DRAFT

Codman Neuro Sciences (logo)
MedStream™ Control Unit

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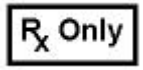
IMPORTANT INFORMATION
Please Read Before Use

MedStream™ Control Unit



FCC ID: T9I-914205

IC: 6518A-914205

IMPORTANT: 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 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.

IMPORTANT: This device complies with the Class B limits for radio noise emissions as set out in the interference-causing equipment standard entitled "Digital Apparatus" ICES-003 of Industry Canada.

Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Brief Product Description

The MedStream Control Unit is part of a system for the intrathecal delivery of selected drugs for pain management or relief of spasticity. It is designed for communicating with and programming the MedStream™ Implantable Programmable Infusion Pump.

CAUTION: Do not use the MedStream Control Unit without ensuring a thorough familiarity with the information contained in this manual, the pump instructions and the MedStream Control Unit Programming Guide. Failure to adhere to these instructions can result in patient complications ranging from failure of the intended therapy to drug underdose or overdose**.**

Indications

The MedStream Control Unit is used to program the MedStream Implantable Programmable Infusion Pump for the medication therapy indicated in the pump Instructions for Use.

Contraindications

There are no known contraindications for the use of the control unit.

Observe all contraindications relating to the use of the prescribed drug.

WARNINGS

Do not modify or change the control unit. Unauthorized changes or modifications to the control unit might cause a malfunction that could result in serious patient injury or death and could void the user's authority to operate the equipment.

Immediately investigate with the control unit if the pump alarm sounds. **Immediately empty the pump reservoir if the error message is "Pump Hardware Failure."** These conditions can cause a drug overdose. See the MedStream Control Unit Programming Guide for further information.

Do not open the control unit case. There are no user serviceable parts. See *Service and Repair.*

Do not immerse the control unit in liquid. Damage to the unit may result.

Do not use the control unit in the presence of flammable gases or near flammable materials.

PRECAUTIONS

Do not use the MedStream Control Unit with any other programmable infusion pump.

Do not rely only on the "fuel gauge" indicator on the control unit screen to determine precisely the life of the pump battery. This indicator provides an **estimate** of the remaining useful life of the pump battery.

Do not place the pump on a metal surface when using the control unit for preoperative preparation.

Do not expose the control unit or the hardware key to electromagnetic fields or ionizing radiation, such as MRI or X-rays.

Be aware that medical electrical equipment needs special precautions regarding electromagnetic compatibility. This equipment must be installed and put into service according to the electromagnetic compatibility information provided in this manual.

Be aware that portable and mobile RF communications equipment can affect medical electrical equipment.

Be aware that the use of cables other than those included with the control unit can result in increased emissions or decreased immunity of the equipment.

Avoid using the control unit adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, observe the system to verify normal operation in the configuration in which it will be used.

Use only the battery charger provided to recharge the control unit battery.

Avoid exposing the control unit to ultraviolet light.

Do not remove the hardware key from its slot in the control unit. The Control Unit software will lock if the hardware key is missing or damaged.

Do not remove or replace the control unit battery.

Use only with computer equipment that complies with IEC60950-1.

Adverse Events

There are no known adverse events associated with use of the MedStream Control Unit.

PRODUCT DESCRIPTION

Control Unit

The MedStream Control Unit is a hand-held, battery-powered, electronic module that houses power and control logic circuits.

The control unit uses radiofrequency to communicate with a MedStream pump. Use the control unit to:

- prepare the pump preoperatively
- initialize the pump and start infusion postoperatively
- refill the pump
- noninvasively check the status of an implanted pump and change the infusion parameters
- deliver a bolus dose of medication directly from the pump's drug reservoir
- view a log of transactions performed with the control unit
- transmit a record of a past transaction or of a pump's current settings to a compatible computer printer

The control unit (see Figure 1) includes the following features:

- Liquid crystal display (LCD) screen
- Power/Escape button
- Roller key and Back button for navigating screens
- Antenna
- Hardware key
- USB port for printer
- USB port for PC
- Strap
- Battery charger connection
- Transmit button

Also included, but not shown:

- Universal battery charger
- USB printer cable, 1.5 m

Control Unit Audible Signals & Alarms
When communication with the pump is successful, the control unit emits a 1-second beep. If communication is not successful, the control unit emits a longer beep (2 seconds) in a lower tone.

The control unit will emit several short beeps to alert the user to a warning or an error condition. Check the LCD screen for the warning message. Refer immediately to the MedStream Control Unit Programming Guide for information regarding warnings and errors and the audible signals. Take appropriate action.

Control Unit Function and Intended Application
The MedStream Control Unit is intended for programming the flow parameters of an implanted MedStream Implantable Programmable Infusion Pump and for transmitting other information to the pump memory.

Universal Battery Charger

Use the battery charger provided with your control unit to recharge the control unit battery. See the instruction booklet packaged with the battery charger. You can operate the control unit while the battery is charging.

Before first use you must charge the control unit for at least 5 hours.

Periodic Recharging Requirements

- Recharge the battery at least every 70 days.
- Whenever possible, allow the battery to fully recharge; i.e., recharge overnight.
- Periodically perform a complete discharge/ recharge cycle.
- Use the control unit with the battery at 40% or more of full charge.

CAUTION: Use only the battery charger included with the control unit to recharge the control unit battery.

USB Printer Cable

Use only the cable provided to connect the control unit to a computer printer. See the MedStream Control Unit Programming Guide for instructions and for a list of compatible printers.

CAUTION: Use only the USB printer cable included with the control unit to connect the control unit to a computer printer. **Use only with** the computer printers listed in the MedStream Control Unit Programming Guide, which comply with IEC 60950-1.

INSTRUCTIONS FOR USE

Setting up the Control Unit

Before first use, use the battery charger provided to charge the control unit for at least 5 hours.

Turn the control unit on by pressing the Power/Escape button. The first time you use the control unit, you must:

- select the language
- set the date
- set the time

All other functions of the control unit are disabled until this information is entered. See the MedStream Control Unit Programming Guide for set-up instructions.

Communicating with a MedStream Pump

You must use the control unit to prepare the pump before implantation and to start the infusion post- operatively. Step by step instructions are included in the Control Unit Programming Guide and in the instructions packaged with the pump.

You must use the control unit for tasks associated with continuing therapy. See the programming guide for instructions regarding:

- Refilling the drug reservoir
- Administering a bolus dose
- Stopping the infusion
- Changing the infusion parameters
- Responding to a pump alarm

You also use the control unit to

- Display a log of the past 100 transactions performed with the control unit
- Sort the transaction log by date, pump identification number, or patient identification
- Transmit a transaction report to a compatible printer. See the Programming Guide for instructions and for a list of compatible printers.

Positioning the Control Unit for Transmission to a Pump (see Figure 2)

When you use the control unit to communicate with the pump, you must first position the control unit antenna so it encircles the patient's skin over the implanted pump. Each time the control unit screen displays **"Activate Transmission?"** you will:

1. Open the antenna to between 110º and 180º
2. Slip your hand through the handle on the back of the control unit
3. Position the control unit so the antenna surrounds the implanted pump and is not more than 7 cm above the **top surface of the pump**
4. Hold the control unit steady while pressing the Transmit button or the Roller key to activate the transmission, until the transmission is complete

Turning Off the Control Unit

Press and hold the Power/Escape button for three seconds to turn off the control unit.

If you do not manually turn off the control unit after each use, the control unit enters the power saver mode to conserve battery power (if the power saver mode has not been deactivated). After 10 minutes of inactivity, the control unit enters a lower power mode. Although the screen is turned off, the control unit is still on. To turn the screen back on, press the Power/Escape button. After an additional 15 minutes in the power saver mode, the control unit will power off.

Instructions for deactivating the power saver mode appear in the Control Unit Programming Guide. When the power saver mode is

deactivated, a message regarding this status will appear when the power is turned on.

Safety Information

The MedStream Control Unit (catalog no. 91-4205) complies with the requirements of:
47 CFR Parts 1, 2, and 15 Federal Communications Commission Rules and Regulations
ICES-003 Digital Apparatus
IEC/EN 60601-1-1 Medical Electrical Equipment – Safety Requirements for Medical Electrical Systems
IEC/EN 60601-1-2 Medical Electrical Equipment – Electromechanical Compatibility
IEC/EN 60601-1-4 Medical Electrical Equipment – Programmable Electrical Medical Systems
RSS 102 Radio Frequency Exposure Compliance of Radiocommunication Apparatus (All Frequency Bands)
RSS 210 Low-power License-exempt Radiocommunication Devices (All Frequency Bands): Category I Equipment

Preventive Maintenance

The control unit performs a self-diagnostic test each time the power is turned on. No user maintenance is required.

Cleaning

Cleaning the Outer Case

Clean the outer case of the control unit with a water-dampened cloth. Do not allow excessive moisture into the control unit.

CAUTION: Do not immerse the control unit in liquid. Do not clean the programmer with aromatic or chlorinated hydrocarbons.

Cleaning the Display

Do not use any cleaning agents on the display. Clean the display only with a soft, dry, lint-free cloth.

NOTE: Scratches on the display can adversely affect device operation by interfering with display option selection. If scratches are present, the control unit might need to be repaired or replaced.

Cleaning the Antenna

Clean the exterior surfaces of the antenna with a damp sponge or soft cloth moistened with water, mild detergent or alcohol. Prevent liquid from entering any system components.

Disinfection

Wipe the outer case of the control unit with antibacterial solution if it is to be used in the sterile field.

Sterilization

CAUTION: Do not sterilize the control unit or the battery charger.

The control unit, USB cable, battery charger and hardware key are nonsterile. To use the control unit and accessories in the sterile field, wrap in sterile plastic drapes.

Service and Repair

Send the MedStream Control Unit for service or repair to:

Codman Neuro Sciences Sàrl
Rue Girardet 29
CH 2400 Le Locle
Switzerland

Always include a repair purchase order and a written description of the problem.

End of Useful Life

Dispose of the equipment in accordance with local ordinances.

Control Unit Technical Specifications

Internal Power Supply (non-removable)	Lithium ion rechargeable battery Nominal voltage: 11.1 V Minimum capacity: 1850mAh Battery configuration: 3S1P Active current limitation: 4.65A ± 1.05A
Charger max. voltage	12.6 V DC
Charger max. current	1.2 A DC
Approximate stand-alone operating time (20 radiofrequency communications with the pump)	9.5 h
Maximum battery recharge time	5 h
Weight	750 g
Dimensions	130 mm W x 60 mm H x 110 mm D
Materials – Outer Surfaces	Case: ABS and SANTOPRENE® elastomer Strap: PVC and polyester

Control Unit
Environmental Conditions

Operating Conditions	
Temperature Range:	10°C to 40°C
Humidity Range:	Relative Humidity 30% to 75% non-condensing
Pressure Range:	Atmospheric Pressure 700 hPa – 1060 hPa
Transport & Storage Conditions	
Temperature Range:	**Transport:** -20 ° C to +50° C **Storage:** +5 ° C to +30 ° C
Humidity Range:	Relative Humidity 10% to 85% non-condensing
Pressure Range:	Atmospheric Pressure 500 hPa – 1060 hPa

Warranty

Codman & Shurtleff, Inc., warrants that this medical device is free from defects in both materials and workmanship for one (1) year from the date of purchase. **Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.**

Appendix A: Tables

Table 1 Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The MedStream Control Unit (Model No. 91-4205) is intended for use in the electromagnetic environment specified below. The customer or the user of the MedStream Control Unit should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The MedStream Control Unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The MedStream Control Unit is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 2 Guidance and Manufacturer's Declaration –Electromagnetic Immunity			
The MedStream Control Unit (Model No. 91-4205) is intended for use in the electromagnetic environment specified below. The customer or the user of the MedStream Control Unit 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 ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical fast transient/burst (EFT) IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and dropout IEC 61000-4-11	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 sec	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Table 3
Guidance and Manufacturer's Declaration –Electromagnetic Emissions
Equipment and Systems That Are NOT Life-supporting

The MedStream Control Unit (Model No. 91-4205) is intended for use in the electromagnetic environment specified below. The customer or the user of the MedStream Control Unit should ensure 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 10 Vrms for ISM Bands	V1 = 3 Vrms V1 = 10 Vrms for ISM Bands	Portable and mobile RF communications equipment should be separated from the MedStream Control Unit by no less than the distances calculated/listed below: D = (3.5/V1)(Sqrt P) 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E1 = 10 V/m	D = (3.5/E1)(Sqrt P) 80 to 800 MHz D = (7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

Table 4
Recommended Separation Distances
Between Portable and Mobile RF Communications Equipment and
the MedStream Control Unit (Model No. 91-4205)
Equipment and Systems That Are NOT Life-supporting

The MedStream Control Unit (Model No. 91-4205) is intended for use in an electromagnetic environment in which radiated disturbances are controlled. The customer or the user of the MedStream Control Unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the MedStream Control Unit as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150 kHz to 80 MHz D = 1.17 (Sqrt P)	Separation (m) 80 MHz to 800 MHz D = 0.35 (Sqrt P)	Separation (m) 800 MHz to 2,5 GHz D = 0.7 (Sqrt P)
0.01	0.12	0.04	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.70
10	3.69	1.11	2.21
100	11.67	3.50	7.00

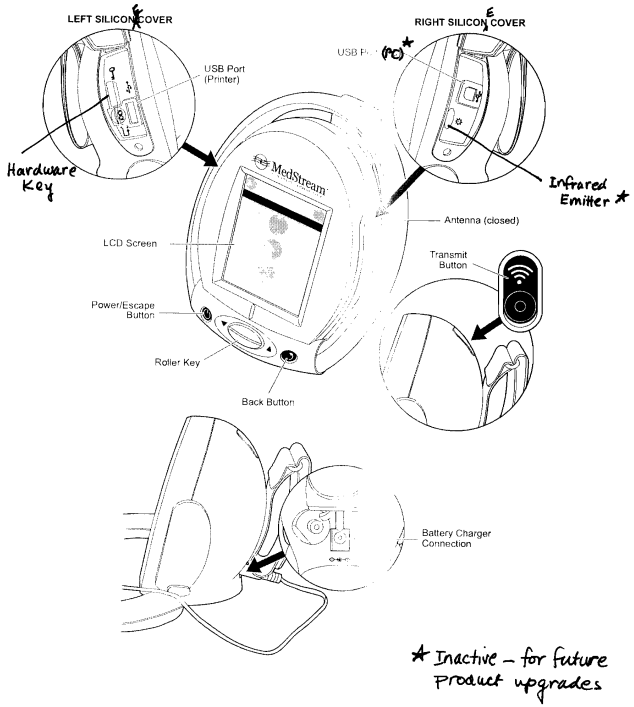
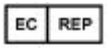

LEFT SILICON COVER
RIGHT SILICON COVER
USB Port (Printer)
Hardware Key
Infrared Emitter ★
Antenna (closed)
LCD Screen
Transmit Button
Power/Escape Button
Roller Key
Back Button
Battery Charger Connection
★ Inactive – for future product upgrades

Figure 1

Figure 2

Symbols:

	Authorized European Representative
	Prescription device only (USA)
	Manufacturer
	Made In
	Attention, consult accompanying document
	Type BF – Equipment with an electrical path to the patient, not including direct cardiac application
	Transport temperature limitations
	Electrical and electronic equipment. Return waste to collection system or treatment and recycling facilities. Applicable in the EU. Follow disinfection instructions before return.

	This product intentionally generates RF energy which may cause interference
 XXXX	This product is ETL listed