R&D Project ID: Damysus WMP/20/003 and implements the features as specified in UIRS Rev. 08 and SRS Rev. 10, issued during March 2021.

This release has been subject to a formal test cycle with details of the verification contained within SOSPC012 Rev D.

For further details of the features implemented refer to the previous delivery note, SODNT008.

If you have any queries please contact your account manager (details above).

1 Package Content

This package contains the PICO Protect Firmware application.

1.1 Content and Structure

Contents of this Release			
Included	Product	Version	Target H/W
☒	PICO Protect Firmware Application	2.1.1	PICO Protect 101-SCH-000004 Rev D

Purpose of the release
This release is a formal release and is being delivered to Smith & Nephew Wound Management to confirm the completion of the formal verification process. This release is covered under the Product Release JIRA (SO-233) PICO Protect Firmware Product Release: SO001-PICO_2.1.1.

Release Type	Fully Verified Release
Release Request #	Damysus WMP/20/003
SVN Tag(s)	URL prefix: "http://svn.bitwisegroup.com/svn/BIT_SO" Tagged locations: "/tags/SO001-PICO_2.1.1"

Statements of Use
This release is for use with the PICO Protect Single Use Negative Pressure Wound Therapy System device and is approved for manufacture.

Limitations of Use / Known Issues
This release has been subjected to a formal test cycle as documented in SOSPC012 Rev D.

Changes since last release
Refer to SODNT008 for details of changes and section 1.2.

The following directory structure and files are provided:

Filename/Folder	Description	Version
firmware\ SO001-PICO_2.1.1.hex SO001-PICO_2.1.1.map SO001-PICO_2.1.1.checksum.txt	PICO Protect Application firmware *Firmware checksum = 63 d0 43 c3 57 5d 3e ae 34 37 3d db 59 bc 6c d8 a1 ed f4 87*	2.1.1
source\ SO001-PICO_2.1.1-source.zip SO001-PICO_2.1.1-source_checksum.txt	PICO Protect Application source code *Zip file checksum = 37 8d 98 9c 2f c1 05 d4 02 41 7f 0f 27 57 65 4f ff 0d 2a fd*	2.1.1

1.2 Features in this Release

The PICO Protect Firmware application delivered in this release represents the Bitwise formal release v2.1.1. The application features are described by the "*Damysus Software Requirements Specification*", Rev. 10 and "*Damysus Software User Interface Requirements Specification*", Rev. 08 Smith & Nephew documents, issued during March 2021.

The following sub-sections are included to highlight the major changes in this formal release compared with the previous formal release, v2.0.1.

1.2.1 Over-Temperature Detection

Over-temperature detection has been implemented on the internal and external pressue sensor temperature values. The current thresholds are 40˚C for the external sensor and 41.5 ˚C for the internal sensor. In the event either temperature value reports higher than its respective threshold, the device transitions to the NRE state.

1.2.2 Voltage Out of Range Checks

The previous release of software contained voltage out of range checks on the battery and boost voltage signals.

The voltage checks ensure the battery is between 2.2V and 3.6V and the boost voltage is between 16V and 33V.

The latest software release ensures that when these checks fail, the device transitions to the NRE state.

1.2.3 ADC Noise Filtering

The ADC module implements the ADC input capture for all ADC channels. It allows each ADC channel to be read individually. A simple averaging filter is implemented within the ADC module to protect against erroneous readings. When an ADC channel read is requested, multiple conversions are performed on the selected channel. The average of these values is then computed and returned. The average filter is controlled by two hardcoded parameters, the number of conversions to perform per ADC read and the delay between conversions. These are currently set to 8 conversions per ADC read with a 5 microsecond delay between conversions

1.2.4 Failed Sensor Reading

During the Monitor/Therapy Delivery state, the previous formal release of software would re-try failed attempts to read the internal and external pressure a total of 20 times, after which it would transition to the FAULT state. This has been modified such that the software transitions to the NRE state on the first failed attempt.

1.2.5 EEPROM Communication Failure

If the operation to write to the EEPROM fails within the Logging Manager module the device now transitions to NRE state. Previously a watchdog reset would have occurred.

1.2.6 Performance Logging

The performance logging record has been modified to integrate the additional sensor temperature. The new record layout is as follows:

#	Field Description	Size (bytes)
1	Differential pressure	2
2	External Pressure	2
3	Pump ON/OFF History	4
4	Battery Voltage (loaded)	2
5	Internal sensor Temperature	2

#	Field Description	Size (bytes)
6	External sensor Temperature	2
7	Device State	1
8	Initial Pump Down duration	1
Total bytes		16

1.2.7 NRE Event

When an NRE event occurs, a final performance record is saved to the EEPROM which contains the reason for the NRE event.

This is stored in the upper 4 bits of the Device State and may contain one of the following values:

Value	NRE Type
0	NRE_NO_EVENT
1	NRE_LOGIC_FAIL_EVENT_E
2	NRE_EXT_SENSOR_UNRELIABLE_EVENT_E
3	NRE_INT_SENSOR_UNRELIABLE_EVENT_E
4	NRE_EXT_SENSOR_OVERHEAT_EVENT_E
5	NRE_INT_SENSOR_OVERHEAT_EVENT_E
6	NRE_VDC_BRIDGE_RANGE_EVENT_E
7	NRE_BAT_EOL_EVENT_E
8	NRE_EEPROM_EOL_EVENT_E

Example: Device State = 0x45

- NRE Event = 4: NRE_EXT_SENSOR_OVERHEAT_EVENT_E
- Device Status = 5: NRE_E

In addition, an 8-bit NRE flag is stored in the EEPROM such that the NRE state persists over a power cycle. The flag value 0x66 is written to address 0x27610 in EEPROM when an NRE event occurs. On power-up, this address in EEPROM is checked for the flag value and, if present, the device enters NRE state directly.

1.3 **Documentation Set**

No additional documentation provided with this release.

2 Build Output Artefacts

This release contains the all source code and binary's

2.1 Installing the PICO Protect Firmware Application

The PICO Protect Firmware application image from the "firmware\" directory must be downloaded via JTAG to the target hardware. Instructions on how to do this are provided in the "PICO Protect Firmware – Software Development Environment Description" Bitwise document, SOSPC006 Revision C.

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