WSI01 User Manual

Table of Contents

Change history

Date	Author	Comments
5-Aug-2025	Timo Hakala	Initial version.

41 Glossary

Term	Description
CE	Conformité Européenne The CE mark means that the product meets the EU regulatory requirements and thus can be used and marketed in the EU.
CFR	Code of Federal Regulations The regulations defined by the US governmental departments and agencies representing a broad area of federal regulations. The title 47 covers telecommunication is maintained by the FCC.
CPU	Central Processing Unit
CSONE	Carescape ONE GEHC patient monitor, the lead product for the WSI module
CxPC	Class 1, 2, 3 or 4 Permissive Change The FCC or ISED process which allows modifications to an already certified device (existing FCC ID or ISED IC).
ECC	Envelope Correlation Coefficient Antenna performance parameter indicating signal correlation between two antennas. The spatial RX diversity requires uncorrelated antennas.
EMC	Electromagnetic compatibility Regulatory requirements relating device's electrical immunity and emissions.
ETSI	European Telecommunications Standards Institute The organization that defines radio and communication standards in Europe. The standards are used to show the RED compliancy.
FCC	Federal Communications Commission Authority that regulates radio communication in US.
FPC	Flexible Printed Circuit
FW	Firmware
GEHC	GE HealthCare
HLA	High Level Assembly GEHC product with all parts included (PWA, display, mechanics etc.)
Host Device	GEHC monitoring device that integrates the WSI module as part of the end product.
HW	Hardware
I2C	Inter-Integrated Circuit Two-wire low speed digital control interface.
IC	Integrated Circuit
IEC	International Electrotechnical Commission A global electrotechnology standards organization
IO	Input Output
ISED	Innovation, Science and Economic Development The authority that regulates radio communication in Canada.
ISO	International Organization for Standardization A global broad range of industry standards organization
KDB	Knowledge Database FCC guidance document to clarify radio certifications requirements and procedures.
LED	Light Emitting Diode

MBAN	Medical Body Area Network GEHC's proprietary radio system for wireless patient monitoring.
MCAL	MBAN Calibration file A host device specific calibration file that enables accurate MBAN TX power control for a host device with fixed antenna. The MCAL file is generated either during Hub PWA manufacturing based on the RF measurements or converted from the WSI SCAL file based on the host device antenna parameters.
MCU	Microcontroller Unit A component integrating CPU, memories and miscellaneous digital peripherals.
MDR	Medical Device Regulation The EU MDR 2017/745 regulates medical devices in the European Union countries.
MWS	MyWorkshop GEHC document database
NB	Notified Body An accredited person and company (typically a test house) which reviews a RED technical file and gives a NB RED certificate if the material complies with the requirements.
NFC	Near Field Communication The standard short range radio technology used for pairing Portrait wireless sensors.
OS	Operating System Computer operating system like Linux or Windows
OTA	Over The Air Test setup or use-case in which radiated RF signals through antennas are used.
PC	Personal Computer
PCB	Printed Circuit Board
PCI-SIG	Peripheral Component Interconnect Special Interest Group The organization that defines and maintains the M.2 standards.
PMU	Power Management Unit Component or block which generates and controls the VDD supplies inside a device.
PPM	Parameter Platform Middleware The Host CPU SW component that enables communication between the host and WSI.
PWA	Printed Wireboard Assembly PCB with components assembled, tested and calibrated
RED	Radio Equipment Directive The EU directive 2014/53/EU (RED) regulates radio devices used and marketed in the European Union member countries. Widely accepted also in other countries in Europe.
RFU	Reserved for Future Use HW or SW component which is included in design but is not used in current design. May be used in some future release of the product.
RX	Receiver or Reception
SAR	Specific Absorption Rate Measures the rate (W/kg) at which a human body absorbs RF energy radiated by the tested radio device. The SAR limit ensures that exposure stays within safe limits.
SCAL	Superset Calibration file WSI module specific calibration file that enables accurate MBAN TX power control for different type of host device antennas. The SCAL generated based RF measurement during the WSI PWA manufacturing. The SCAL fie is generated based RF measurement during the WSI PWA manufacturing.

SMBUS	System Management Bus Two-wire communication protocol, derivative of the I2C
SW	Software
TX	Transmitter or Transmission
UART	Universal Asynchronous Receiver/Transmitter Main communication interface between the WSI and host device
UK	United Kingdom
USB	Universal Serial Bus Standard interface for connecting peripheral to PCs and other devices
VSWR	Voltage Standing Wave Ratio Indicates the quality of the RF matching.
WSI	Wireless Sensor Interface GEHC radio module that enables wearables sensors in the GEHC monitoring products.

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43 References

GEHC documents	
[1]	Title: Carescape ONE v2 RED (EU) technical file MWS: DOC3164515 Description: The RED technical file includes the material relating to the CSONE V2 EU radio certification.
[2]	Title: WSI01 FCC (US) Technical File MWS: DOC3181238 Description: The FCC technical file includes the material relating to the WSI01 US radio module certification.
[3]	Title: WSI01 ISED (Canada) Technical File MWS: DOC3181243 Description: The ISED technical file includes the material relating to the WSI01 Canada radio module certification
External datasheets	
[4]	Title: I-PEX MHF4L datasheet Internet: https://www.i-pex.com/product/mhf-4l Description: WSI MBAN RF (antenna) connector I-PEX MHF4L datasheet which is used as the
[5]	Title: DF57H-2P-1.2V(21) datasheet Internet: https://www.hirose.com/product/p/CL0666-0104-7-21 Description: WSI NFC RF (antenna) connector Hirose DF57H-2P-1.2V(21) datasheet
[6]	Title: MBAN W3494_TDS (without dock) MWS: DOC3167940 Description: CSONE MBAN antenna Pulse W3494 datasheet
[7]	Title: NFC W3965_TDS_V02_20240429 MWS: DOC3167940 Description: CSONE NFC antenna Pulse W3965 datasheet
Miscellaneous external documents and specifications	
[8]	Title: PCI Express M.2 Specification, Revision 5.1 Internet: https://pcisig.com/specifications Description: PCI-SIG M.2 specification, which defines M.2 interface used between WSI module and the host device. The document is available only for the PCI-SIG members. GEHC is a PC-SIG member which enables free access to the document after registration.
[9]	Title: FCC KDB 996369 - D04 Module Integration Guide V02 Internet: https://apps.fcc.gov/oetcf/kdb → KDB publication number 996369 → D04 Description: The FCC document explains how modules are certified and used in host products.
[10]	Title: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum Internet: https://www.etsi.org/deliver/etsi_en/300300_300399/300328/02.02.02_60/en_300328v020202p.pdf Description: The ETSI standard which covers radio devices using the 2.4 GHz ISM band.
[11]	Title: Code of Federal Regulations - Title 47 Internet: https://www.ecfr.gov/current/title-47 Description: The collection of the FCC parts (CFR Title 47) which regulate the radio communication in the US.
[12]	Title: ISED Radio Standards Specifications (RSS) Internet: https://ised-isde.canada.ca/site/spectrum-management-telecommunications/en/devices-and-equipment/radio-equipment-standards/radio-standards-specifications-rss Description: The collection of the ISED radio standards (RSS) which regulate the radio communication in Canada.

1 Introduction

This document provides instructions how to integrate the Wireless Sensor Interface (WSI) module into host products. The target audience is system and design engineers working on the host device development.

The WSI module (Figure 1) enables the wireless sensors to connect to the host device (typically a patient monitor). The WSI is used exclusively in GEHC's internal products. The WSI is not a standalone device and requires a compatible host CPU. The WSI is an M.2 module, which is the industry standard for enabling radio (e.g. WLAN, Bluetooth or cellular) functionality in laptop and desktop PCs.

The module is powered by the host device. The UART interface enables communication between the WSI and host device. The OTA communication utilizes GEHC's proprietary MBAN radio technology. The standard NFC technology is used to pair the wireless sensors with the host device. The MBAN and NFC antennas are not integrated into the WSI module and are instead part of the host device assembly.

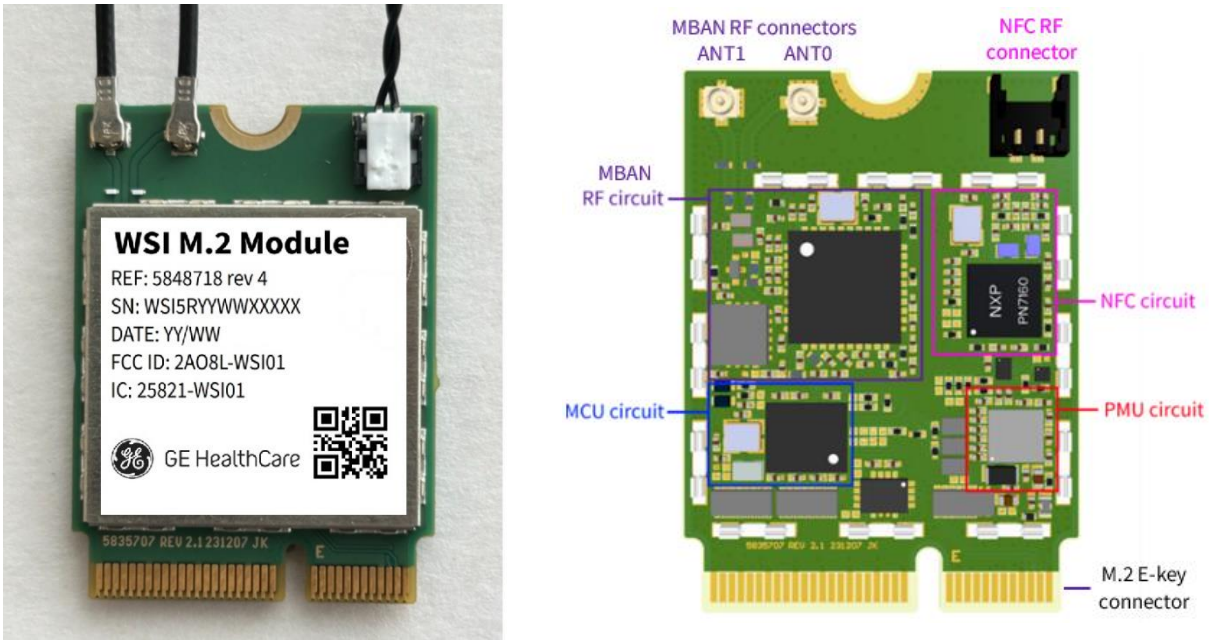

Figure 1: WSI module (top view with and without RF shield and antennas)

2 WSI HW Description

The WSI key operation parameters are listed in Table 1.

Table 1: WSI operating conditions, connectors and interfaces

Operating conditions	
Supply voltage (VDD)	3.3 V ± 5 %
Power consumption	Active mode average < 100 mW Active mode peak < 1 W (recommended that the host device power supply can deliver peak currents up to 1 A)
Operating temperature [1]	0 - 65 °C
Operating humidity range [1]	10 % to 90 % (relative humidity non-condensing)
Atmospheric pressure [1]	616 - 1075 hPa
Physical connectors and size	
Digital interface to the host device	PCI-SIG M.2 E key connector on the host device PCB
NFC RF interface to the external antenna	Hirose DF57H-2P-1.2V(21) connector on the WSI PCB
MBAN RF interface to the external antennas	2x I-PEX MHF4L receptable RF connector on the WSI PCB
M.2 formfactor	2230 (WSI PCB is 22 mm wide and 30 mm long)
Logical and electrical interfaces	
UART	1 Mbaud, HW flow control enabled, 1.8 V IO (excluding open drain wake up signal output)
I2C	100 kHz or 400 kHz clock (standard or fast mode), 1.8 V IO
GPIO	5x 1.8 V GPIO pins for the RF disable and RF COEX signals
MBAN	2360 – 2500 MHz (GEHC proprietary radio protocol) 50 Ω, max TX power ≤ 12 dBm (conducted)
NFC	13.56 MHz (standard IEC/ISO 14443) Reading distance ≥ 10 mm

[1] The WSI ambient condition inside the host device mechanics

A typical connection diagram between the WSI module and the host device is presented in Figure 2. The mandatory signals are: VDD, GND, UART and RF disable signals. Two LED signals are optional, if there is a need to visually monitor the WSI's state and activity. The RFU signals are internally connected in the WSI module but not currently used in the normal WSI operation. The WSI antennas (NFC and 2x MBAN) are external components and thus part of the host device HLA.

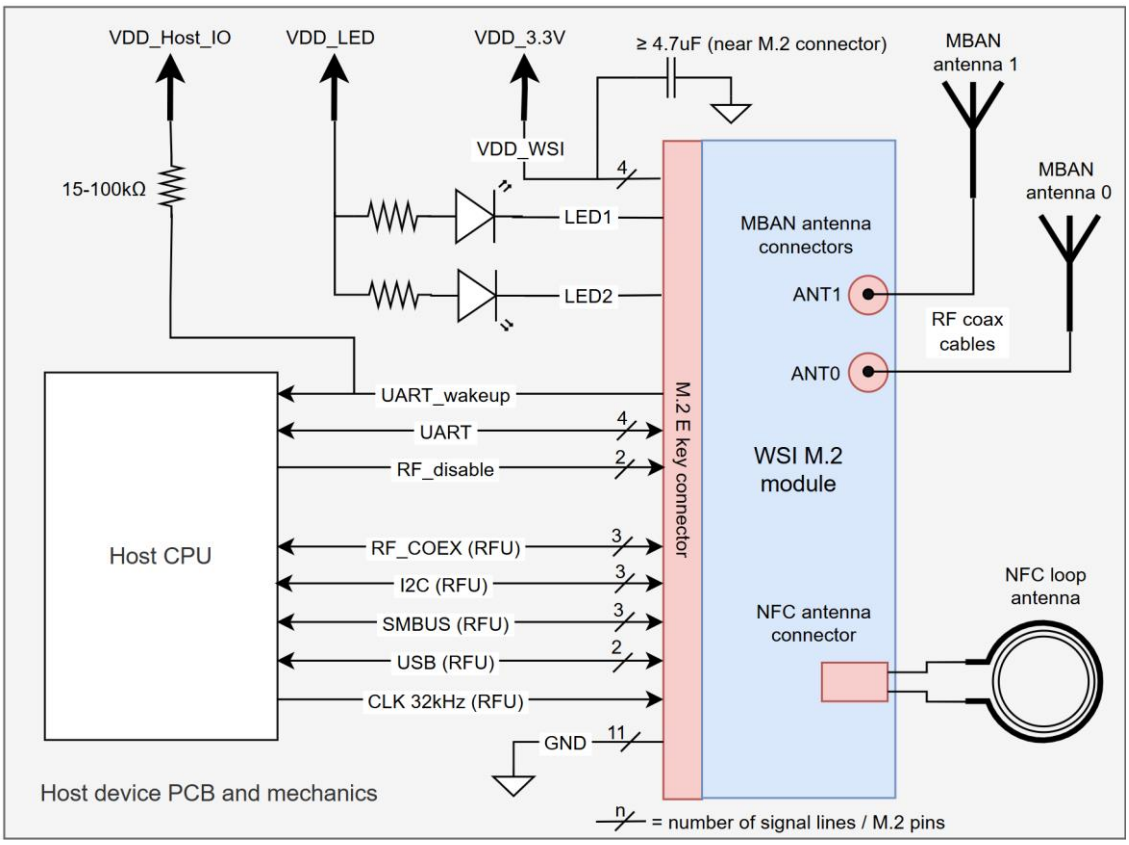

Figure 2: Typical WSI integration diagram

2.1 WSI M.2 Interface

The WSI module is connected to a host device via the PCI-SIG M.2 E-key interface. The M.2 details are defined in the PCI Express M.2 Specification [8]. The WSI M.2 pins used and their functions are listed in Table 2. The color coding in the table is:

- green = GND
- red = VDD
- blue = signal used in the current WSI operation
- white = signal connected in the WSI, but not used in the current operations (RFU)
  - COEX pins must be connected
  - Other pins should be connected if the interface is available in the host device
- grey = signal not used nor connected in the WSI

Table 2: M.2 key E pin numbering and WSI01 pin functions

Pin	M.2 pin name	I/O	Functions in the WSI module	Rated voltage
1	GND		Module ground	0 V
2	PWR_3V3	I	Supply voltage for the module	3.3 V
3	USB_P	I/O	USB 2.0 data+. Not used in the current WSI operation (RFU).	3.3 V
4	PWR_3V3	I	Input power to the module	3.3 V
5	USB_N	I/O	USB 2.0 data-. Not used in the current WSI operation (RFU).	3.3 V
6	LED_1_OUT#	O	Active low open drain LED control. WSI controls module status LED1 on the host side via this pin.	3.3 V
7	GND		Module ground	0 V
8	PCM_CLK/I2S_SCK	I/O	Not used	-
9	SDIO_CLK/SYSCLK_OUT	O	Not used	-

10	PCM_SYNC/I2S_WS	I/O	Not used	-
11	SDIO_CMD	I/O	Not used	-
12	PCM_IN/I2S_SD_IN	I	Not used	-
13	SDIO_DATA0	I/O	Not used	-
14	PCM_OUT/I2S_SD_OUT	O	Not used	-
15	SDIO_DATA1	I/O	Not used	-
16	LED_2_OUT#	O	Active low open drain LED control. WSI controls module status LED2 on the host side via this pin.	3.3 V
17	SDIO_DATA2	I/O	Not used	-
18	GND		Module ground	0 V
19	SDIO_DATA3	I/O	Not used	-
20	UART_WAKE_OUT#	O	Active low open drain UART wake up for the host. Requires pull up on the host side (recommended 15 kΩ to 100 kΩ).	3.3 V
21	SDIO_WAKE_IN#	I	Not used	-
22	UART_TX_O	O	UART Transmit Data connected to RXD on the Host.	1.8 V
23	SDIO_RST#/TX_BLNK_OUT	O	Not used	-
24-31	M.2_E_KEY_SLOT	-	A physical empty slot in the module PCB specifies the E key version of the M.2 standard.	-
32	UART_RXD_IN	I	UART Receive Data connected to TXD on the Host.	1.8 V
33	GND		Module ground	0 V
34	UART_RTS_O	O	UART Ready to Send connected to CTS on the Host.	1.8 V
35	PETp0	I/O	Not used	-
36	UART_CTS_I	I	UART Clear to Send connected to RTS on the Host.	1.8 V
37	PETn0	I/O	Not used	-
38	VENDOR2		SMBUS I2C Interrupt. Pull up resistor on the WSI module. The interface is internally used by the WSI (controls e.g. NFC and PMU ICs). Communication from the host is not needed nor allowed. (RFU)	1.8 V
39	GND		Module ground	N/A
40	VENDOR1		SMBUS I2C SDA. Pull up resistor on the WSI module. The interface is internally used by the WSI. Communication from the host is not needed nor allowed. (RFU, but must be connected)	1.8 V
41	PERp0	I/O	Not used	-
42	VENDOR0		SMBUS I2C SCL. Pull up resistor on the WSI module. The interface is internally used by the WSI. Communication from the host is not needed nor allowed. (RFU, but must be connected)	1.8 V
43	PERn0	I/O	Not used	-
44	COEX3_IO	I	Radio coexistence signal from the host informs the WSI when the WLAN RX is active. Not used in the current WSI operation (RFU but must be connected).	1.8 V
45	GND		Module ground	N/A
46	COEX_RXD_IN	I	Radio coexistence signal from the host informs the WSI when the WLAN TX is active. Not used in the current WSI operation (RFU but must be connected).	1.8 V
47	REFCLKp0	I	Not used	-
48	COEX_TXD_OUT	O	Radio coexistence signal requests the host to interrupt the WLAN TX while the signal is active. Not used in the current WSI operation (RFU but must be connected).	1.8 V
49	REFCLKn0	I	Not used	-
50	SUSCLK32k_IN_3v3	I	32.768 kHz clock from the host device. Not used in the current WSI operation (RFU).	3.3 V
51	GND		Module ground	0 V

52	PERST0_3v3#	I	Not used	-
53	CLKREQ0#_3v3	I/O	Not used	-
54	W_DIS2_IN_3v3#	I	Active low, debounced signal when applied by the system it will disable radio operation on the Module.	1.8 V
55	PEWAKE0#_3v3	I/O	Not used	-
56	W_DIS1_IN_3v3#	I	Active low, debounced signal when applied by the system it will disable radio operation on the Module.	1.8 V
57	GND		Module ground (PCB)	N/A
58	I2C_DATA	I/O	I2C data to Module MCU. Open Drain with pull up on the host device. Not used in the current WSI operation (RFU).	1.8 V
59	RES/PETp1	I/O	Not used	-
60	I2C_CLK	I	I2C clock input from Host to Module MCU. Open Drain with pull up on the host device. Not used in the current WSI operation (RFU).	1.8 V
61	RES/PETn1	I/O	Not used	-
62	I2C_ALERT#	O	IRQ line to the host processor. Open Drain with pull up on the host device. Not used in the current WSI operation (RFU).	1.8 V
63	GND		Module ground	0 V
64	RES/VIO 1.8 V	I	Not used	-
65	RES/PERp1	I/O	Not used	-
66	UIM_SWP/PERST1#	I/O	Not used	-
67	RES/PERn1	I/O	Not used	-
68	UIM_PWR_SNK/CLKREQ1#	O	Not used	-
69	GND		Module ground	0 V
70	UIM_PWR_SRC/GPIO_1/PE WAKE1#	I	Not used	-
71	RES/REFCLKp1		Not used	-
72	PWR_3V3	I	Supply voltage for the module	3.3 V
73	RES/REFCLKn1		Not used	-
74	PWR_3V3	I	Supply voltage for the module	3.3 V
75	GND		Module ground	0 V

The standard M.2 E key module PCB pin numbering and the pin allocation in the WSI are shown in Figure 3.

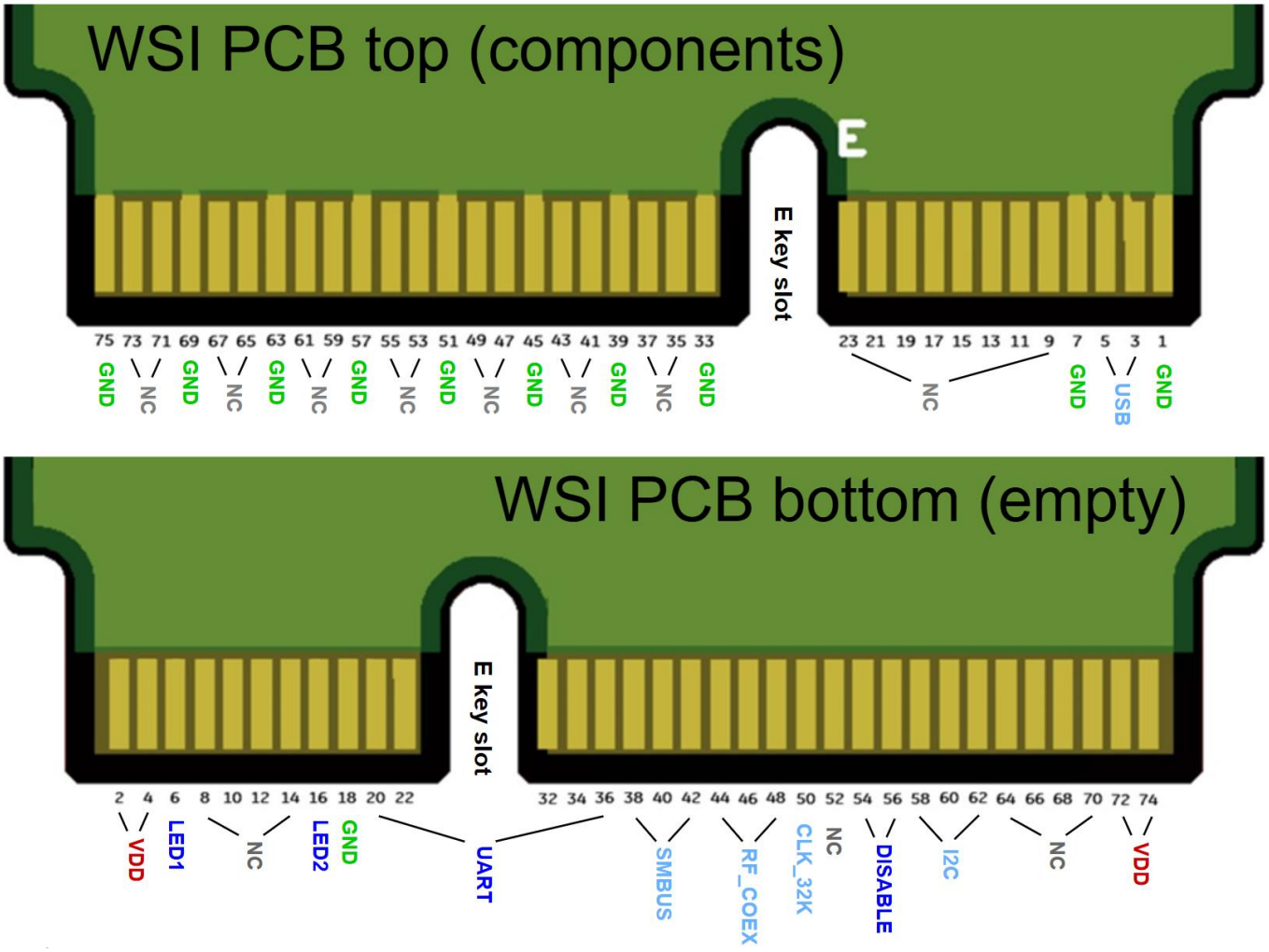

Figure 3: M.2 E key module PCB pin numbering and WSI pin allocation

2.2 NFC Antenna

The NFC antenna is an external component outside the WSI module and thus part of the host device HLA. The antenna is connected to the WSI using the Hirose DF57H-2P-1.2V(21) connector on the WSI PCB. The connector datasheet is provided the reference [5]. The current WSI NFC antenna matching is optimized for the Pulse W3965 antenna (Figure 4) which is used in CSONE V2. For any other NFC antenna, the reading distance may be degraded. In addition, all WSI radio certifications have been performed using the Pulse W3965 antenna. Thus, it is strongly recommended to reuse the same antenna in other WSI host devices, if the FPC antenna size (19 mm x 32 mm) is applicable for the host device. Changing the antenna (type or gain) requires update to the WSI FCC and ISED module certifications via the CxPC process. The antenna cable (65 mm in CSONE) can be lengthened if needed. The reading range should be ≥ 10 mm when measured from the outer surface of the host device against the GEHC Sensor Battery. This enables easy device pairing and good user experience.

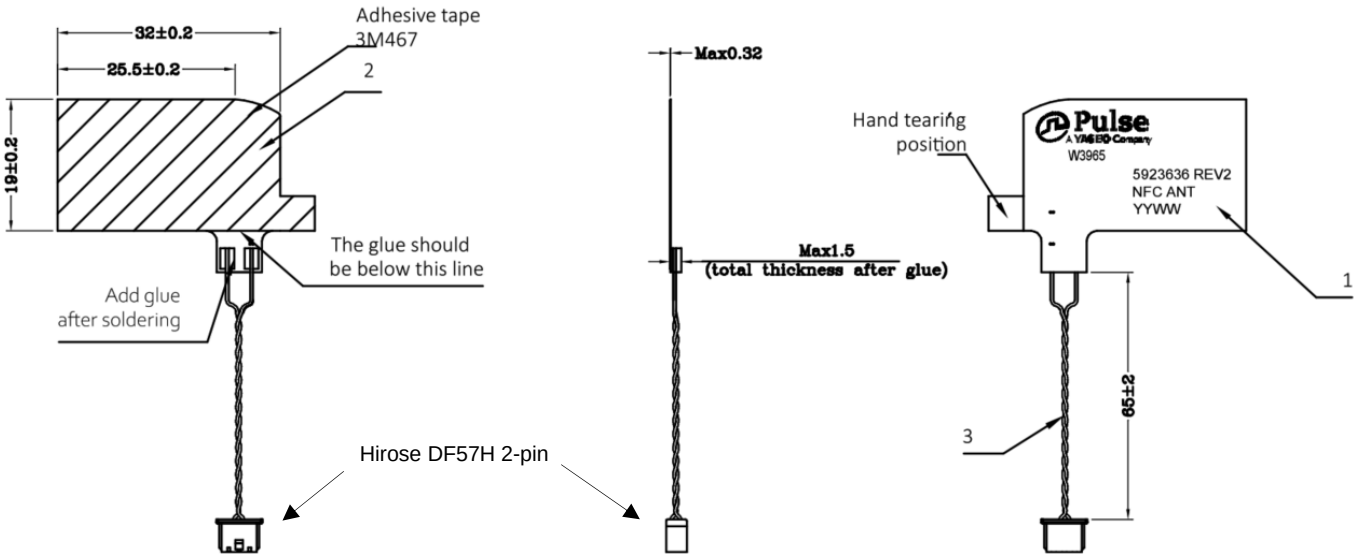

Figure 4: Pulse W3965 NFC antenna used in the CSONE

2.3 MBAN Antennas

Like the NFC antenna, also the MBAN antennas are external components and thus are part of the host device HLA. The MBAN operation requires two antennas to enable spatial TX and RX diversity. The MBAN antenna requirements are listed in Table 3. “Shall” indicates the minimum acceptable antenna performance, while “should” means a feasible performance target for a good antenna design. The same requirements are valid for both antennas. All parameters are defined in free space over the full MBAN frequency range. The antenna connector is the refence point for all values.

Table 3: MBAN antenna requirements

parameter	should be	shall be	comments
frequency range	N/A	2360-2500 MHz	Includes all MBAN bands (US, ISM and EU).
impedance	N/A	50 Ω	Standard 50 Ω RF impedance
return loss	≥ 10 dB (VSWR 1.9)	≥ 6 dB (VSWR 3.0)	Inverted S11 values.
total antenna efficiency	-3 dB (≥ 50%)	≥ -5 dB (≥ 32%)	Includes all losses after the antenna connector (mismatch, conductive and radiated).
peak gain	≤ 3 dBi	≤ 5 dBi	The highest gain in the 3D radiation pattern. Defines the maximum allowed conducted TX power.
ECC	≤ 0.2	≤ 0.1	The correlation between the antennas
antenna connector	N/A	MFH4L or MHF4 plug	I-PEX MHF4(L) is the standard M.2 RF connector. MHF4L and MHF4 are intermateable.
RX desense due to the host device	≤ 3 dB	≤ 6 dB	The RX degradation is the radiated MBAN sensitivity delta between the unpowered host device (only MBAN active) vs. the host device operation under heavy load. The heavy load means high CPU activity, a lot of data traffic in memory lines, high PMU activity (e.g. battery charging), continuously changing image on display and potentially noisy accessories connected to the host. Any TX signals from other radios are excluded from the requirement. The desense is minimized by shielding the noisy components (CPU, PMU etc.) in the host device and locating the antennas as far as possible from those. The WSI design team can help with the desense measurements.

The lead host device CSONE uses the Pulse W3494 [6] (size 59 mm x 22 mm) as the WSI MBAN antenna. The W3494 FPC includes two radiators with their own coaxial cables. The connection between the antenna and the WSI are:

- W3494 Port 1 (P1) ←→ WSI ANT0
- W3494 Port 2 (P2) ←→ WSI ANT1

All WSI radio certifications are made by using the Pulse W3494 antenna. It is strongly recommended to use the same antenna in the other WSI host devices. Changing the antenna (type or gain) requires update to the WSI FCC and ISED module certifications via the CxPC process. If reusing W3494 is not possible then the new antenna should be selected collaboratively by host device and WSI design teams.

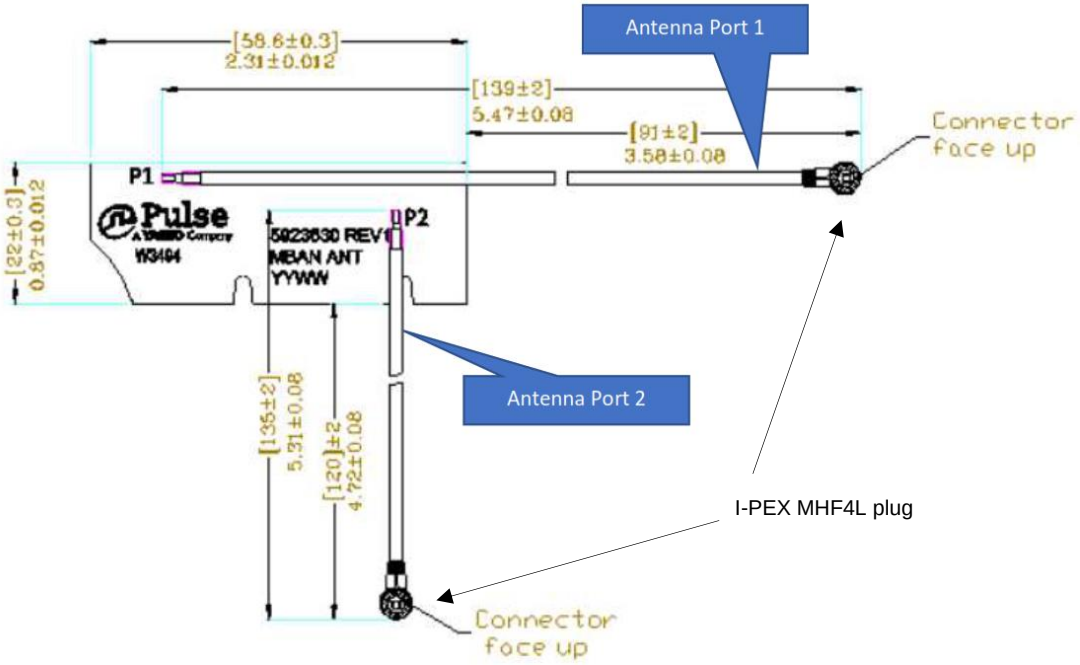

Figure 5: Pulse W3494 MBAN antennas used in the CSONE

3 WSI SW Description

The WSI SW functions are divided between the WSI module and host device CPUs as shown in Figure 6. In normal operation the host device interacts only with the WSI Data MCU and all communication goes through the PPM SW.

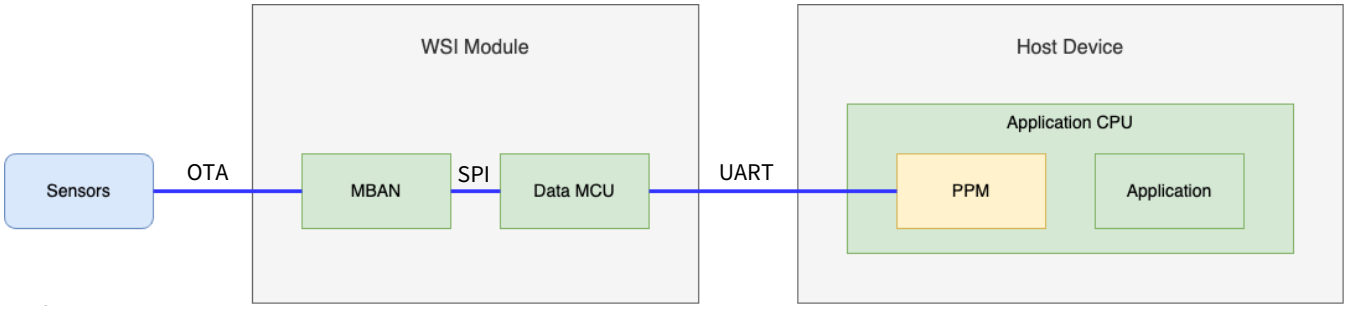

Figure 6: CPUs (green boxes) executing the WSI related SW

3.1 WSI.conf file

The WSI.conf file includes radio regulatory configuration which defines the rules for how the MBAN radio is used during the normal clinical operation. The radio parameters include the allowed MBAN channels (i.e. used frequencies) and maximum power used by the MBAN TX. These parameters are typically controlled by the local radio regulators like the FCC in the US and RED in the EU. The default conf file is the same for every host device but the file content shall be modified according to the regulatory domain before customers can use the host device. In practice this means that during the initial field installation process in the conf file shall be updated with the valid parameters in that specific target country. The conf parameters shall not be accessible for the end user via any type of UI. The conf file modification shall be made either by a GEHC field engineer or trained hospital biomedical engineer. The WSI radio certification is valid only with the correct configuration parameters. Thus, it is a mandatory and critical step to define the correct parameters for every customer device. The WSI.conf file parameters are listed in Table 4.

Table 4: WSI.conf file parameters

parameter	value	description
version	1 (other integers are RFU)	Config file format number. The default value is 1. Increase for incompatible format changes.
bandSelection_US_MBAN_indoor	0 (1 is RFU)	Enables (=1) or disables (=0) the US MBAN indoors frequency band 2360-2390 MHz (MBAN channels 0-11). The default value 0 shall not be changed. The band can be enabled only in the US and only when the host device is connected to the Axone network. Thus, the value shall always be 0 and the parameter is RFU.
bandSelection_US_MBAN_anywhere	0 or 1	Enables (=1) or disables (=0) the US MBAN anywhere frequency band 2390-2400 MHz (MBAN channels 12-14). The default value is 0. The band shall be enabled (=1) only in installations in the US.
bandSelection_ISM	1 (0 is RFU)	Enables (=1) or disables (=0) the global ISM frequency band 2400-2483.5 MHz (MBAN channels 15-46). The default value is 1. The band shall always be enabled as the sensor communication is not possible without the ISM band. The parameter is RFU.
bandSelection_EU_MBAN	0 (1 is RFU)	Enables (=1) or disables (=0) the EU MBAN frequency band 2483.5-2500 MHz (MBAN channels 47-52). The default value 0 shall not be changed. The WSI MBAN radio is not certified to operate on the EU MBAN band. When (and if) the certification will be completed the band can be used in the EU countries. The parameter is RFU.
regulatoryDomain	WORLD ETSI FCC	Defines the radio regulatory rules for the MBAN operation. The default is WORLD, which shall be changed to ETSI or FCC during installation. WORLD is the superset of all (known) radio regulatory limitations. Thus, the WORLD should not be used in any target country as it unnecessarily degrades the radio performance and reliability. ETSI defines the radio communication to comply with the RED and European standards (EN 300 328) [10]. The ETSI shall be used in all installations in Europe. In addition, it is also used in some other countries which follow the EU radio regulation. FCC defines the radio communication to comply with the FCC rules (parts 15 and 95) [11]. The FCC shall be used in installations in the

		US and Canada. In addition, it is used in some other countries which follow that the FCC radio regulation.
enabledChannels	CSV channel list or channel range(s) (RFU)	Enables arbitrary user defined MBAN channels to be used in the MBAN communication. The defined channel list active only when all four bands are disabled (=0). The enabled channels are defined by using CSV channels list (allowed value 0-52) or defining the channel ranges by using dash sign (e.g. 20-30). The default is 15-45, but the value is ignored in the configuration assuming the ISM band is enabled as instructed. The parameter is RFU.

3.2 WSI_antenna.conf file

The WSI_antenna.conf file includes information about the peak gains (dBi) of the host device MBAN antennas. Every WSI module is calibrated during the PWA manufacturing to provide accurate TX power to the MBAN antenna connectors. However, the WSI is a generic module which can be used with different types of host device antennas and thus the correct calibration values should be selected based on the actual host device antenna gains. The PPM SW converts (by using the MCU utility convert_scal command) the generic WSI calibration file (SCAL) to a host device specific calibration file (MCAL) by using the antenna parameters in the WSI_antenna.conf file. The conversion happens automatically if a valid configuration file is stored in the host device. The WSI_antenna.conf file parameters are listed in Table 5. The gain values are given with two digits as plain number (e.g. 2.67 without the unit dBi).

Table 5: WSI_antenna.conf file parameters

parameter	value	description
antenna0_US_MBAN_indoor	number (e.g. 3.80)	2360-2390 MHz peak gain (dBi) of the antenna connected to the WSI ANT0 connector.
antenna0_US_MBAN_anywhere	number	2390-2400 MHz peak gain (dBi) of the antenna connected to the WSI ANT0 connector.
antenna0_ISM	number	2400-2483.5 MHz peak gain (dBi) of the antenna connected to the WSI ANT0 connector.
antenna0_EU_MBAN	number	2483.5-2500 MHz peak gain (dBi) of the antenna connected to the WSI ANT0 connector.
antenna1_US_MBAN_indoor	number	2360-2390 MHz peak gain (dBi) of the antenna connected to the WSI ANT1 connector.
antenna1_US_MBAN_anywhere	number	2390-2400 MHz peak gain (dBi) of the antenna connected to the WSI ANT1 connector.
antenna1_ISM	number	2400-2483.5 MHz peak gain (dBi) of the antenna connected to the WSI ANT1 connector.
antenna1_EU_MBAN	number	2483.5-2500 MHz peak gain (dBi) of the antenna connected to the WSI ANT1 connector.

3.3 WSI SW

The module includes the WSI SW in the Data MCU flash memory which is automatically executed when the WSI is powered on. There are two types WSI SW versions:

- WSI manufacturing SW: Enables all R&D functionality including MBAN Test Mode commands
- WSI clinical SW: Enables normal clinical use (i.e. using wearable sensors)

4 WSI Radio Certifications

The WSI is a radio device, which means it shall comply with the radio standards and regulations defined by the local authorities in every country where it is used and marketed. The compliance with these rules is confirmed through radio certification. The certification process varies from country to country, unfortunately a global radio certification does not exist. Only the EU, US and Canada were in scope for the WSI NPI project. The additional effort and cost of radio certification are significantly smaller if the existing antennas are reused in new host devices. At the moment, this refers to the CSONE V2 antennas. If new antennas are needed, the selection should be made in collaboration with the WSI design team to ensure the new antennas work well with the WSI and can be reused in future host devices.

4.1 EU RED

The WSI.conf parameters for the EU (RED) operation:

```
version=1                          # Current file format is 1
bandSelection_US_MBAN_indoor=0     # Disabled
bandSelection_US_MBAN_anywhere=0   # Disabled
bandSelection_ISM=1                # Enabled
bandSelection_EU_MBAN=0            # Disabled
regulatoryDomain=ETSI              # Follows ETSI standards
enabledChannels=15-45              # Default value (ignored)
```

The WSI EU radio certification is based on the requirements defined in the Radio Equipment Directive (RED) 2014/53/EU. The RED compliance is shown by adding the CE mark (covers all EU requirements, not only radio) to the host device. Although the RED binding regulation only in the EU member countries, it is widely accepted in other European countries such as the UK, Switzerland and Turkey.

The RED does not recognize radio module concept. Therefore, certification shall be done at the host device level covering radios in the device under a single certificate. Typically, a RED notified body (NB) is asked to review the technical file (TF) to confirm that the host device meets the RED requirements. The accredited test houses (e.g. SGS, TUV, Intertek etc.) offer NB services. After review a RED NB certificate is issued. The RED certification covers the following areas:

- Safety and health of users
- Electromagnetic compatibility (EMC)
- Efficient use of the radio spectrum

The WSI is a used in medical devices for which the general safety and EMC requirements are covered by the EU medical regulation (MDR). Therefore, the WSI RED NB certificate is limited to SAR and radio requirements.

Although a stand-alone WSI module cannot be certified, the most of the existing WSI material can be reused in the TF of a new host device, including:

- Design files (schematic, layout, part list etc.)
- Conducted RF test reports (assuming existing antennas are reused)
- RF exposure evaluation report

The material is included in the CSONE RED TF [1] can be used as an example.

The SAR compliance of a host device is based on limb exposure conditions, assuming only user's hands are exposed to RF energy. The maximum SAR_{10g} for a limbs is ≤ 4.0 W/kg. The RF exposure evaluation report shows that the maximum theoretical SAR_{10g} of the WSI module is 0.60 W/kg (combined MBAN + NFC). This means that the WSI module can be integrated to radio products that are used solely by limbs and have SAR_{10g} contribution ≤ 3.40 W/kg from other integrated radios.

RED certification always requires radiated emission measurements (according to EN 300 328) using the actual host device HLA. Therefore, RED certification cannot be completed using only the test reports from

other host devices. At a minimum some radiated measurements need to be performed in an accredited radio laboratory. In case that a host device does not reuse the antennas already tested in another host device also new conducted WSI testing is also required.

4.2 US FCC

The users of the WSI module must understand that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The WSI.conf parameters for the US (FCC) operation:

```
version=1                          # Current file format is 1
bandSelection_US_MBAN_indoor=0     # Disabled
bandSelection_US_MBAN_anywhere=1   # Enabled
bandSelection_ISM=1                # Enabled
bandSelection_EU_MBAN=0            # Disabled
regulatoryDomain=FCC               # Follows FCC rules
enabledChannels=15-45              # Default value (ignored)
```

The FCC in the US allows modular certification for radios. The general FCC guidance regarding radio modules is provided in the FCC KDB 996369 [9]. In practice a certified radio module can be used in new host devices with little or no additional certification effort. The prerequisites for using a certified radio module are:

- The module is used as defined in the module's FCC ID grant (e.g. with approved antennas)
- The host device includes applicable FCC ID labeling (e.g. contains FCC ID: 2AO8L-WSI01).
    - E-labeling on host device's screen is acceptable.
- If the module is integrated in a host device with other radios the manufacturer must ensure that the host product meets the FCC's co-located transmitters requirements defined in the FCC parts 15 and 95 [11].
    - In practice this means that simultaneous operation of the different radios must not generate emissions (typically intermodulation products) above the allowed limit.
    - This does not require ID modification or sending test reports to the FCC.

If the module is used in a way not allowed by the existing ID, the FCC C2PC process is required to enable the new use case.

The WSI is certified as FCC radio module ID: 2AO8L-WSI01. All related material is included in the WSI01 FCC technical file [2]. The grantee code 2AO8L belongs to GEHC Finland and the contact person for the code is Timo Hakala. Any changes needed to the WSI FCC ID must be agreed with GEHC Finland, after which Timo Hakala updates the module ID via the C2PC process. The initial WSI FCC ID allows use only with the CSONE antennas.

The WSI is intended for use in portable devices operating within 20 cm of the body of the user. The FCC SAR compliance is based on the RF exposure evaluation report [2] which shows the following WSI module SAR values (combined MBAN + NFC):

- Extremities (limbs) only use cases: SAR_{10g} is 0.14 W/kg
    - The FCC limit for extremity configuration is $SAR_{10g} \leq 4.0$ W/kg
    - This is the normal use case for WSI hosts which are used solely by extremities (i.e. hands).
- Head and body worn use cases: SAR_{1g} is 0.35 W/kg
    - The FCC limit for head and body-worn configuration is $SAR_{1g} \leq 1.6$ W/kg
    - These use cases are allowed for the WSI, but they are not typical for patient monitors.

This means that the compliance is shown through calculations, and therefore no SAR measurements were made. The WSI module can be integrated in a host device with other radios if the SAR contribution from other radios is:

- In extremity use cases: $SAR_{10g} \leq 3.86$ W/kg
- In head and body-worn use cases: $SAR_{1g} \leq 1.25$ W/kg

The FCC labeling requires the following texts and warnings to be included in WSI host device's user manual:

- §15.19(a) requires the text:
  - "*This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.*"
- §95.2593(c) requires the text:
  - "*This device may not interfere with stations authorized to operate on a primary basis in the 2360-2400 MHz band, and must accept any interference received, including interference that may cause undesired operation.*"
- §95.2595(c) requires the text:
  - "*This transmitter is authorized by rule under the MedRadio Service (47 CFR part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 2360-2400 MHz band, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the MedRadio Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.*"

4.3 Canada ISED

The WSI.conf parameters for the Canada (ISED) operation:

```
version=1                          # Current file format is 1
bandSelection_US_MBAN_indoor=0     # Disabled
bandSelection_US_MBAN_anywhere=0   # Disabled
bandSelection_ISM=1                # Enabled
bandSelection_EU_MBAN=0            # Disabled
regulatoryDomain=FCC               # FCC rules are valid also for ISED
enabledChannels=15-45              # Default value (ignored)
```

The ISED radio standards are available in reference [12]. The WSI is certified as the ISED radio module IC: 25821-WSI01. The ISED radio regulation requirements and certification process in Canada are quite similar to the US FCC system. However, the process is independent, and the FCC approval is not valid in Canada. Nevertheless, much of the material in the ISED technical file [3] is the same as in the FCC technical file [2]. The company code 25821 is owned by GEHC Finland and the contact person is Timo Hakala. This means that if IC changes are needed, only Timo Hakala can request them.

The ISED SAR exemption calculation differs from the FCC requirements. Therefore, the ISED SAR compliance is based on actual SAR measurement performed inside the CSONE host device. This means that the new SAR measurements are needed for every new host device and based on the new test reports the module certification must be be updated via the ISED C4PC process.

Valid ISED labeling is required (contains IC: 25821-WSI01). E-labeling on host device's screen is accepted.

4.4 Other Countries

Countries other than the US, EU and Canada were not in scope of the WSI NPI program. It will be agreed later who is responsible for the certifications in other countries and how that work will be organized between the WSI team and host device programs.

The existing EU and US certifications can be leveraged in other countries. FCC and RED rules, standards and test reports are accepted in many countries. In such cases, certification is mainly paperwork, and no new measurements are needed. On the other hand, some countries (e.g. China, Japan and South Korea) require a

full set of measurements and certification against their own national standards and requirements. The conclusion is that every new country needs to be decided, managed and studied separately. In some cases, required extra work may be negligible while is others, the process can be very laborious.