FS-U/FS-D/FS-S Footswitch

Instructions for Use

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Company Contact

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EC REP

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Note: You can contact Mindray Customer Service Department or sales representative to obtain the instructions for use in paper form.

Statement

Notification of Adverse Events

As a health care provider, you may report the occurrence of certain events to SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD., and possibly to the competent authority of the Member state in which the user and / or patient is established.

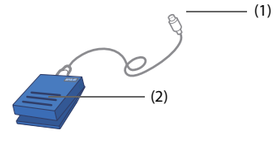
These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. provides only the highest quality products.

1.1 Product Introduction

The models of the footswitches are listed in the following table:

Model	Description
FS-U	Footswitch for ultrasonic surgical instrument
FS-D	Double-pedal footswitch for HF instrument
FS-S	Single-pedal footswitch for HF instrument

1.1.1 Single-Pedal Footswitch for HF Instrument



(1) Generator connector: connects the generator

(2) Pedal: activates bipolar coagulation modes

1.1.2 Double-Pedal Footswitch for HF Instrument

(1) Generator connector: connects the generator

(2) Left pedal (yellow): activates monopolar cutting modes

(3) Right pedal (blue): activates monopolar/bipolar coagulation modes

1.1.3 Footswitch for Ultrasonic Surgical Instrument

(1) Generator connector: connects the generator

(2) Left pedal: activates the MIN mode

(3) Right pedal: activates the MAX mode

1.2 Intended Use

The product is used to activate ultrasonic surgical instruments or HF instruments during ultrasonic surgery or electrosurgery.

1.2.1 Intended Medical Conditions

This equipment is used in medical institutions.

1.2.2 Intended Users

This equipment is for use only by qualified medical personnel. Inappropriate use of the equipment by untrained medical personnel may result in hazardous electrical output.

1.2.3 Intended Patient Population

The attending physician must decide whether the foreseen application is admissible based on the general condition of the patient.

1.2.4 Contra-indications

None

1.3 Safety Information

CAUTION

- **This footswitch is compatible only with generator specified by Mindray. Using other generator may cause product damage, patient injury, or failure to meet the claimed specifications.**
- **No modification of this equipment is allowed. All safety checks or maintenance involving any disassembly of the equipment should be performed by professional service personnel. Otherwise, undue equipment failure and possible health hazards could result.**
- **This equipment contains no user serviceable parts. In case of any equipment failure, contact the service personnel.**

1.4 Cleaning and Disinfecting the Footswitches

The footswitches are not intended to come into contact with the patient. Thus, they are not disinfected before leaving the factory. Clean and disinfect the footswitches before the first use and after each use.

1.4.1 Cleaning

Before cleaning the footswitches, consult local or your hospital's regulations for cleaning of medical equipment. To clean the footswitches, follow this procedure:

1. Turn off the generator and disconnect the power cord.
2. Disconnect the footswitches from the generator.
3. Clean the surface of the footswitches with a mild cleanser. For detailed operation instructions, refer to the instructions for use of the cleanser.
4. Remove the cleanser residue from the surface and dry the footswitches.

Below are cleansers of which the efficacy has been tested:

Product Name	Manufacturer
Water	/
Ethanol, 75%	/
3M Biofilm Removal Multi-Enzyme Cleaner	3M

NOTE

- **Remove dirt in the gaps of the footswitches during cleaning.**

1.4.2 Disinfection

Disinfect the footswitches as required in the local or your hospital's servicing schedule. Clean the footswitches before disinfection. Dilute and use the disinfectants in accordance with the instructions of use provided by their manufacturers. Use only the disinfectants recommended in this section.

The following table lists the recommended disinfectants:

Product Name	Manufacturer
Alpet® D2 Surface Sanitizing Wipes	BEST SANITIZERS INC™
CIDEX® OPA	Gilag GmbH International Advanced Sterilization products
Isopropanol, 70%	Shanghai Hushi Chemical Co., Ltd
Metrex CaviWipes™	METERX® RESEARCH
PDI Sani-Cloth® Plus Germicidal Disposable Cloth	PDI Inc.
PDI Super Sani-Cloth® Germicidal Disposable Wipe	PDI Inc.
Sodium hypochlorite bleach, 0.5%	Tianli Chemical Co. Ltd.
HEALTH ESSENCE Disinfecting Effervescent Tablets	Beijing ChangJiangMai Medical Science Technology Co. Ltd.
HEALTH ESSENCE Surface Disinfectant	Beijing ChangJiangMai Medical Science Technology Co. Ltd.
Health Essence Bis-QACs Disinfectant	Beijing ChangJiangMai Medical Science Technology Co. Ltd.
Dian'erkang Surface Wipes	Shanghai Likang Disinfectant Hi-Tech Co., Ltd
Dian'erkang Surface Disinfectant	Shanghai Likang Disinfectant Hi-Tech Co., Ltd
Dian'erkang Spray Disinfectant	Shanghai Likang Disinfectant Hi-Tech Co., Ltd
Glutaraldehyde, 2%	Caoshanhu
Ethanol, 75%	/
Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach	Clorox

1.4.3 Consequences Caused by Inappropriate Cleaning and Disinfection

Using detergents or methods other than those recommended might cause the following consequences:

- Color change on the surface of the device

- Corrosion of metal parts
- Cracks or distortion of cords, connectors and the housing of the device
- Reduced service life of cords
- Equipment malfunction

1.5 Disposal

At the end of its service life, the device must be disposed of in compliance with the local or hospital's guidelines regulating the disposal of such products. Clean and disinfect the device before disposal.

1.6 Service Life

The service life of the footswitch is 10 years.

1.7 Environmental Condition

Item	Temperature (°C)	Relative Humidity (Non-condensing)	Barometric (kPa)
Operating condition	10 - 30	15% - 85%	70 - 106
Storage/transportation condition	-20 - 60	10% - 95%	50 - 106

1.8 Physical Specifications

Dimension	FS-U/FS-D: 347mm x 186mm x 65mm
	FS-S: 103mm x 73mm x 29mm
Weight	FS-U/FS-D: 2.1 kg
	FS-S: 0.4 kg

1.9 Equipment Symbols

Symbol	Description	Symbol	Description
	Date of manufacture		Manufacturer
MD	Medical Device		Temperature limit
	Humidity limitation		Atmospheric pressure limitation
20	Environmentally-friendly use periods of electronic products (20 years)		Refer to instruction manual/booklet
UDI	Unique device identifier	EC REP	Authorized representative in the European Community
SN	Serial number		Dispose of in accordance to your country's requirements
	Caution, consult accompanying documents		Operating instructions
IPX8	Protected against the effects of continuous immersion in water		
CE	The product bears CE mark indicating its conformity with the provisions of the REGULATION (EU) 2017/745 on medical devices and fulfills the general safety and performance requirements of Annex I of this regulation. Note: The product complies with the Council Directive 2011/65/EU.		

The general meaning assigned to geometric shapes, safety colors and contrast colors for safety signs are as follows:

Geometric Shape	Meaning	Safety Color	Contrast Color	Graphical Symbol Color
	Mandatory action	Blue	White	White