capsule™

what it takes to connect.

Capsule Neuron 2 Hardware Installation and Maintenance Guide

DRAFT

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English

Contents

Introducing the Capsule Neuron 2 1

Overview

The Capsule Neuron 2 is Capsule's point-of-care hardware platform for device connectivity. It is a flexible and scalable platform that you can configure to operate in various care areas of the hospital. In high acuity environments, such as the ICU, the Capsule Neuron 2 typically runs Capsule's Status Application to enable continuous collection of vital signs for one patient from multiple devices. In low acuity, non-critical care settings (such as med-surg), the Capsule Neuron 2 typically runs Capsule's Mobile Vitals Plus Application to enable the automatic collection, validation, and transmission of vital signs from multiple patients to the EMR directly from the point of care.

Note: Do not operate the Capsule Neuron 2 until after you read and understand these instructions. Pay particular attention to all warnings and cautions.

Note: For information about the administration of DataCaptor software, IT personnel should refer to the *DataCaptor System Administrator's Guide*.

Note: To operate the Capsule Neuron 2, clinicians require training in the procedures described in the *Capsule Neuron Status Application Clinical User's Guide* and the *Capsule Neuron Mobile Vitals Plus Application Clinical User's Guide*.

Note: To operate any medical device that connects to the Capsule Neuron, clinicians must be separately trained in the use of that device.

Intended Use

The intended use of the DataCaptor™ system is for data collection and clinical information management, either directly or through networks with independent bedside devices.

Capsule's hardware and software are not intended for monitoring purposes, nor is the software intended to control any of the clinical devices (independent bedside devices/information systems) to which it is connected. There is no other known contraindication for the use of the Capsule Neuron 2 system.

Caution: Do not modify the Capsule Neuron 2, cables, or any part of the DataCaptor Connectivity software, or mount the device in any way other than instructed in Capsule documents. Any modification to the hardware or software can prevent proper functioning and cause damage to the connected medical device.

About this document

Product

The product described in this document is the "Capsule Neuron 2" (part number: DC-NU2-UMPC). For brevity and clarity, that product is referred to in the rest of this document as the "Capsule Neuron". This means that all references to "Capsule Neuron" in this document shall be understood as applying to part number DC-NU2-UMPC.

Purpose

This document provides:

- instructions for installing, mounting, and connecting the Capsule Neuron hardware
- instructions for maintaining, cleaning, and storing the device and its accessories
- details of technical characteristics and regulatory compliance of the device

Audience

The target audiences for this document are:

Audience	Description
Biomedical staff	The biomedical staff ensures that the medical equipment is safe, functional, and properly configured for the clinical environment. They install, inspect, and maintain biomedical devices and support systems to adhere to medical standard guidelines.
Clinicians	Clinicians are health care providers who interact with patients in a medical environment, such as a registered nurse, nurse technician, respiratory therapist, or anesthesiologist.

Notes, cautions, warnings

Where necessary, Capsule documents highlight any applicable warnings, cautions, and notes to avoid risk of injury to individuals or damage to equipment. There are three levels of information:

Warning:	Indicates a hazard with a medium level of risk which, if not avoided, could result in death or serious injury.

Caution:	Indicates a hazard with a low level of risk which, if not avoided, could result in minor or moderate injury or severe damage or malfunctioning of the equipment.

Note:	Directions to clarify specific information to assist the user, and to avoid the risk of damage to the equipment described in this guide and/or any other equipment or goods, and/or cause environmental pollution.

Related documents

Capsule provides the following additional documents for use with the Capsule Neuron.

Document	Description	Audience
DataCaptor System Administrator's Guide (English only)	provides information on deployment scenarios and instructions on how to install, upgrade, and configure the DataCaptor software solution, including troubleshooting tips. Available from the: • **Help** menu of the Web Administration Console • Capsule Customer Portal	Hospital IT staff
Capsule Neuron Status Application Clinical User's Guide	provides information on how to use the Status application, along with troubleshooting advice and hardware cleaning instructions. Available from the: • **Help** menu of the Web Administration Console • Capsule Customer Portal • icon in the application	Clinicians
Capsule Neuron Mobile Vitals Plus Application Clinical User's Guide	provides information on how to use the MVP application, along with troubleshooting advice and hardware cleaning instructions. Available from the: • **Help** menu of the Web Administration Console • Capsule Customer Portal • icon in the application	Clinicians

Manufacturer's information

Capsule Tech, Inc.

300 Brickstone Square, Suite 203
Andover, MA 01810 USA
Phone: 1-978-482-2300
Toll Free: 1-800-260-9537

Capsule Technologie
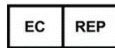
9 Villa Pierre Ginier
75018, Paris France
Phone: (+33) 1 5334 1400

Getting additional information

For more information, or to order additional products (Capsule Neurons, or accessories including batteries, power cables, printed copies of documents), contact your reseller or Capsule directly:

USA	EMEA & APAC
Capsule Tech, Inc. 300 Brickstone Square, Suite 203 Andover, MA 01810 USA Phone: 1-978-482-2300 Toll Free: 1-800-260-9537	**Capsule Technologie** 9 Villa Pierre Ginier 75018, Paris France Phone: (+33) 1 5334 1400
US Technical Support Phone: 1-800-260-9537 E-mail: support@capsuletech.com	**EMEA & APAC Technical Support** Phone: (+33) 1 5334 1400 E-mail: emea.support@capsuletech.com

Table of abbreviations

The table provides an alphabetical list of the main abbreviations used in this document.

Abbreviation	Meaning
AC	Alternating Current
CE	*Conformité Européenne* (= *European Conformity*)
CISPR	*Comité International Spécial des Perturbations Radioélectriques* (= *Special international committee on radio interference*)
DIM	Device ID Module
DTS	DataCaptor Terminal Server
EN/IEC	European Norm / International Electrotechnical Commission
FCC	Federal Communications Commission
GB	Gigabyte
LAN	Local Area Network
LED	Light Emitting Diode
MVP	Mobile Vitals Plus
RoHS	Restriction of the use of Hazardous Substances
VAC	Voltage in Alternating Current
WEEE	Waste Electrical and Electronic Equipment Directive
WLAN	Wireless Local Area Network
WPA	Wireless Protected Access

Setting up the Capsule Neuron

2

What's in this chapter

Follow the instructions in this chapter to setup the Capsule Neuron. Deployment follows these steps, in this order:

- **Unpacking and inspecting the package contents**
- **Installing the batteries in the Capsule Neuron**
- **Deploying the Capsule Neuron**
  - **Mounting the Capsule Neuron on the wall**
  - **Mounting the Capsule Neuron on a roll stand**
- **Connecting the Capsule Neuron to the power supply**
- **Before you use the Capsule Neuron for the first time**

Note: This document does not describe the configuration of the Capsule Neuron on a local network. Refer to the *DataCaptor System Administrator's Guide*.

Unpacking and inspecting the package contents

Before you install the Capsule Neuron in a clinical setting, you must inspect and set it up according to instructions.

Contents of a product shipment

The table describes the contents of a Capsule Neuron shipment.

Item	Shipment characteristics
Capsule Neuron	In one carton, you find the Capsule Neuron itself, wrapped in plastic and sandwiched between two blocks of polyethylene foam. Each Capsule Neuron is shipped along with: • Main battery The main battery is in position inside the Capsule Neuron, but the battery pins are not yet in contact with the battery socket on the Capsule Neuron, and the battery is not yet fixed in place. • Power brick The power brick is shipped wrapped in plastic. • Screws and washers Four M4 Phillips-head screws and their associated washers are shipped in a plastic bag with the Capsule Neuron. These screws are available for attaching the Capsule Neuron to a mounting bracket, depending on the deployment selected.

Item	Shipment characteristics
Power Cable	The electrical cable that is used to connect the Capsule Neuron power brick to the electrical mains outlet is shipped in a separate carton from the Capsule Neuron. This cable is always adapted to local requirements.
Extended battery (optional)	If ordered, extended batteries are shipped in a separate carton, where possible, the same carton as for the cables. Each extended battery is packed in its own unit box.
This document	Printed copies of this *Capsule Neuron 2 Hardware Installation and Maintenance Guide* are shipped separately, in the same carton as the cables, where possible. The number of copies depends on the number of Capsule Neurons in the shipment.
Additional elements	Depending on the contents of your order, other connectivity elements such as serial cables, patch cables, and DIMs, could be present in the shipment. If yes, these are typically shipped in the same carton as for the cables.

Unpacking the cartons

Note: If the carton is broken, open, or damaged in any way, do not accept the shipment.

1. Turn the carton so that the arrow on the package is pointing up.
2. Cut the tape on the carton.

Caution: Be careful to cut only the tape and not, for example, the Capsule Neuron.

3. Take each item out of the carton.
4. Check all items against the packing list, and against the list in **Contents of a product shipment** above.
5. Remove the packing material and examine each item for any signs of shipping damage.
6. Save all packing materials, the invoice and the bill of lading. You will require them if you need to process a claim with the carrier.

Hardware installation prerequisites

You need the following tools (not included) to install the Capsule Neuron:

- a cruciform-tip screwdriver
- a Phillips-head PH0 screwdriver

In addition, depending on how you intend to mount the Capsule Neuron, you could require certain hardware:

- If you select to deploy the Capsule Neuron on a roll stand, you must source a roll stand pole extension with VESA 75 or VESA 100 interface suitable for the model of your roll stand. Contact your roll stand manufacturer for options.

- If you select to deploy the Capsule Neuron on a wall-mount, then you require a mounting solution that is VESA 75/100-compatible.

Installing the batteries in the Capsule Neuron

Installing the main battery in the Capsule Neuron

The Capsule Neuron is shipped with the main battery in position but not yet fixed in place.

1. Push the main battery towards its connection port.
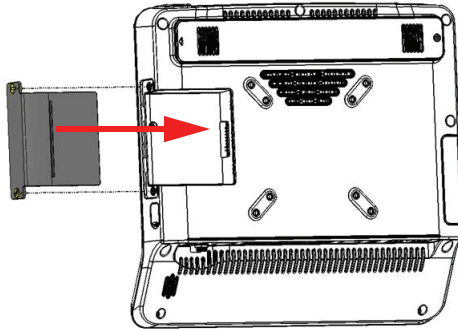
2. Use a screwdriver or other tool to screw in the two screws that hold the main battery in place.
3. Tighten the screws until the battery is connected to its pins. Do not overtighten.
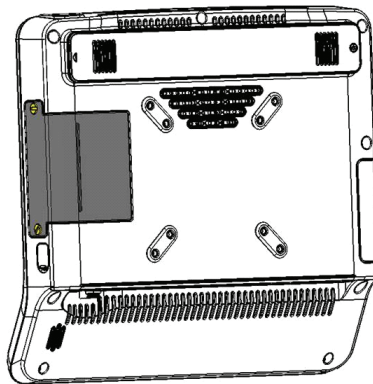
Installing the optional extended battery in the Capsule Neuron

1. Turn the Capsule Neuron so that the screen is facing away from you.
2. Use a screwdriver to unscrew the screw that holds the extended battery faceplate in position.
3. Push the loose faceplate to the left, then lift the faceplate away from the Capsule Neuron.
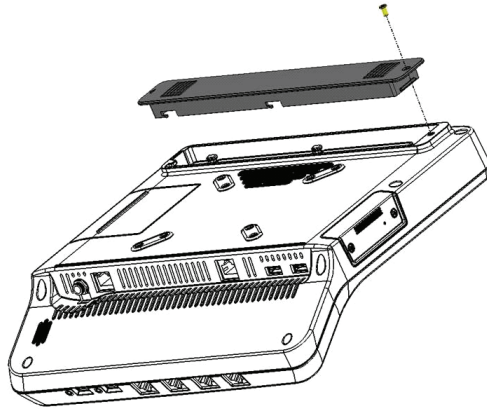
4. Position the extended battery at the same point where you lifted the faceplate. Because of the arrangement of the pins, you cannot position the extended battery incorrectly.
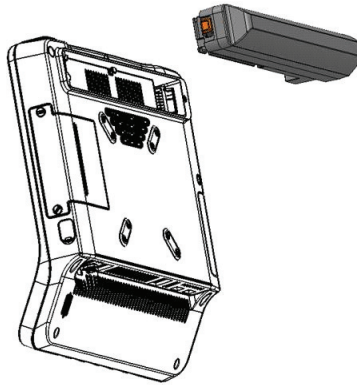
5. Slide the extended battery to the right. Continue sliding until the left side of the extended battery is flush with the left side of the extended battery slot.
6. Push the locking button on the extended battery to the down position.
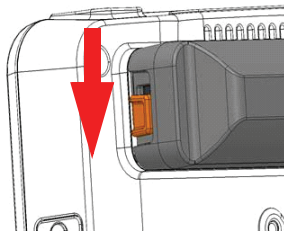
Deploying the Capsule Neuron

In typical deployments of the Capsule Neuron, you can mount it on the wall, or mount it on a roll stand or other mobile configuration.

Note: For compliance with EN/IEC 60601-1, the Capsule Neuron is not classified as a portable device. Instead, the Capsule Neuron must be deployed as one of:
- Mobile device
- Fixed device

Precautions for all deployments

Caution:
- Do not place the Capsule Neuron inside furniture or inside any enclosed space. This could prevent correct cooling of the device and interfere with radio communications.
- Operate the Capsule Neuron only within these environmental conditions:
  - Temperature: +10°C to +40°C (+32°F to °+104°F)
  - Atmospheric pressure: Atmospheric pressure: 700 hPa to 1060 hPa
  - Altitude: -100 meters to +2000 meters (-328 feet to +6560 feet)
  - Humidity: 10% to 95% RH non-condensing
- Do not stack the Capsule Neuron or place it next to other equipment. If you do, then check it for normal operation running its usual configuration.
- In semi-private rooms, connectors must be placed or labeled so that they clearly indicate the bed for which they collect data.

Considerations for wall-mounted deployments

When you are deciding where to place the Capsule Neuron at the point of care, Capsule recommends that you take account of the following considerations.

- Mount the Capsule Neuron near the head of the bed or on the head wall in the patient room.
- To allow clinicians easy access to the Capsule Neuron touch screen, mount the Capsule Neuron no more than 1.5 meters (5 feet) or less than 1 meter (3 feet, 3 inches) from the ground.
- If there are medical devices connected to the ports on the Capsule Neuron, position the Capsule Neuron on the same side of the bed as those devices.
- Make sure that you take account of the length of the cables required to connect the Capsule Neuron and the medical devices.
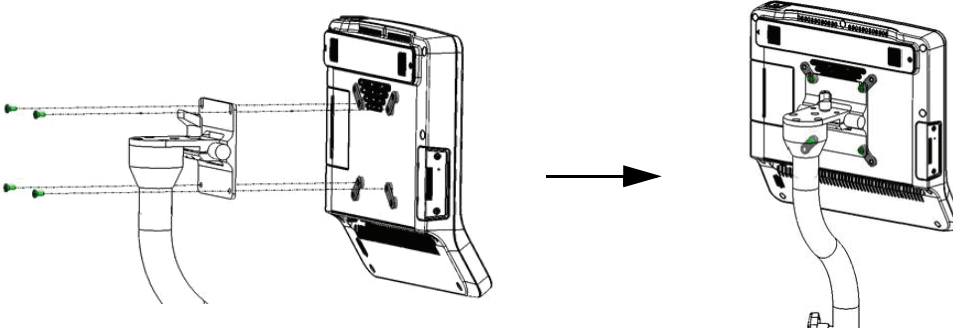
Mounting the Capsule Neuron on the wall

Caution: For Capsule Neurons that are installed above the patient, take adequate precautions to prevent them from falling on the patient.

Attach the Capsule Neuron to your selected VESA 75/100 wall-mounted solution. Refer to the instructions from the solution manufacturer.

Mounting the Capsule Neuron on a roll stand

1. Mount the Capsule Neuron to the roll stand. Refer to the manufacturer's instructions for the roll stand as required.

2. To fix the device to the mounting bracket, use the four screws and washers that are delivered with your Capsule Neuron, or the screws delivered with your roll stand pole extension.

Connecting the Capsule Neuron to the power supply

Once deployed, on a wall or roll stand for example, you can connect the Capsule Neuron to the power supply.

Power requirements

The Capsule Neuron is designed to use the IEC 60601-1-compliant, external DC power supply and power cables that are provided with the Capsule Neuron. For precise information, refer to the *Technical Information* in chapter 5 of this document.

Cautions:

- Always use the hospital-grade, AC power cable delivered with the product to connect the Capsule Neuron to an AC power source. Do not, under any circumstances, use any other cable than the one provided, even to provide extra cable length. The use of any other cable can result in increased emissions or decreased immunity of the device with regards to electromagnetic interference.
- Do not connect the Capsule Neuron to an AC outlet that is controlled with a switch or dimmer.
- Do not, under any circumstances, remove the grounding conductor from the power plug.
- Do not use extension cords or adapters of any type.
- The power cable, supply, and plug must remain intact and undamaged.
- The power plug must remain accessible to unplug the device from the power supply mains if necessary.

Connecting the Capsule Neuron to the power supply

1. The power brick that was shipped with your Capsule Neuron has a power cable on one end, and an open plug on the other end. Plug that power cable into the Capsule Neuron at the DC-in power connector (as illustrated).

2. Tighten the locking mechanism on the DC-in power connector to lock the power plug in place.

3. Plug the power cable that was shipped with your Capsule Neuron into the open plug on the power brick.

4. Plug the other end of that power cable into a grounded electrical outlet (generally 3-prongs). The Capsule Neuron switches on automatically.
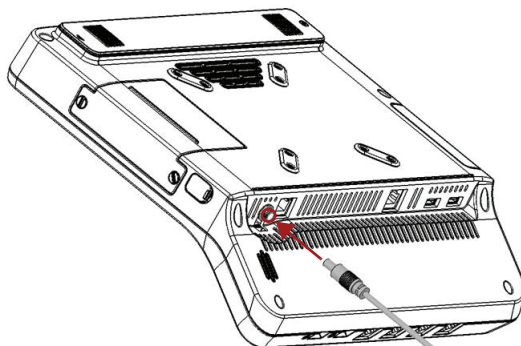
Caution: For safety, cables are designed to prevent inadvertent disconnection if someone accidentally pulls on them. However, make sure that you route cables so that they do not present a tripping hazard.

Warning: You must only connect the Capsule Neuron's power brick to an appropriate power source. To avoid risk of electric shock, use a grounded (3-prong) electrical power outlet.

Before you use the Capsule Neuron for the first time

For all deployments, before you use the Capsule Neuron for the first time, you must completely charge its battery.

1. Set up the Capsule Neuron as described in this chapter:
   - install the main battery
   - install the extended battery, if you use one
   - connect the Capsule Neuron to the electrical mains

2. The battery/ies start to charge as soon as you plug the Capsule Neuron into the electrical mains. Allow the main battery to charge for about two hours.
   If you have installed both the main battery and the optional extended battery, allow the two batteries to charge for about six hours.

For a fuller description of the batteries, and the charging / discharging process, refer to "Working with the batteries" on page 21.

Operating the Capsule Neuron

3

Components on the Capsule Neuron

Legends on the drawings

In the legend for the drawings that follow:

- Individual components keep the same numbers on each drawing. For example, the USB ports on the bottom of the Capsule Neuron are shown with the number ⑥. When you see the number ⑥, you know that it represents only these ports.

- Colors have meaning. A blue ● circle indicates a medical-grade connector. A yellow ● circle indicates network connection (Ethernet). All other components are indicated with red ● circles.

View from the front
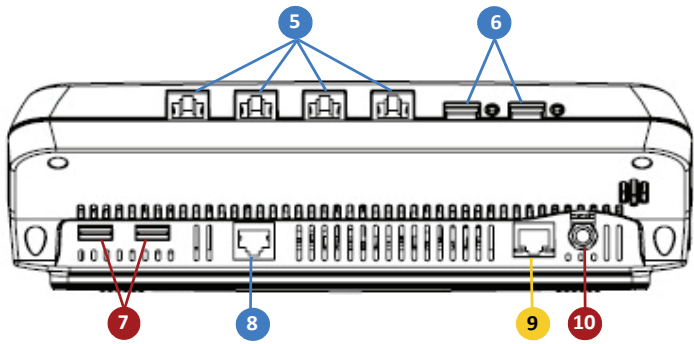
1. Light sensor
2. Touch screen
3. Status LED
4. RFID badging area
5. Serial ports
6. USB ports

View from the bottom

5	Serial ports (4) - front-accessible
6	USB ports (2) - front-accessible
7	USB ports (2) - rear-accessible
8	Serial port (1) - rear-accessible
9	Ethernet connection
10	DC power-in connector

3/4 view from the back
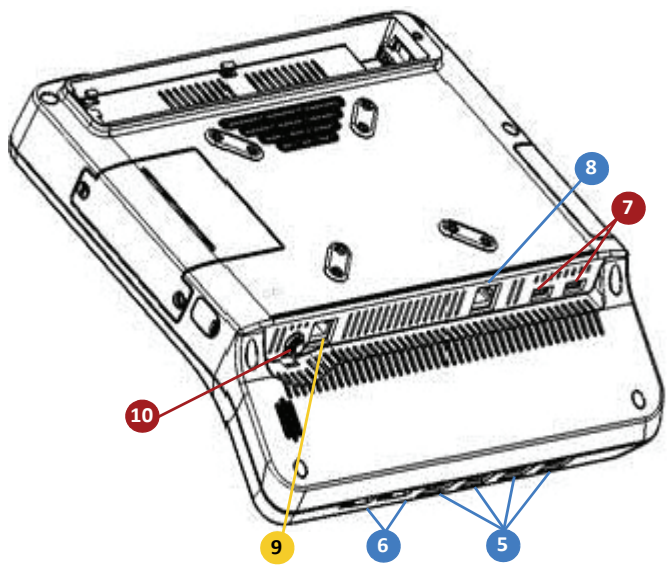
5	Serial ports (4) - front-accessible
6	USB ports (2) - front-accessible
7	USB ports (2) - rear-accessible
8	Serial port (1) - rear-accessible
9	Ethernet connection
10	DC power-in connector

View from the back
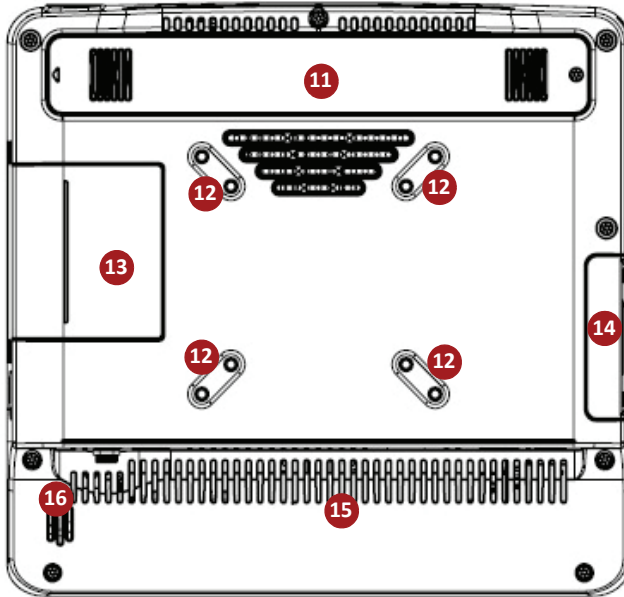
11	Extended battery emplacement
12	Mounting plate screwholes (VESA 75/100 configuration)
13	Main battery
14	Covered USB port
15	Aeration vents
16	Speaker

Views from the side
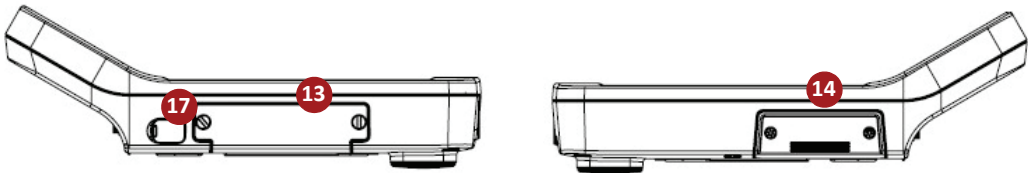
13	Main battery
14	Covered USB port
17	Anti-theft slot

Connectivity

The ports on the Capsule Neuron are used to connect medical or other devices. A blue line on these ports indicates a medical-grade connection port. A yellow line indicates the Ethernet connection port. The tables describe the ports.

Serial Ports

Location	Characteristics	Number	Purpose
Front	Galvanic isolated RS-232 with RJ45 connector	4	Used to connect medical devices with serial interfaces
Rear	Galvanic isolated RS-232 with RJ50 connector	1	Used to connect medical devices with serial interfaces

USB Ports

Location	Characteristics	Number	Purpose
Front	Galvanic isolated, Type A USB 2.0 full-speed	2	Used to connect medical devices with USB interfaces
Rear	Galvanic non-isolated, Type A USB 2.0 high-speed	2	Used to connect external USB, non-medical devices such as barcode scanners
Side (left)	Galvanic non-isolated, Type A USB 2.0 high-speed	1	Additional USB, non-medical device connection

Ethernet Port

Location	Characteristics	Number	Purpose
Back	RJ45 connector	1	Used to connect to the hospital-internal, wired network (Ethernet)

Powering on the Capsule Neuron

For information on connecting the Capsule Neuron to the power supply, refer to "Connecting the Capsule Neuron to the power supply" on page 14.

Power on the Capsule Neuron

The Capsule Neuron switches on automatically when you plug it into any power source.

For manual operation, press the Power On/Off button, shown at position (A) on this illustration of the top view of a Capsule Neuron:

A   **Power On/Off button**
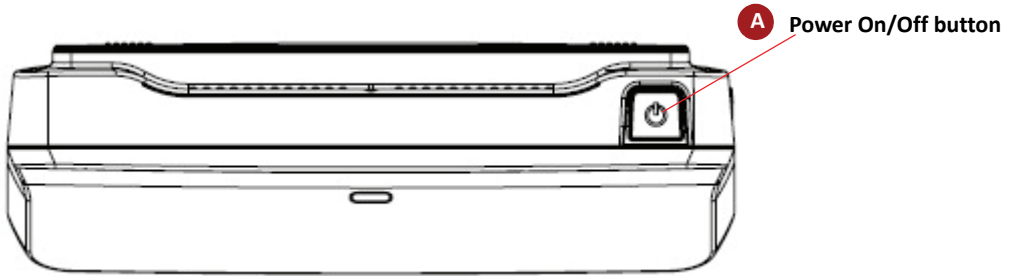
Power Off the Capsule Neuron

To power off the Capsule Neuron, press the On/Off button again.

If the Capsule Neuron does not shut down properly for any reason, you can do a hard shutdown. Press and hold the power button for four seconds.

Working with the Capsule Neuron touch screen

The Capsule Neuron screen is a 10.1-inch (25.6-centimeter) touch screen. It is antiglare treated, and readable from multiple angles.

Screen brightness adjusts automatically to the level of ambient light, dimming or brightening in parallel with the current level of luminosity in the room. If the screen goes completely dark, the Capsule Neuron is said to be in 'sleep' mode, and you can wake it up by touching the screen.

Reading the status LED

The Capsule Neuron provides a single LED, located on the front of the device below the screen.

LED	Capsule Neuron Status
Off	Capsule Neuron is not running.
Blue - Blinking	Capsule Neuron is booting.
Blue	Capsule Neuron has finished booting, and is EMR-connected.
Red	Capsule Neuron has finished booting, and is **not** EMR-connected.

Working with the batteries

For instructions on installing the main battery, and the optional extended battery, refer to "Installing the batteries in the Capsule Neuron" on page 11.

Note: Before you use each Capsule Neuron for the first time, you must fully charge its battery/ies, as described in "Before you use the Capsule Neuron for the first time" on page 15.

Battery Lifetime Terminology

When describing the Capsule Neuron, the following terms are used:

- **Battery autonomy** refers to the amount of time that the Capsule Neuron can remain fully functional in case of a disconnect from the electrical mains.
- **Battery life span** refers to the total time that the battery lasts before you must replace it.

Battery Summary

Characteristic	Main Battery	Extended Battery
Autonomy	**150 minutes** (2 hours 30 minutes) of functional operation when unplugged from AC mains, with a new, fully-charged battery	**240 minutes** (4 hours) of functional operation when unplugged from AC mains, with a new, fully-charged battery When used together, the two batteries together provide about **360** minutes (6 hours) of autonomy.
Charging time	**120 minutes** (2 hours)	**240 minutes** (4 hours) for the extended battery alone **360 minutes** (6 hours) to charge both batteries
Charging	First charged / Last discharged	Last charged / First discharged
Life span	After 500 complete charging cycles, remaining capacity is about 80%. Alternatively, after 12 months of continuous use, remaining capacity is about 50%.	After 500 complete charging cycles, remaining capacity is about 80%. Alternatively, after 12 months of continuous use, remaining capacity is about 50%.
Shelf-life	3 months	3 months
Replaceability	By biomed user - requires no tools other than a screwdriver	By clinical user - requires no tools other than a screwdriver

Charging the batteries

To charge the batteries, plug the cable from the Capsule Neuron power brick into the AC power mains (wall socket).

To monitor the batteries during the charging process, check the battery information displayed on the screen, and described in the Capsule document, *Clinical User's Guide* for the *Mobile Vitals Plus* application.

Removing a battery

Caution: Before you remove a battery, make sure that the Capsule Neuron is receiving power, either from the electrical mains, or from at least one charged battery that is installed in the Capsule Neuron.

Removing the main battery

Refer to the illustrations for **Installing the main battery in the Capsule Neuron** on page 11.

1. Use a screwdriver or similar tool to unscrew the two screws that hold the battery in place.
2. Pull the battery gently away from the Capsule Neuron to disconnect the battery from the pins.
3. Remove the battery.

Removing the extended battery

Refer to the illustrations for **Installing the optional extended battery in the Capsule Neuron** on page 11.

1. To release the extended battery, push the locking button to the up position.
2. Slide the extended battery to the left.
3. Lift the battery out and away.
4. If desired, and if you have retained the faceplate, you can replace the faceplate on the empty battery slot. Use a screwdriver and the screw that you removed when you installed the extended battery.

Swapping a battery

To swap a charged battery in place of a discharged battery, or to swap a new replacement battery for a depleted battery:

1. Make sure that the Capsule Neuron is plugged into the electrical mains outlet.
   Alternatively, if you are working with both the main battery and an extended battery, make sure that the battery that you are not replacing is charged and continues to supply power to the Capsule Neuron at all times.
2. Remove the battery, as described above under **Removing a battery**.
3. Install the new battery, as described in "Installing the batteries in the Capsule Neuron" on page 11.

Connecting the Capsule Neuron to the network

Connecting to a wired network

1. Plug one end of the LAN cable into the Ethernet connector, located on the rear panel of the Capsule Neuron, and marked with a yellow line. In the illustrations, on page 17 for example, this connector is labeled 9 .
2. Plug the other end of the same cable into the network socket (typically on the wall).

Connecting to a wireless network

No special procedures are required on the Capsule Neuron for wireless connection. However, each Capsule Neuron must be configured in the Web Administration Console to use the wireless network. Refer to the "DataCaptor System Administrator's Guide" for more.

Checking the wired connection

On the Ethernet jack, there are two small LEDs. When you plug in the Ethernet connection cable, you can check the connection through the behavior of these LEDs:

LEDs	State	Meaning
Link/Act	Off	The Capsule Neuron is not connected to the LAN
	Blinking	Network activity
	On	Link is active
10/100/1000	Off	Connected to the LAN at 10 MB speed, or Not connected
	Green	Connected at 100 MB speed
	Orange	Connected at 1000 MB speed

Checking the wireless connection

You cannot check the wireless connection using Capsule Neuron hardware components. You must use the network connection information displayed on the screen, and described in the *Clinical User's Guide* for the *Mobile Vitals Plus* application or the *Status* application.

Connecting a vital signs monitor to the Capsule Neuron

Before you connect

Before you connect a vital signs monitor to the Capsule Neuron, you must program its Capsule Device ID Module (DIM). A Capsule DIM is required for all devices connected to the Capsule Neuron. For information on how to program a Capsule DIM, refer to the "DataCaptor System Administrator's Guide". The Device ID Module (DIM) supports plug-and-play connectivity. Its automatic device identification feature allows users to connect and re-connect any biomedical device to the Capsule Neuron with ease. The separate DIM attached to each device through a cable assembly allows the Capsule Neuron to:

- automatically identify the attached device

- initialize the appropriate DataCaptor Device Interface (DDI)
- detect when the device is disconnected and re-connected

Caution: If you use unapproved cables to connect medical devices to the Capsule Neuron, you could cause damage to or malfunctioning of the medical device.

Connecting the cables

1. Attach the device cable from the device to the DIM (Device ID Module).
2. Attach the DIM patch cable to the RJ45-end of the DIM.

Device cable	DIM	DIM patch cable

Connecting the devices

1. Attach the RJ45-end of the cable assembly into one of the ports of the Capsule Neuron. Refer to the description of "Connectivity" on page 18 for the set of available ports.
2. Connect the other end of the cable assembly to the back of the vital signs monitor.
3. Tighten the thumb screws and secure the assembly behind the monitor.

For more on using the Capsule Neuron with the vital signs monitor

This manual does not describe the use of the Capsule Neuron with vital signs monitors. Instead, refer to the following documents:

Subject	Where to look
How to configure Capsule Neuron	*DataCaptor System Administrator's Guide*
How to operate Capsule Neuron	*Capsule Neuron Status Application Clinical User's Guide*
	Capsule Neuron Mobile Vitals Plus Application Clinical User's Guide

Maintaining the Capsule Neuron

4

Capsule recommends that you carry out regular maintenance activities as described in this guide to ensure correct operation of the device.

Periodic cleaning and disinfection

Caution: When cleaning or disinfecting the Capsule Neuron, batteries, and cables, you must power off the device first. However, you can use standard computer screen solution to wipe down the Capsule Neuron touch screen (for example, to remove fingerprints) during normal operation, while it is powered on.

Periodically clean and disinfect the elements in the Capsule Neuron, including cables and batteries, by wiping the outer case with a lint-free cloth, lightly moistened with warm water and a mild, non-abrasive cleaning solution containing any of the compatible cleaning agents below (follow the manufacturer's guidelines):

- 70% isopropyl alcohol

- CaviCide®

- Clorox Healthcare™ Bleach Germicidal Cleaner

- ANIOSURF Premium, Bacteranios SF, SURFA'SAFE, WIP'ANIOS

- 10% bleach solution

- Clorox® Disinfecting Wipes

- Sani-Cloth®, Sani-Cloth® Plus, Super Sani-Cloth®, Sani-Cloth® HB, Sani-Cloth® Bleach Wipe

Cleaning Precautions

Caution:
- To avoid damage to the Capsule Neuron, try to limit contamination and minimize the need for disinfectants.
- Since the Capsule Neuron is not completely watertight:
    - Do not spray cleaning liquid or foam on the Capsule Neuron, or submerge or soak it for cleaning.
    - Never spray or squirt any type of liquid directly on the Capsule Neuron; spray the liquid, gel, or foam on a cloth and then use that cloth to rub on the device.
    - Do not spill liquids on or around the unit.
    - Do not expose the power cable or power brick to liquid.
    - Make sure that the cover on the USB port is securely fastened.
- Do not use any other agent than those listed. (Contact Capsule for assistance if your cleaning agent is not on the list.)
- Do not use harsh solvents.
- Do not clean, disinfect, or sterilize any part of the system by autoclaving or with the use of ethylene oxide gas (gas sterilization).
- Do not touch, press, or rub the display panel with abrasive cleaning compounds, instruments, brushes or rough-surface materials.

Periodic maintenance of the Capsule Neuron

Authorized Access

Certain components on the Capsule Neuron are only accessible to Capsule technical support personnel. These elements are held in place using special screws referred to as "hexalobular internal".

However, other components on the Capsule Neuron, such as the main battery, can be removed by biomed staff, for purposes of maintenance or cleaning, for example. These elements are held in place using Philips screws.

Inspections

Caution: Power off the Capsule Neuron before you inspect the power cable and power brick.

Once per year, carry out an inspection of:

• the power cable
• the power brick

Look for any visible or other damage, overheating, or corrosion. A damaged power cable or power brick can affect the operation of the Capsule Neuron. Replace damaged components with new components.

Storing the Capsule Neuron

If the Capsule Neuron is not in use, make sure that you respect its storage conditions:

• Temperature: -20°C to +60°C (-4°F to +140°F)
• Humidity: 0% to 95% RH non-condensing
• Atmospheric pressure: 500 hPa to 1060 hPa

Maintenance of the Capsule Neuron batteries

Cleaning

When cleaning the Capsule Neuron batteries, apply the cleaning procedures and precautions described above under **"Periodic cleaning and disinfection"**.

Short-term maintenance

For daily usage purposes, it is recommended that you keep the batteries in charge mode; that is, keep the batteries installed in the Capsule Neuron, and keep the Capsule Neuron connected to the electrical mains.

Long-term storage and maintenance

Shelf life of the batteries

Both the main and the extended batteries for Capsule Neuron have a shelf life of **three months**. This limit applies to batteries that are not in use (that is, if they are not either in the process of charging, or being used to supply power to the Capsule Neuron).

If the battery fully discharges, during storage for example, then you must replace it.

Storing the batteries

If the Capsule Neuron is not in use for an extended period of time, we recommend that you:

1. Charge the battery completely.
2. Remove the fully charged battery from the Capsule Neuron (refer to "Removing a battery" on page 22).
3. To maximize the battery life span, make sure that you store the battery within the recommended parameters:
   - Temperature: -20°C to +60°C (-4°F to +140°F)
   - Humidity: 0% to 95% RH non-condensing
   - Atmospheric pressure: 500 hPa to 1060 hPa
4. Store the battery and the Capsule Neuron separately.

Technical Information

<div style="text-align: right">**5**</div>

Guidance and manufacturer's declaration

Electromagnetic Effects

The Capsule Neuron radiates and consumes radio frequency energy. It has been designed and evaluated to comply with the emission and immunity requirements of EN/IEC 60601-1-2, but electromagnetic interference may occur if not installed correctly and used in accordance with the instructions in this manual. Refer to the Tables in this chapter for detailed information regarding declaration and guidance related to emission, immunity, and separation distances.

> **Caution:**
> - Portable and mobile radio frequency devices, such as mobile phones, can impact the correct functioning of this device and should not be used in close proximity of this device.
> - Use of accessories, power adapters and cables other than those specified may result in increased emission and/or decreased immunity of the Capsule Neuron.

Electromagnetic Emissions

The Capsule Neuron is intended for use in the electromagnetic environment specified below. The customer or the user of the Capsule Neuron should make sure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Capsule Neuron uses RF energy only for its internal function; its RF emissions are therefore very low and are not likely to cause any interference to nearby electronic equipment
RF emissions CISPR 11	Class A	**Class A**: The Capsule Neuron is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Note: U_T is the AC mains voltage prior to application of the test level.

Electromagnetic Immunity (ESD, EFT, Surge, Dips and Magnetic Field)

The Capsule Neuron is intended for use in the electromagnetic environment specified below. The

customer or the user of the Capsule Neuron should ensure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±8 kV air	±8 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for input/output Lines	±1 kV for input/output Lines	
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV line(s) to earth	±2 kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	>95% voltage dips in U_T for 0.5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Capsule Neuron requires continued operation during power mains interruptions, it is recommended that the Capsule Neuron be powered from an uninterruptible power supply.
	40% U_T (60% dip in U_T) for 5 cycles	60% voltage dips in U_T for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	30% voltage dips in U_T for 25 cycles	
	<5% U_T (>95% dip in UT) for 5 sec	>95% voltage interruption in U_T for 5 seconds	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.

Electromagnetic Immunity (RF Conducted and Radiated)

The Capsule Neuron is intended for use in the electromagnetic environment specified in the table. The customer or the user of the Capsule Neuron should make sure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Capsule Neuron, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $$d = 1.17\sqrt{P}$$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with this symbol:

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Capsule Neuron is used exceeds the applicable RF compliance level above, the Capsule Neuron should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Capsule Neuron 2.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Capsule Neuron

The Capsule Neuron is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Capsule Neuron can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Capsule Neuron as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance in meters according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Capsule Neuron technical specifications

| Capsule Neuron Part Number: DC-NU2-UMPC	
Dimensions	Width: 265 mm (10.4 inches) Height: 210 mm (8.3 inches) Depth: 45 mm (1.8 inches)
Weight	2.3 kg (3.5 kg with batteries)
Mounting options	VESA 75/100 standard mounting bracket
Electrical ratings	20 V DC, 3.53 A
External power supply	100-240 V AC, 1.22-0.68 A, 47-63 Hz, 60 W max
Battery	Main: Lithium-Ion Battery Pack 3S1P 2600 mA Extended: Lithium-Ion Battery Pack 3S2P 5200 mA
Operation conditions	Continuous
Protection against ingress of water	IPX2
EN60601-1 Classification	No classification, no applied parts
Display size	10.1 inch (25.6 centimeter), resistive touch screen, resolution 1024x600
Display brightness	375 cd/m²
Contrast	400:1
Memory	1 GB
Storage	16 GB SSD
Network connectivity	10/100/1000 base-T LAN WLAN IEEE 802.11 a/b/g/n
WLAN security	WPA & WPA2 personal, WPA & WPA2 enterprise Encryption: TKIP, AES
Wireless range	10-20 meters, depending on Wi-Fi network configuration
Cooling	Passive cooling system (fanless)
Operating environment	• Temperature: 0°C to +40°C (+32°F to +104°F) • Humidity: 10% to 95% RH non-condensing • Atmospheric pressure: 700 hPa to 1060 hPa
Transport and storage environment	• Temperature: -20°C to +60°C (-4°F to +140°F) • Humidity: 0% to 95% RH non-condensing • Atmospheric pressure: 500 hPa to 1060 hPa

Device Identification Module (DIM) technical specifications

DIMs do not require an external power supply and use standard DB9 and RJ45 connections. The Device ID Module is a medical grade product compliant with IEC 60601-1 requirements.

Device ID Module P/N B1-DIM-CT-01	
Features	• Provides Automatic Device Identification • DB9 Serial Port Input • RJ45 Serial Port Output • Powered from the Capsule Neuron, Terminal Server, or DTS and RTS lines
Dimensions	• Length: 69 mm (2.7 inches) • Width: 38 mm (1.5 inches) • Height: 22 mm (0.9 inches) • Weight: 50 grams (1.76 ounces)
Power requirements	• +/- 6V output voltage • 3 to 8 milliamp power consumption
Temperature	• Operating: 0° C - 55° C (32° F to 130° F) • Storage: -30° C to +85° C (-22° F to +185° F)
Relative humidity	• Operating: 0 to 99% non-condensing • Storage: 0 to 99% non-condensing
Atmospheric pressure	• Operating: 700 hPa to 1060 hPa • Storage: 500 hPa to 1060 hPa
Certifications	• EN60601-1, EN60601-1-2 • CE Marking, RoHS-compliant

Regulatory Information

Explanation of Device and Packaging Symbols

Symbol	Description
	Read the operating instructions before using the medical device.
LOT	Lot number
QTY	Quantity
REF	Product part number
SN	Product serial number
REV	Product revision
GW	Gross weight
NW	Net weight
	Temperature limitation for transport and storage
	Air pressure limitation for transport and storage
2017-06	Shelf-life of Capsule Neuron's battery (with date three months after manufacture)
	Manufactured date
	Manufactured for
	Do not use if package is damaged

Symbol	Description
	Fire hazard
	Relative humidity (non-condensing) for transport and storage
ETH	Ethernet MAC address
	Ethernet
WiFi	Wi-Fi MAC address
	Caution: consult accompanying documents before using
	Power symbol
	Non-ionizing radiation
FC	Compliance with FCC Regulations
CE	Compliance with European directives
Rx Only	Caution: United States Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner
	Separate collection for electrical and electronic waste (WEEE directive and Battery directive)
	Direct current (DC)
	USB connection
IOIOI	Serial connection

Symbol	Description
EC REP	Address of the legal representative for the European market

Safety and Regulatory Compliance

English

EN/IEC

Capsule Neuron complies with EN/IEC 60601-1 and EN/IEC 60601-1-2.

- Data Integrity: Capsule Neuron does not compromise the data coming from the medical device. This does not include data not being delivered or delays in data delivery.
- Medical Device Integrity: Capsule Neuron does not compromise the operation of the connected medical devices.

Federal Communications Commission

Capsule Neuron 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 A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Note: For operation within 5.15 ~ 5.25GHz / 5.47 ~5.725GHz frequency range, Capsule Neuron 2 is restricted to indoor environment. The band from 5600-5650 MHz will be disabled by the software during the manufacturing and cannot be changed by the end user. This device meets all the other requirements specified in Part 15E, Section 15.407 of the FCC Rules.

Caution: Capsule 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.

FCC 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.

Declaration CE

The Capsule Neuron are class I devices that comply with the requirement of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices and carry CE-marking accordingly.

The Capsule Neuron complies with the requirement of the Council Directive 1999/5/EC of March 9, 1999 concerning radio equipment and telecommunications terminal equipment and carry CE-marking accordingly.

The DataCaptor ID Module (DIM) complies with the requirement of the Council Directives 2006/95/EC of December 12, 2006 concerning electrical equipment designed for use within certain voltage limits and 2004/108/EC of December 15, 2004 concerning electromagnetic compatibility.

Batteries in the Capsule Neuron 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 that 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.

RoHS and WEEE Compliance

The Capsule Neuron, and DIM do 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 Neuron, DIM and cables should be collected separately and not disposed of with household waste. Refer to the next section on *Recycling and the Environment* for more details.

Recycling and the Environment

Improper disposal of IT equipment can have a negative impact on health and the environment. The Capsule Neuron, DIM and serial cables should be deposited at an appropriate facility to enable recovery and recycling. Packaging and manuals can also be recycled according to your local recycling

scheme.