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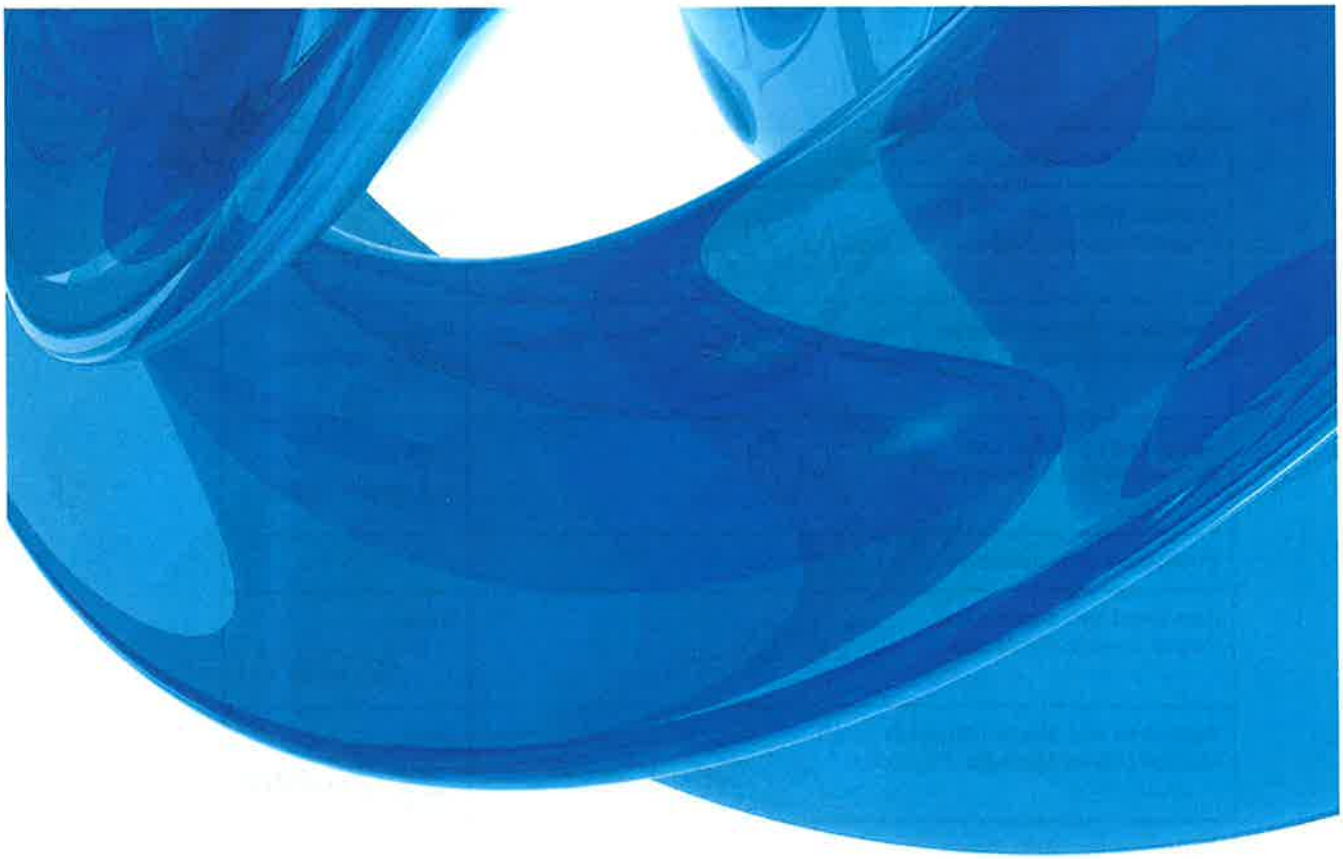
Klemcap: Software Requirements Specification

PHOTOCURE

SAGENTIA



Mike Cox
23 May 2011

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Revision History

Revision	Issue Date	Prepared by	Authorized by	Reason/Description
01	05/10/2009	Mike Cox	Mike Cox	Initial version
02	02/12/2009	Mike Cox	Mike Cox	Update following specification review
03	16/03/2010	Mike Cox	Mike Cox	Update following code implementation • Microprocessor changed to PIC12F683 (to increase memory) • TBD values filled in (mostly self-test limits and treatment times) • Board test now also checks current with LEDs off • LEDs now continuously illuminated at end of board test • Device test can only be entered from initial WAIT state • Power-On Self Test now also checks current with LEDS off • Basic health check no also checks current with LEDS off • Treatment mode and device test mode now have different lower limits for substrate temperature check • Data logging interval changed (memory constraints) • Now need to cycle power and restore battery voltage to acceptable levels to move device from SHUTDOWN state to FAULT state • There is now no transition from FACTORY_DEFAULT state to SHUTDOWN state. The device remains in FACTORY_DEFAULT state permanently. • FACTORY_FAULT error codes defined • Now need to cycle power and restore battery voltage to acceptable levels to move device from SHUTDOWN state to NOTIFY state • Sundry other notes and clarifications
04	26/04/2010	Mike Cox	Mike Cox	Update following final phase 2 review: • Separate PLACEBO variant in addition to normal CLINICAL variant • More user-friendly and unambiguous indication of success/failure following POST in normal treat use case (RED or GREEN LEDs illuminated continuously for 10s) • Low temperature limit for full health check in treatment mode and device test modes removed • Time that power must exceed 2.7V for return from SHUTDOWN state to NOTIFY or from FAULT state to NOTIFY reduced from 10s to 1s • LED current max/min limits relaxed to +/- 10%
05	06/05/2010	Mike Cox	Mike Cox	Update following formal software verification testing: • 4.1.1, 4.1.2, 4.1.3 – "hello" code specified as five rapid flashes rather than four • 4.1.1, 4.1.3, 4.2.1 – note added that there is a single flash of red LEDs during POST • 4.2.4 - VLED and ILED error codes swapped

06	23/05/2011	Mike Cox	Mike Cox	Update following changes to WAIT state and ABSORB state LED indication in software v1.1.4 • 1.2 – reference to 2010 phase II clinical trial removed • 4.1.1 WAIT state – 'wait code' changed to green LED alternating 1s ON and 1s OFF • 4.1.1 ABSORB state – 'absorb code' changed to one flash ON of GREEN LED and RED LEDs every 20s (interleaved red and green flashes alternating at 10s intervals)

Contents

1 Product Overview

1.1 Product Description

The device is a single-use disposable used to provide photodynamic treatment (PDT) of the cervix in women with Cervical Intra-epithelial Neoplasia (CIN) caused by persistent Human Papilloma Virus (HPV) infection. The device forms one part of a drug-device combination therapy and combines delivery of a PDT drug formulation to the cervix and photo-activation of the drug using a LED-based light source contained within the device.

The device is self-contained and self-powered and is intended to be fitted inside the vaginal cavity in contact with the cervix for a period of several hours during which time the therapy is performed. The treatment procedure is as follows:

- HAL ointment is applied to the device cavity.
- The device is fitted to the cervix by a trained healthcare professional (gynaecologist / colposcopist)
- The cup in the device is used to hold the drug (ointment) against the cervix for an initial absorption period of several hours
- A light source integrated into the cup and matched to the absorption wavelength required for photo-activation of Photo-Active Porphyrins (PAP) is automatically activated and delivers the required light dose to provide the therapy
- The healthcare professional or patient removes the device

Current treatment methods involve colposcopy follow-up only or removal of potentially cancerous cells through surgical means, which increases the risk of bleeding, infection, stenosis and pre-term labour. This product is a non invasive therapy for targeting the specific cells resulting in less physiological change and damage to the cervix.

The requirements in this document are based on a device with these characteristics.

The system-level requirements for the product are detailed in the latest version of the Klemcap Product Requirements Specification (ref KLEM_DI04_0001)

1.2 Intended Use

It is intended that the device covered by this specification will be used for a phase II clinical study in combination with Photocure's specially-formulated pharmaceutical compound (Cevira ®).

The requirements in this specification are tailored for the needs of a trials device and it is anticipated that changes to the device may be needed for subsequent phase III trials and/or commercial production

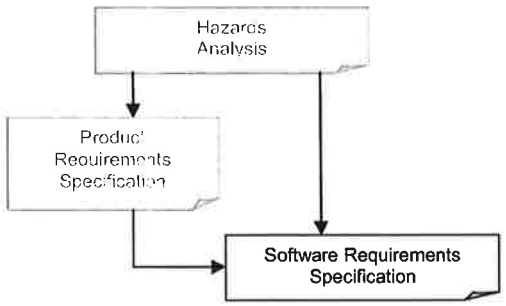
2 Scope of Specification

2.1 Purpose

The purpose of this specification is to document the requirements for the Klemcap software subsystem.

2.2 Context of Specification

This specification should be considered alongside other related product documentation, in particular the top-level requirements defined in the Product Requirements Specification. The following diagram defines the relationship of this document with the other system/subsystem requirements specifications. References for relevant documentation can be found in the Bibliography below (section 2.7)



2.3 Marking of Requirements

Requirements are stated in distinct and uniquely numbered paragraphs in order to allow future traceability of individual requirements and to provide a framework for change control.

Safety-related requirements that relate directly to a risk control measure in the device risk register are marked accordingly by appending the label [R] at the end of the requirement text.

Some requirements are accompanied by explanatory text that qualifies the origin, purpose or interpretation of the requirement and in such cases the explanatory text is preceded by the label "note" and is printed in blue italic, thus:
Note: this is explanatory text

Text in red is reserved for requirements that are yet 'to be determined' (TBD) or are subject to further qualification, thus:
This requirement is TBD

2.4 Interpretation of Requirements

Product requirements are defined as either 'required', in which case their implementation is considered mandatory, or as 'desired', in which case implementation is recommended but may be subject to various feasibility, technical and/or cost constraints, as yet to be determined.

In addition, the requirements presented in this specification are composed of statements containing the words "shall", "must", "should" and "may" whose interpretation is as follows:

- Requirements using the words "shall" or "must" are mandatory
- Requirements using the word "should" are non-mandatory recommendations
- Requirements using the word "may" are design or functional options to be considered for possible implementation.

In areas where product characteristics are not yet defined and/or are subject to choice, then they are marked as "TBD", i.e. to be determined.

2.5 Structure of Specification

Section 1 of this specification provides a general overview of the product. This information is provided to establish a context within which the requirements can be considered but does not specifically form a part of the product requirements.

Section 2 defines the scope, context and structure of the specification. It also defines how requirements are to be interpreted together with the protocol to be used for amending requirements.

Section 3 sets out the general factors that affect the software subsystem and its requirements. This section does not state specific requirements. Instead, it provides a context for those requirements which are defined in Section 4.

Section 4 defines specific software subsystem requirements for the product. Requirements in this section will be subject to formal verification through the provision of objective evidence (i.e. through test, inspection or analysis).

2.6 Change of Specification

This specification is subject to revision control and any proposed amendments to released specifications will be managed using an agreed change control system.

2.7 Related Documents

Klemcap: Product Requirements Specification (ref KLEM_DI04_0001)
Klemcap: Device Risk Register (ref KLEM_DO06_0001)

2.8 Acronyms

The following acronyms apply throughout this specification:

ADC	Analogue to digital converter
GPIO	General purpose input/output
LED	Light emitting diode
EEPROM	Electrically Erasable Programmable Read Only Memory
RAM	Random Access Memory
NV	Non-volatile
PDT	Photo-dynamic therapy
POST	Power-on self test
TBD	To be determined

3 Background

This section is intended to set out the general factors that affect the software subsystem and its requirements. This section does not state specific requirements. Instead, it provides a context for those requirements which are defined in Section 4.

3.1 Product Functions

The device has one primary product function:

Function	Purpose	Comment
Activate unit	Applies power to the unit and causes the device software to step through the fixed treatment sequence (wait, absorb, illuminate, notify, shutdown)	

3.2 User Characteristics

Users of the Klemcap software fall into two categories.

- **Clinician** Activates, installs and (optionally) removes device.
- **Patient** Optionally removes device following treatment

3.3 System Context

A general product overview is provided in Section 1.1. The software resides on a self-powered electronic platform mounted within the device that incorporates:

- A 3V photo-lithium battery
- A reed switch to enable power to the device (using an external magnet)
- A microcontroller with integrated RAM, EEPROM, Flash, GPIO and ADC (software host)
- A chain of 7 red/orange LEDs
- A regulator circuit to generate the drive voltage for the LED chain
- Circuitry to measure
  - LED current
  - LED voltage
  - LED substrate temperature
  - Voltage reference (to check power rail)
- A green status LED

3.3.1 Microcontroller

The selected microcontroller is the PIC12F683 from Microchip. Each microcontroller includes:

- 2048 words of on-chip Flash (program) memory
- 256 bytes of on-chip EEPROM memory (non-volatile data)
- 128 bytes of on-chip SRAM (data) memory
- GPIO lines (6, shared with ADC channels)
- ADC (4 channel, 10-bit)
- Watchdog (to reset processor in case of software malfunction)

3.3.2 User Interface

The external user interface consists of:

- Red treatment LEDs – used to convey status information (error codes)
- Green LED – visible through cup and used to deliver status information (successful operation)
- Magnet to hold device in powered-down state (device activated when removed)
  – not accessible to device software

3.3.3 Hardware Interfaces

The software subsystem interfaces to the following elements of the electronics hardware, many of which are internal to the microcontroller:

Hardware	Interface	Description
Regulator	GPIO	To enable drive current for treatment LEDs
ADC	Internal	Used to measure: - voltage reference (to check power rail) - LED current - LED voltage - board substrate temperature.
EEPROM	Internal	Non-volatile memory for storing non-volatile run-time parameters and for logging data
Green LED	GPIO	To provide visual status information (see also Engineering Interface)
Watchdog	Internal	To reset/disable device in case of processor malfunction
Engineering Interface	GPIO	Generates a serial data stream to output engineering and development data (shared with the green LED).

In addition to the above interfaces that are directly accessible to the software, the programming/test interface (multiplexed with other microcontroller signals/functions) is used in a special programming mode (hardware selectable) to program the microcontroller Flash/EEPROM via a serial interface. In addition, the microcontroller is configured to monitor certain programming/test interface pins at power-up in order to determine whether the device should enter a special board test mode.

3.4 Device Variants

For clinical trials purposes the device is produced with two different software variants:

Device Variant	Purpose	Description
CLINICAL variant	Normal clinical variant used to deliver the planned therapy for the clinical study	Implements all normal functions of the device defined in this specification
PLACEBO variant	Placebo device for use in blinded clinical study	Implements all normal functions of the device with the exception that the device does not deliver the therapy during the normal treatment period (i.e. RED treatment LEDs are not turned on during the normal illumination period). Otherwise all observed behaviour and status/error codes are identical with the CLINICAL variant.

4 Specific Requirements

4.1 Use Cases

The following section contains a set of use cases that describe the external behaviour of the software subsystem. A use case is a description of a specific interaction that a user may have with the software.

There are three modes / use cases for the Klemcap:

Mode	Use Case	Description
TREATMENT	Treat	This is the normal mode of use for the device
BOARD TEST	Board test	Special factory test mode to permit test of the bare board
DEVICE TEST	Device test	Special factory test mode to permit end-of-line test of the complete unit

4.1.1 Treat

In TREATMENT MODE the software progresses sequentially through a fixed sequence of internal software states as follows:

- WAIT (system is re-initialised and start from beginning following a power-cycle)
- ABSORB (system continues from point of interruption following a power cycle)
- ILLUMINATE
- NOTIFY
- SHUTDOWN
- EXHAUSTED (battery physically exhausted – processor no longer operates)

In addition there is an additional FAULT state which is entered if a fault is detected in states WAIT, ABSORB or ILLUMINATE.

The software shall exhibit the behaviour defined in the following use case.

Use case name	Treat
Description	Normal mode of use for delivery of therapy
User(s)	Clinician
Pre-conditions	The system is powered-down and de-activated (magnet fitted)
WAIT STATE	
Flow	1. Clinician removes magnet 2. System executes Power-On Self Test (POST) - note: single RED LED flash during POST 3. System displays initial 'hello code' - five rapid flashes of GREEN LED and RED treatment LEDs - GREEN LED only for 10s 4. System displays 'wait code' - alternating 1s ON and 1s OFF continuous sequence for GREEN LED 5. System performs BASIC 'health check' every 20s 6. After total elapsed time of 15 ± 0.3 minutes in WAIT state the system transitions to the ABSORB state

Variations	**POST fails** 2a. System enters FAULT state and an error code - RED LED only for 10s - three rapid flashes of RED treatment LEDs every 10s **BASIC health check fails** 5a System enters FAULT state and an error code is displayed - three rapid flashes of RED treatment LEDs every 10s
ABSORB STATE	
Flow	7. System displays 'absorb code' - one flash ON of GREEN LED and RED treatment LEDs every 20s 8. System performs BASIC 'health check' every 10s 9. After total elapsed time of 5 ± 0.1 hours in ABSORB state the system transitions to the ILLUMINATE state Note: absorb code LED pattern is interleaved with RED flashes and GREEN flashes alternating at 10s intervals
Variations	**BASIC health check fails** 8a System enters FAULT state and an error code is displayed - three rapid flashes of RED treatment LEDs every 10s **PLACEBO variant** 9a. After total elapsed time of 9.6 ± 0.1 hours in ABSORB state the system transitions to the NOTIFY state
ILLUMINATE STATE	
Flow	10. The RED treatment LEDs are turned on 11. System displays 'illuminate code' - one flash OFF of RED treatment LEDs every 10s 12. System performs FULL 'health check' every 10s 13. After total elapsed time of 4.6 ± 0.1 hours in ILLUMINATE state - the RED treatment LEDs are turned off - the system transitions to the NOTIFY state Note: the ILLUMINATE time (treatment time) is fixed and is determined by characterisation of the devices (i.e. time for integrated optical irradiance to reach worst-case minimum dose levels)
Variations	**FULL health check fails** 12a The RED treatment LEDs are turned off 12b System enters FAULT state and an error code is displayed - three rapid flashes of RED treatment LEDs every 10s
NOTIFY STATE	
Flow	14. System displays the 'success code' - two rapid flashes ON of GREEN LED every 10s 15. When battery volts drop below a minimum acceptable threshold (2.5 V) for a period exceeding 10s - the system transitions to the SHUTDOWN state
SHUTDOWN STATE	
Flow	16. System turns off all peripherals (i.e. LEDs) and idles in a 'safe' mode until the battery is exhausted
Variations	None
EXHAUSTED STATE	
Flow	17. None – system is dead (battery exhausted and processor unable to function)
Variations	None

4.1.2 Board Test

The software shall exhibit the behaviour defined in the following use case.

Use case name	Board test
Description	Special factory mode for testing assembled PCB (BOARD TEST MODE)
User(s)	Manufacturing technician
Pre-conditions	1) Board already programmed via programming/test interface 2) Board powered off 3.0V ± 1% supply 3) Board powered-up with the following programming/test interface signals pulled to Vdd: - GP0/ICSPDAT - GP1/ICSPCLK Note: Board will operate off 2.5 – 3.0V supply but performance at 3.0V ± 1% is preferred to test accuracy of voltage reference measurement.
Flow	1. System waits for pull-ups to be removed from programming interface - wait until analogue voltage are < 1.5V before continuing 2. System performs checksum check on EEPROM 3. System measures voltage reference input to see if within permissible limits - 2.925V < Vref < 3.075V 4. System measures thermistor input to see if within permissible limits - 15℃ < Temp < 30℃ 5. System measures LED current to see if within permissible limits (LEDs OFF) - LED chain current < 512µA 6. System illuminates RED treatment LEDs for 5s - to allow external visual inspection of LEDs - to allow external measurement of total supply current 7. System measures LED current to see if within permissible limits (LEDs ON) - 17.45mA < LED chain current < 21.32mA 8. System measures LED chain voltage to see if within permissible limits (LEDs ON) - 11.65V < LED chain voltage < 16.00V 9. System extinguishes RED treatment LEDs 10. System displays initial 'hello code' to signify successful self-test - five rapid flashes of GREEN LED and RED treatment LEDs 11. System outputs Fosc/5 on engineering output pin (until power removed) - accessible as micro GP4 on programming/test interface. 12. System illuminates RED treatment LEDs (until power removed) Note: Red treatment LEDs remain continuously illuminated and do not 'blink' off Note: Limit values do not include added tolerances for worst-case measurement error
Variations	**Self test fails** (at any point) 10a. System enters FACTORY FAULT state and an error code is displayed - error encoded as sequence of long/short flashes (see section 4.2.4) - error code repeated every 10s (until power removed)

Note: independent measurement of total supply current allows efficiency of the regulator to be confirmed.

4.1.3 Device Test

The software shall exhibit the behaviour defined in the following use case.

Use case name	Device test
Description	Special factory mode for testing finished device (DEVICE TEST MODE)
User(s)	Manufacturing technician
Pre-conditions	1) System in the initial WAIT STATE period In TREATMENT MODE (i.e. must not have progressed into ABSORB state or beyond) 2) System activated/deactivated (by removing/replacing magnet) three times with each activation lasting less than 10s (increments power cycle counter) Note: power cycle counter reset if any period of activation exceeds 10s
Flow	1. System activated (4th time) by removing magnet - system enters device test mode 2. System performs Power-Up Self Test (POST) - note: single RED LED flash during POST 3. System displays initial 'hello code' to signify successful self-test - five rapid flashes of GREEN LED and RED treatment LEDs 4. System illuminates RED treatment LEDs (until power removed) - system performs FULL 'health check' every 10s Note: Red treatment LEDs remain continuously illuminated and do not 'blink' off
Variations	**Self test fails or FULL health check fails** 2a. & 4a. System enters FACTORY FAULT state and an error code is displayed - error encoded as sequence of long/short flashes (see section 4.2.4) - error code repeated every 10s (until power removed)
Post-conditions	Power cycle counter reset to zero Heartbeat counter set to zero LED on-time counter records illumination test time for red treatment LEDs

Note: device test allows a measurement of optical output to be made

4.2 Functional Requirements

4.2.1 Power-on Self Test (POST)

1. The system shall carry out the following sequence of operations as part of the POST [R]:

	Test	Description
a)	EEPROM	Checksum test of EEPROM
b)	Battery capacity	If the heartbeat count is still zero (i.e. treatment not yet started) then the POST shall check that the recorded LED on-time from previous device test activities (as recorded by LED on-time counter) does not exceed the permitted limit. Limits: If heartbeat counter = 0 then LED on time counter < 30 minutes
c)	Battery voltage	Measure reference voltage input and check if inferred battery voltage within permissible limits Limits: 2.6V < Battery volts < 3.3V
d)	Temperature sensor	Measure temperature input and check if within permissible limits Limits: Temp < 40℃
e)	LED current	Illumination OFF: Measure LED current and check if within permissible limits Limits: LED chain current < 512μA Illumination ON: Measure LED current and check if within permissible limits Limits: 17.45mA < LED chain current < 21.32mA
f)	LED chain voltage	Measure LED voltage input and check if within permissible limits Limits: 11.65V < LED chain voltage < 16.00V Note: with LED chain illuminated

Note: Limit values do not include added tolerances for measurement error
Note: There is a single flash of the red LEDs during POST

2. The system shall flag an abnormal condition if any of the POST tests fail [R]

4.2.2 Periodic Health Check

1. In TREATMENT MODE, the system shall maintain a non-volatile 'heartbeat count' that is incremented at intervals of 10s as the treatment progresses
   Note: the heartbeat interval determines the fundamental system timing granularity

2. In TREATMENT MODE the system shall perform a periodic device 'health check' at each heartbeat. Either a BASIC HEALTH CHECK or a FULL HEALTH CHECK shall be performed according to the operating state as defined in the following table:

State	Health check interval	Health check to be performed
Wait	20s	BASIC
Absorb	10s	BASIC
Illuminate	10s	FULL
Notify	-	None
Shutdown	-	None

3. The BASIC HEALTH CHECK shall include a measurement of the following parameters which shall be checked to ensure that they fall within permissible limits

Parameter	Permissible range
LED current	LED chain current < 512µA Note: confirms LEDs turned off
Battery voltage	2.6V < Battery volts < 3.3V

Note: Limit values do not include added tolerances for measurement error

4. The FULL HEALTH CHECK shall include a measurement of the following parameters which shall be checked to ensure that they fall within permissible limits [R]

Parameter	Permissible range
LED current	17.45mA < LED chain current < 21.32mA
LED voltage (across chain)	11.65V < LED chain voltage < 16.00V
Board substrate temperature	Temp < 53℃
Battery voltage	2.5V < Battery volts < 3.3V

Note: Limit values do not include added tolerances for measurement error

5. The system shall flag an abnormal condition if any of the measured health check parameters fall outside the permissible range [R]

4.2.3 Data Logging

1. While delivering the optical therapy (i.e. ILLUMINATE STATE in TREATMENT MODE) the system shall periodically log the measured FULL HEALTH CHECK parameters (as raw ADC values) in non-volatile EEPROM at intervals of 2560 seconds (including time zero).

4.2.4 Faults

Fault state

1. In TREATMENT MODE the system shall enter the FAULT STATE if any abnormal condition is detected during the following operational states
   - WAIT
   - ABSORB
   - ILLUMINATE
2. Once in FAULT STATE the system shall remain in the FAULT STATE until the battery voltage drops below a minimum acceptable threshold (2.5 V) at which point the system shall transition to the SHUTDOWN state
3. While in the FAULT STATE the therapy shall be discontinued and the system shall provide a single visual error indication consisting of three rapid flashes of the RED treatment LEDs repeated continuously every 10s
4. Once the system has moved from FAULT STATE to SHUTDOWN state the system shall continuously monitor the battery voltage and shall revert to the FAULT STATE if the power is cycled (i.e. off and then on) and on restoration the battery voltage is restored to acceptable levels (> 2.7 V) for a period exceeding 1s

Factory fault state

5. In BOARD TEST MODE or DEVICE TEST MODE the system shall enter the FACTORY FAULT STATE if any abnormal condition is detected

6. While in FACTORY FAULT STATE the system shall provide a visual error indication comprising a coded sequence of long/short flashes of the RED treatment LEDs that can indicate the nature of the detected fault as follows:

Error Code	Description
SHORT – SHORT - SHORT	Battery voltage outside permitted range
LONG – SHORT - SHORT	Low level ADC error
SHORT – LONG – SHORT	Low-level EEPROM error or EEPROM checksum test failed
LONG – LONG – SHORT	An unexpected watchdog reset occurred
SHORT – SHORT – LONG	Insufficient battery capacity remaining to complete treatment
LONG – SHORT – LONG	Board substrate temperature outside permitted range
SHORT – LONG – LONG	LED current outside permitted range
LONG – LONG - LONG	LED chain voltage outside permitted range

4.2.5 Watchdog

1. An on-chip watchdog timer shall be used to reset the microcontroller in the event of a software malfunction. The watchdog timer shall trigger a reset if the system fails to reset the timer within an interval of 2 seconds. [R]

2. In TREATMENT MODE the system shall enter the FAULT STATE in the event of an unexpected watchdog reset [R]

3. In BOARD TEST MODE or DEVICE TEST MODE the system shall enter the FACTORY FAULT STATE in the event of an unexpected watchdog reset

4.2.6 Power Cycling

1. The system shall respond to a power-cycle event (i.e. magnet replaced/removed) in the following manner according to the operating mode and state

Original State		Final State after single power cycle		
Mode	**State**	**Mode**	**State**	**Comment**
Treatment	Wait	Treatment	Wait	Reset heartbeat count and restart from beginning of wait state
	Absorb		Absorb	Restore heartbeat count and continue from point of interruption (10s granularity) Do NOT execute POST
	Illuminate		Illuminate	Restore heartbeat count and continue from point of interruption (10s granularity) Do NOT execute POST
	Notify		Notify	Continue in notify state Do NOT execute POST
	Shutdown		Shutdown	Continue in shutdown state Do NOT execute POST
Board test	n/a	Board test	n/a	Restart board test
Device test	n/a	Treatment	Wait	Start treatment (in wait state with power cycle counter reset)
Treatment	Fault	Treatment	Fault	Continue to signal fault status from original treatment Do NOT execute POST
Board test	Factory Fault	Board test	n/a	Restart board test
Device test	Factory Fault	n/a	Factory Fault	Continue to signal fault status from original device test Do NOT execute POST

2. During the initial WAIT state period In TREATMENT MODE the system shall count the number of power cycles and shall transition to the DEVICE TEST MODE after three consecutive power cycles in which the period of device activity does not exceed 10s
   Note: a 'power cycle counter' is used to record the number of qualifying power cycles.

3. In the SHUTDOWN state the system shall continuously monitor the battery voltage and shall revert to the NOTIFY state if the power is cycled (i.e. off and then on) and on restoration the battery voltage is restored to acceptable levels (> 2.7 V) for a period exceeding 1s

4.2.7 Non-volatile Data

The systems shall store all required non-volatile data parameters in the EEPROM. These shall include (but are not limited to):
a) Current state in TREATMENT MODE (i.e. wait, absorb, illuminate, notify, shutdown, fault, factory fault)
b) Last recorded error code (if any)
c) Heartbeat counter
d) Power cycle counter
e) Total LED on time (LED on-time counter)