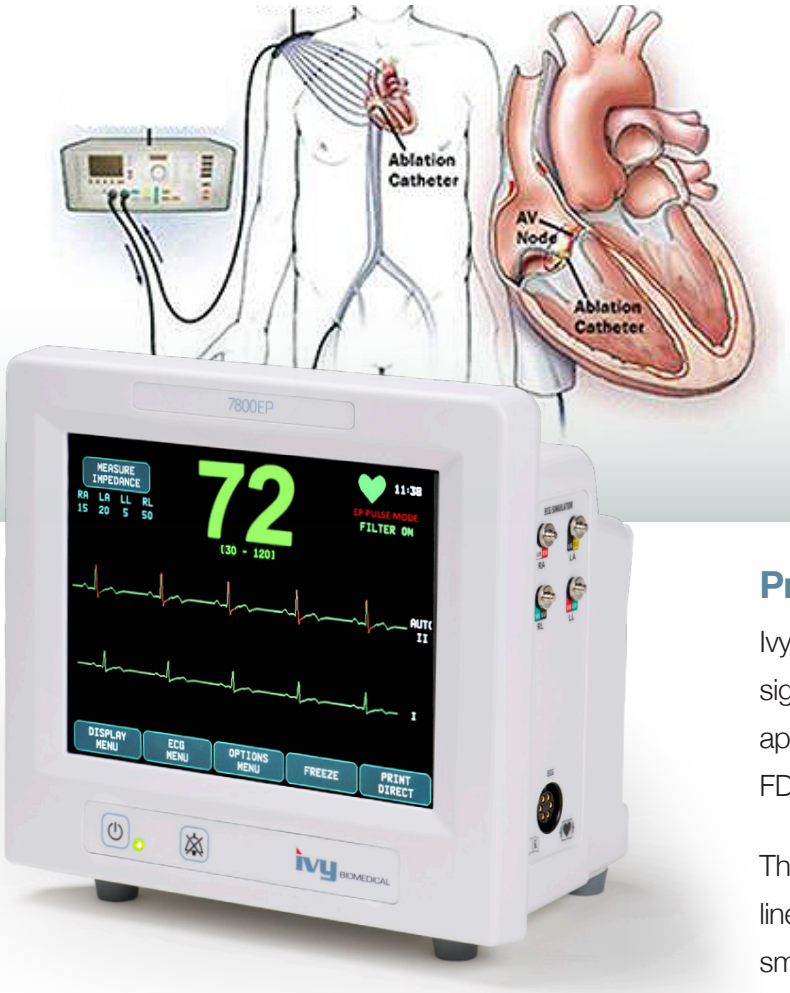
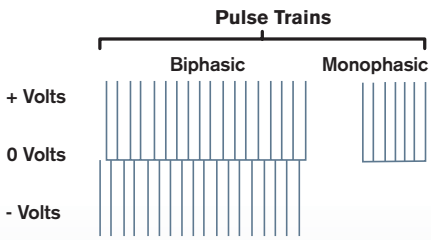
Cardiac Gating Monitor
Ablation & Lithotripsy Applications

Model **7800EP**





Key Features

- Optimized for PFA noise filtering
- Proprietary ultrafast ECG baseline recovery following PFA pulse delivery
- *SureShot*™ algorithm ensures reliable triggering during energy application
- Compatible with most cardiac mapping / navigation systems
- Precision ECG R-wave peak detection
- 4 lead ECG configuration with auto lead select
- On-screen color-coded trigger pulse indication
- Patient isolation/protection
- Optional strip chart recorder
- Universal power supply/voltage
- FDA 510(k) cleared

Product Description

Ivy Biomedical Systems' Model 7800EP is specifically designed for use in Pulsed Field Ablation (PFA) & Lithotripsy-applications, and has received 510k clearance from the FDA specifically for use with these systems.

The Model 7800EP provides ultrafast active ECG baseline recovery upon impulse energy delivery, enabling smooth, uninterrupted ablation procedures. Proprietary *SureShot*™ algorithm prevents triggering in the event of sub-optimal ECG signals, ensuring application of energy occurs only during optimal signal conditions. Additional filtering suppresses interference typically associated with certain cardiac mapping/navigation systems commonly used in ablation procedures.

Value added features such as automatic ECG lead selection ensures that the best trigger vector will be used, while a built-in ECG simulator allows for pre-procedure testing of the entire system. An optional strip chart recorder is also available for hardcopy documentation of ECG rhythms.

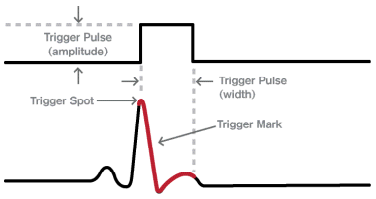
The Model 7800EP also provides a large 8.4" display, Ethernet communication, electrode impedance check function, and ECG data file capture and USB storage utilizing an external system trigger input.

Technical Specifications

Model 7800EP

Synchronized ECG Trigger Output*

Trigger Delay*	< 2ms*
R-to-R Accuracy	±75µs dither (typ.) @ 1mV input
Pulse Width**	1, 50, 100 or 150 ms
Pulse Amplitude**	0V to +5V or -10V to +10V
Pulse Polarity**	Positive or Negative
Source/Sink Current:	8mA @ 3V / 16mA (Max)



* Input signal test conditions: ½ sine wave, 60ms width, 1mV amplitude, 1 pulse/sec; Clinical Settings: 2-8ms delay dependant on QRS width

** Pre-configured at the factory only

ECG

Configuration	4-Lead system
Trigger Lead Selection	I, II, III, or AUTO
Second Lead Display	I, II, III
ECG Simulator	Integrated
Patient Isolation	>4 kV rms, 5.5 kV peak
Frequency Response	0.67 - 100Hz unfiltered 1.5-40Hz Filtered
Notch Filter	50/60 Hz (auto)
CMRR	≥ 90dB
Tall T-wave Rejection	≤ 1.2 * R-wave
Pacer Rejection (user on/off)	0.1 to 2ms pulse width @ ±2 to ±700 mV
Defibrillator Protection	360 J discharge; < 5 sec recovery time (Type CF)

Cardiotach

Adult	10-300 bpm
Pediatric/Neonate	10-350 bpm
Accuracy	±1% ±1 bpm
Resolution	1 bpm
Sensitivity	300 µV peak
HR Averaging	Exponential @ 1Hz; 2 or 8 sec max response time

EP Pulse Mode

EP Pulse amplitude	+/-5kV (biphasic or monophasic)
ECG Baseline Recovery	< 150ms (ultra-fast)
Trigger Suppression	Proprietary signal quality *SureShot*™ algorithm
Cardiac Navigation Systems	Proprietary mapping frequency suppression filter

(Specifications subject to change without notice)

Alarms

Heart Rate	High / Low HR Limit adjust
Asystole	R-to-R interval > 6 sec
ECG Lead Off	Each detached lead
Check ECG Lead	Lead imbalance > 0.5V

Display

Type	Active Matrix TFT Color Touch Screen LCD
Resolution	640x480 pixels
Size	8.4" (21.3 cm) diagonal

Input/Output Interface

Synch Output	BNC; Provides trigger pulse output synch to ECG R-wave peak
ECG Output	¼" stereo jack; Provides trigger pulse and analog ECG waveform outputs
Aux Conn	DB-9; X-Ray On interface; ECG trigger pulse; ECG waveform
RS-232 Comm	Micro DB-9; device interface
Ethernet Comm	RJ-45; 10BaseT, IEEE 802.3 (2 channels)
Data Storage	USB 2.0 Type A 200 ECG Events (FIFO)

Mechanical

Size (HxWxD)	22.1x23.5x15.5 cm (8.7x9.25x6.1 inches)
Weight	2.54 kg (5.6 lbs.)
Case Material	Polycarbonate

Electrical

Input Voltage	100-120Vac; 200-230Vac
Frequency	50/60 Hz
Power Consumption	45 VA (max.)
Power Recovery	Auto if power restored within 30 seconds

Environmental

Water Resistance	IPX1

Operating

Temperature Range	5°C to 40°C
Relative Humidity	0% to 90% non-condensing
Altitude	-100m to +3,600m

Storage

Temperature Range	-40°C to +70°C
Relative Humidity	5% to 95% non-condensing
Altitude	-100m to +14,000m

For additional specifications, refer to Operator Manual

CE 2862

Options

Integrated Recorder	2 trace, direct thermal
Mounting Plate	3" adaptor for rollstand
Roll Stand	with 3" receiver plate

Accessories

Electrodes	Low impedance; 10% KCl wet gel sponge type
ECG Leads	4-lead metallic with pinch clips; AHA or IEC color code; 24", 30" or 36" lengths available
Trunk Cable	40", 5', 10' cable with 6-pin AAMI connector

Globalization

User Interface	12 selectable languages
Operator's Manual	English; Other
Registrations	TBD

Compliance & Certifications

ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
IEC 60601-1 Edition 3.1 (2012)/EN 60601-1:2006 + A1:2013 + A12:2014
IEC 60601-1-2:2014+AMD1:2020, Edition 4.1
IEC 60601-1-6:2010 (Third Edition) + A1:2013; IEC 62366:2007 (First Edition) + A1:2014
IEC 60601-1-8:2006 (Second Edition) + Am.1:2012
IEC 60601-2-27 (2011)
IEC 62304:2006
CAN/CSA-C22.2 No. 60601-1:2014
CAN/CSA-C22.2 No. 60601-1-2:2016
EU MDR 2017/745
CE 2862
ISO 13485:2016
RoHS 2011/65/EU
WEEE 2012/19/EU
FDA/CGMP
MDSAP

Notified Body

Intertek Medical Notified Body AB,
Identification Number 2862
MDR Classification IIb

Authorized Representative

EC REP: Emergo Europe
CH REP: MDSS CH GmbH

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