SmartLinx Vitals Plus Regulatory Notice

Introduction

SmartLinx Vitals Plus® is a Patient Monitoring system which includes hardware and software, as well as a centralized configuration, for the collection, management, and transmission of clinical information, in both critical and non-critical care environments.

This Notice contains regulatory information for the system and is therefore an extension of the *SmartLinx Vitals Plus Installation and Maintenance Guide*. It details the compliance statements that the product requires for its certification and approval. Capsule Technologies, Inc. is therefore committed to delivering products compliant with standards, laws and regulations.

Certification Marks

c UL us	Recognized component		Separate collection for electrical and electronic waste (WEEE directive and Battery directive)
c S us	NRTL mark for USA and Canada	GTIN	Global Trade Item Number
Rx Only	Federal law restricts this device to sale by or on the order of a physician (USA audiences only)	UDI	Unique Device Identifier

Regulatory compliance and approvals

USA

Federal Communications Commission

SmartLinx Vitals Plus complies with Part 15 of the FCC Rules. Operation is subject to two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

Note: The revision number of each SmartLinx Neuron is found on the label located on the rear of the device, where it is indicated using the **REV** symbol. If this revision number is **4.0** or greater, then the system is Class B-compliant. Contact your Capsule representative for more information.

Note: For operation within 5.15 ~ 5.25GHz / 5.47 ~5.725 GHz frequency range, SmartLinx Vitals Plus is restricted to indoor environment. This device meets the requirements specified in Part 15E, Section 15.407 of the FCC Rules.

Caution: Capsule Technologies is not responsible for any radio or television interference caused by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the user's authority to operate the equipment.

Caution:	Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 cm between the radiator and your body.

Note: The country code selection is for non-US model only and is not available on all US models. Per FCC regulation, all Wi-Fi products marketed in the USA must fixed to US-operation channels only.

European Union

Note: FILAC-thermometer-equipped configurations of SmartLinx Vitals Plus are not available in the European Union.

CE Declaration

CE 0459

SmartLinx Vitals Plus complies with the essential requirements and other relevant provisions of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices, and carries CE-marking accordingly.

SmartLinx Vitals Plus complies with essential requirements and other relevant provisions of the Council Directive 2014/53/EU of April 16, 2016 concerning radio equipment and SmartLinx Neuron 2 carries CE-marking accordingly. This equipment may be operated in:

Austria	Greece	Norway
Belgium	Hungary	Poland
Bulgaria	Iceland	Portugal
Croatia	Ireland	Romania
Cyprus	Italy	Slovakia
Czech Republic	Latvia	Slovenia
Denmark	Liechtenstein	Spain
Estonia	Lithuania	Sweden
Finland	Luxembourg	Switzerland
France	Malta	Turkey
Germany	Netherlands	United Kingdom

Certain countries have specific restrictions for, or prohibitions on devices that operate in the 5 GHz band. Specifically in certain European countries, for example, some frequencies should be restricted to indoor use. You are advised to respect local requirements.

For a copy of the full RED Declaration of Conformity, contact your Capsule Technologies representative.

RoHS and WEEE Compliance

SmartLinx Vitals Plus does NOT contain any of the following substances (in concentrations exceeding legal threshold limits):

- Lead
- Mercury
- Cadmium
- Hexavalent Chromium
- Polybrominated Biphenyls (PBB)
- Polybrominated Diphenyl Ethers (PBDE)

In the European Union, SmartLinx Vitals Plus components and accessories should be collected separately and not disposed of with household waste. For details, refer to the section on “Disposal”.

Batteries in the SmartLinx Vitals Plus system are not based on mercury, lead or cadmium technologies. The batteries used in this product are in compliance with the Council Directive 2006/66/EC.

Chromium, lead, mercury, or cadmium are not intentionally added to packaging materials and are not present in a cumulative concentration greater than 100 ppm as incidental impurities. No halogenated plastics or polymers are used for packaging material. Packaging is compliant with the Council Directive 94/62/EC.

Canada

Innovation, Science and Economic Development Canada (formerly *Industry Canada*) Statement

This device complies with RSS-210 of the Innovation, Science and Economic Development Canada (ISED) 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.

Caution:	(i)	the device for operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems;
	(ii)	the maximum antenna gain permitted for devices in the bands 5250-5350 MHz and 5470-5725 MHz shall comply with the e.i.r.p. limit; and
	(iii)	the maximum antenna gain permitted for devices in the band 5725-5825 MHz shall comply with the e.i.r.p. limits specified for point-to-point and non point-to-point operation as appropriate.
	(iv)	users should also be advised that high-power radars are allocated as primary users (i.e. priority users) of the bands 5250-5350 MHz and 5650-5850 MHz and that these radars could cause interference and/or damage to LE-LAN devices.

Radiation Exposure Statement

This equipment complies with IC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 cm between the radiator & your body.

Disposal

As you use the Vitals Plus system, you will accumulate solid wastes that require proper disposal or recycling. These include system components, batteries, patient applied parts, and packaging materials.

Recycling and the Environment

Improper disposal of IT and medical equipment can have a negative impact on health and the environment. We recommend that you dispose of Capsule Technologies products, including all electronic devices, cables, batteries, and so on, at an appropriate facility to enable recovery and recycling. You can also recycle packaging and guides according to your local recycling regulations.

In the European Union, for assistance with the recycling of Capsule Technologies products, visit our customer site: https://customers.capsuletech.com/environment

Vitals Plus components

At the end of its service life, the products described in this manual, as well as their accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of the product, contact Capsule Technologies or its representatives.

Patient Applied Parts

Certain patient applied parts, listed here, are intended for single use, and should be disposed of properly as medical waste in accordance with regional body-controlled guidelines and hospital protocol:

- Temperature probes
- Single-use SpO2 sensors
- Single-use blood pressure cuffs
- Scanner sheaths
- Reposable caps

Other patient applied parts should be cleaned according to manufacturer instructions. Inspect reusable applied parts for wear, replace as necessary, and dispose of used product as medical waste in accordance with regional body-controlled guidelines and hospital protocol:

- Multi-patient reusable cuffs
- Reusable SpO2 sensors

Batteries

The sealed, rechargeable batteries contain lead and can be recycled. Discharge (deplete) batteries prior to disposal. Place the battery in packaging which electrically isolates its contents. Do not puncture or place the battery in a trash compactor. Do not incinerate the battery or expose it to fire or high temperatures. Dispose in accordance with regional body-controlled guidelines and hospital protocol.

Warning:	Improper disposal of batteries may create an explosion or contamination hazard. Always recycle batteries according to local regulations. Never dispose of batteries in refuse containers. Do not wrap them in metal or aluminum foil. Wrap them in newspaper before disposing of them. Do not burn them. Battery may explode if overheated.

Packaging Material

Retain original packaging materials for future use in shipping the system and its accessories. The recommendation includes corrugated shippers and inserts. Whenever possible, recycle the packaging of accessories and patient applied parts.

Standards and Regulations

Field	Standard or regulation
Medical device safety	IEC 60601-1 IEC 60601-1-2 IEC 80601-2-30 (NIBP) ISO 81060-2 (NIBP) ISO 80601-2-56 (Temperature) IEC 80601-2-61 (Pulse oximeter) IEC 60601-2-49 (Patient monitoring)

Field	Standard or regulation
	IEC 60601-1-8 (Alarms)
Medical device usability	IEC 60601-1-6 IEC 62366-1 IEC 62366
Medical device Software – Software Lifecycle Processes	IEC 62304
EMC/EMI	FCC 47 CFR Part 15 sub-part B ETSI EN 301 489-1 ETSI EN 31 489-3 ETSI EN 301 489-17 CAN ICES-003 B / NMB-003 B
Radio	SmartLinx Neuron 2 complies with • FCC 47 CFR Part 15 subparts C and E • ETSI EN 300 328 • ETSI EN 301 893 • RSS-210 • RSS-247
RF exposure	ANSI/IEEE C95.1 EN 62311 RSS-102

Legal Notice

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