

SurgASSIST™

Wireless Remote Control Unit (RCU)

Instructions For Use

Introduction

The SurgASSIST™ System Remote Control Unit is the hand held portion of the remote control sub-system. The entire wireless system consists of this hand held battery-powered unit and a radio frequency receiver-antenna mounted within the Power Console (PC100).

The wireless RCU is capable of providing remote control operation of the Power Console (PC) within a 15-foot radius of the instrument.

Description

The SurgASSIST™ Remote Control Unit is a battery powered, hand held device that transmits control commands to the Power console. A battery capable of supplying power throughout the life of the Remote is permanently installed in the hermetically sealed case. Each Remote Control Unit is preprogrammed with a unique identification code. When the Remote is used to power-on the Power Console, this identification code is read and stored by the Console. The Console with the stored identification code will then only respond to commands sent by its corresponding Remote Control.

Interference from other remotes in the area is prevented by the summation of the following:

- 1 Each command issued from the remote control is of very short duration, the probability of any two remotes being activated at exactly the same time is unlikely.
- 2 The Remote Control identification number precedes every command sent. The Power Console will only respond to commands sent from the Remote identified when the system was initially turned on.
- 3 The receiver sensitivity is reduced to minimize long-range reception from possible interfering transmissions. The physical closeness of its own remote with its relatively high RF output level should easily overpower any interfering signal.



Figure 1: Wireless Remote Control Key Functions

Procedure

1. Prior to switching “ON” the SurgASSIST System Power Console, verify that the hand-held “Wired Remote Control Unit” is not attached to the front panel PC connection. Switch “ON” the Power Console located on the rear panel. PC indicator continuously flashes.
2. With the hand-held Wireless Remote Control within a 15 foot perimeter of the SurgASSIST System Power Console, press the “ON Key of the remote. The power On indicator located on the PC display panel will illuminate continuously. The Wireless Remote Control Unit will now be **MATED** to that Power Console via radio frequency (RF) link. All Remote Control key commands to that Power Console will now exist via RF link
3. Utilize the Wireless Remote Control Unit identically to that of the Wired Unit. Refer to SurgASSIST Operator’s Manual, REF OPMA, for complete System operation.
4. When the Power Console is Reset or Turned “OFF” via rear panel switch, the MATED Remote Control Unit will no longer become MATED. Re-MATING will occur with the Wireless Remote Control Unit the next time the Power Console is turned “ON” and the RCU is keyed as in step No. 2, above.

WARNING

In the extremely unlikely event that the Power Console power indicator lights continuously before the Remote Control pushbutton is pressed, it may indicate that the console locked to another remote. If this should occur, simply toggle the Power Console power switch momentarily to the “OFF” position and repeat step No. 1.

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device must not cause harmful interference, and, (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC ID: XXXABC123

Performance

Operating Range

The operating range is required to be at least 15 feet.

Battery Life

A fresh battery within a Remote Control Unit has sufficient capacity to last at least 2000 procedures.

If the command pushbutton is continuously held down, RF transmission is terminated after 5 seconds and will only resume when the next command is issued. *

Battery Shelf life: > 90 % capacity remaining after 7-year storage at a temperature not to exceed 37°C.

Low Battery Warning

A low battery warning will be displayed on the PC message panel when the remaining battery capacity is estimated to be insufficient to complete at least 100 surgical procedures. This is intended as information to the user that the surgical procedure can continue, but the RCU should be replaced prior to starting another set of procedures on the next patient. If the user elects to continue without replacing the Remote, the "Battery Empty" message will be displayed when the battery counter decrements by an amount equivalent to 50 additional procedures.

Battery Empty Message

This message will be displayed when the amount of battery energy available is estimated to be less than what is required to complete at least 50 procedures. The PC will not respond to any of the Power Console control commands issued from this remote.

Display of this message continues until the battery is depleted beyond its capacity to power the RCU transmitter.

Battery Timers

A series of timers protect the battery from excessive power drain. The processor will automatically disconnect itself and the RF module from the battery within 100 ms after the last transmission. A hardware timer will temporarily disconnect the battery after 10 seconds if any pushbutton is continuously held down.

Radio Frequency (RF) Characteristics (USA, Canada and Europe)

Center Frequency (Carrier)

418 MHz

Maximum Transmission Period

5 seconds (controlled by processor)

Controls and Indicators

RCU Controls

The design and placement of the control pushbuttons allow the user to comfortably operate the Remote Control Unit with one hand. A set of four pushbuttons arranged as compass points (North, South, East and West) control the steering portion of the shaft. Other pushbuttons are arranged by size and shape to allow commands to be sent without the need to continuously view the Remote. The other functions are Steering Release, Open / Close, Fire, and On.

Number of Commands

Any combination of pushbuttons may be depressed simultaneously. All combinations will be transmitted to the PC.

Messages

Messages are displayed on the Power Console to provide user feedback after each pushbutton is depressed. The messages listed are specific to operation of the Remote Control Unit

Message	When Displayed
A short blink of the PC "Power" indicator lamp shows receipt of a command.	Momentarily when any transmitted command is received.
"Remote control Battery low Replace after procedure Press on To continue"	Displayed when the Remote is matched with the PC and the battery capacity counter is less than 12. Sufficient capacity remains for less than 100 surgical procedures.
"Replace Remote Control Now"	Displayed when battery capacity cannot be deemed sufficient to complete a procedure. The battery capacity counter is less than 6.

Available Battery Capacity

The counter within the Remote Control Unit will decrement by one count for each standard period of time of operation. The Remote Control will keep track of elapsed usage and subtract usage from available battery life.

Input and Output Connections Required

- RCU Inputs and Outputs

The RCU is hermetically sealed and does not require any user accessible input or output connections. Internal connections include the transmitter antenna and battery terminals.

- Receiver Antenna

The receiver antenna is permanently mounted within the Power Console.

Power Requirements

- RCU

The Remote Control Unit is powered by a high temperature lithium battery that is not field replaceable.

- Battery

High temperature (150 C) lithium AA cell 3.8 VDC, 1.6 Ah

- Input Voltage

2.8 to 4.0 VDC

Environmental Requirements

RCU

The RCU is intended for use in normal indoor environments. The case is hermetically sealed, capable of total submersion while cleaning or sterilization procedures are conducted.

Battery Disposal: The battery is not accessible for replacement. Once a RCU battery is determined to be at its useful end, contact your local Environmental Agency for the proper disposal of lithium batteries. **DO NOT DIS-ASSEMBLE REMOTE CONTROL UNIT TO ACCESS BATTERY. DISPOSE OF REMOTE CONTROL HANDLE IN ITS ENTIRITY.**

Operating Ambient Conditions

- **Ambient Temperature**

The ambient operating temperature range is 10°C to 40°C (50°F to 104°F)

- **Relative Humidity**

10% to 100% RH

Storage and Distribution Conditions

- **Ambient Temperature**

The anticipated temperature extremes are -40°C to 70°C (-40°F to 150°F)

- **Relative Humidity**

10% to 100% RH

Sterilization

- **Type of Sterilization Allowed**

Ethylene Oxide gas, Liquid chemical systems containing peracetic acid.

Steam Autoclave.

Standard Recommendations for Autoclave Steam Flash Sterilization

CHARACTERISTICS OF ITEM	GRAVITY	VACUUM
Nonporous Non-Lumened	3 minutes @ 270°F (132°C) with no weight restrictions, load size restrictions or density restrictions. Instruments must be properly decontaminated	3 minutes @ 270°F (132°C) with no weight restrictions, load size restrictions or density restrictions. Instruments must be properly decontaminated

Number of Sterilization Cycles Allowed

The Remote Control Unit has been qualified to function after a minimum of 200 autoclave Flash Sterilization cycles, hospital ETO cycles and Steris I, peracetic acid cycles without exhibiting material degradation or other functional defects.

WARNINGS:

DISPOSE OF REMOTE CONTROL UNIT IN THE PROPER FASHION. DO NOT EXPOSE UNIT TO EXCESSIVE HEAT (>160 C) AS INTEGRAL BATTERY MAY HAVE CATASTROPHIC FAILURES.

CONSULT LOCAL ENVIRONMENTAL REGULATIONS FOR PROPER DISPOSAL OF LITHIUM ION BATTERIES.

DO NOT CRUSH, PUNCTURE, OR ATTEMPT TO DISASSEMBLE A REMOTE CONTROL UNIT.

ENSURE THAT ALL HOSPITAL STEAM STERILIZATION AUTOCLAVES HAVE PROPER TEMPERATURE FAULT CIRCUITS INSTALLED.



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