

購買（英文）規格書

COMMODITY DESCRIPTION

關稅分類番號 H.S. NO.	品目番號 ITEM NO.	品目及規格 DESCRIPTION	單位 UNIT	數量 QUANTITY
		Pulsed Field Ablation System	set	1

A. Feature:

The Pulsed Field Ablation (PFA) System is an advanced technology designed for the treatment of arrhythmias. The generator produces high-voltage, ultra-short electrical pulses, which are delivered to the electrodes located at the distal tip of the connected ablation catheter (Pulsed Field Ablation Catheter). These pulses are repeatedly transmitted to the targeted areas of the heart, forming an electric field. This field increases the transmembrane potential of the cells, inducing irreversible electroporation in the cell membrane. Ultimately, the inability of the cell membrane to recover leads to cell death, enabling targeted ablation of the myocardial cells responsible for arrhythmias.

The system is composed of the generator, built-in software, an ECG monitor, a remote control, and a foot pedal, all working together to facilitate effective procedures. The system is used in conjunction with a dedicated catheter to deliver pulsed field energy precisely to the targeted lesion.

The software includes functionalities to perform energy charging and delivery commands, along with additional features to ensure the safety of the catheter and generator during operation.

B. Specification:

1. Size

- Height: 11.3in / 28.73cm
- Depth: 16.9in / 43.10cm
- Width: 23.6in / 60cm
- Weight: <55lbs / <25kgs

2. Other Specifications

- Power Input: 250V (The system can be connected to the standard

main power supply of the respective country where it is provided.)

- Power Output: 1,500V (baseline to peak), Bipolar, Biphasic waveform
- Operational Environment
 - * Temperature: 15-30°C (59-86°F)
 - * Humidity: 30-75%

C. Configurations:

1. PFA generator w/ power cable	1ea
2. PFA cardiac trigger monitor w/ power cable	1ea
3. PFA remote control	1ea
4. PFA foot switch	1ea
5. PFA electrogram (EGM) cable	1ea
6. PFA cart	1ea

D. Remarks:

1. The equipment should be installation by contractor.
2. Three years warranty after the installation and correct operation.
3. Manufactured products must be delivered within one year based on the inspection date.
4. Products that are not scheduled to be discontinued within one year after delivery must be delivered.
5. A report must be summited after conducting a preventive inspection in accordance with the hospital medical equipment inspection regulations within the warranty period.
6. 보증기간 제외품목: 없음.