Capsule Vitals Plus Regulatory Notice on Neuron 3

Introduction

Capsule 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 Document

This Notice contains regulatory information for the system and is therefore an extension of the *Capsule 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.

Terminology and Capsule Branding

Capsule Technologies is rebranding its products, for example, replacing the term **SmartLinx** with the name of the company, **Capsule**. However, many of our products, software and software services continue to operate using the term **SmartLinx**. Instead of trying to change everything all at once, the transition will be progressive, in a measured and controlled manner. In this document, for example, we have started the process by changing:

From	**To**
SmartLinx Medical Device Information System	Capsule Medical Device Information Platform
SmartLinx MDIS	Capsule MDIP
SmartLinx Vitals Plus	Capsule Vitals Plus
SmartLinx Neuron	Capsule Neuron

If you have any questions or concerns, contact your Capsule representative.

Certification Marks

c UL us	Recognized component		Separate collection for electrical and electronic waste (WEEE directive and Battery directive)
c S us	NTRL 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

Capsule 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: Vitals Plus systems that integrate any revision of the Capsule Neuron 3 are Class-B compliant.

Note: For operation within 5.15 ~ 5.25GHz / 5.47 ~5.725 GHz frequency range, Capsule 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: This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. Unauthorized changes or modifications could void the user's authority to operate the equipment.

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 be fixed to US-operation channels only.

RoHS and WEEE Compliance

Capsule 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, Capsule 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 Capsule 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.

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

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

- Single-use blood pressure cuffs
- Single-use SpO_2 sensors
- Temperature probes
- Scanner sheaths
- Reposable caps

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

- Sampling lines

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 SpO_2 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) ISO 80601-2-61 (Pulse oximeter) IEC 80601-2-49 (Patient monitoring) IEC 60601-1-8 (Alarms) IEC 60601-2-55 (Capnography)
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 IEC 60601-1-2
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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