

EP-TRACER[®] 2 Portable

The portable electrophysiological measurement system to support Conduction System Pacing (CSP)-Procedures

**schwarzer
cardiotek**
SMART. PRECISE. RELIABLE.

EP-TRACER 2* simplifies and improves CSP Procedures

The innovative electrophysiological measurement system is perfectly suited to support CSP implantations due to specific excellent features. With its fully-integrated stimulator it assists the programmer unit during pacing lead placement.

With the EP-TRACER 2 the morphology of the 12-channel surface ECG can be displayed simultaneously during stimulation. Due to its small and handy footprint, the EP-TRACER 2 can be easily hand carried to any place where the user may want to put it into operation.



* EP-TRACER with software version 2

Features of the EP-TRACER 2 Portable

Amplifier

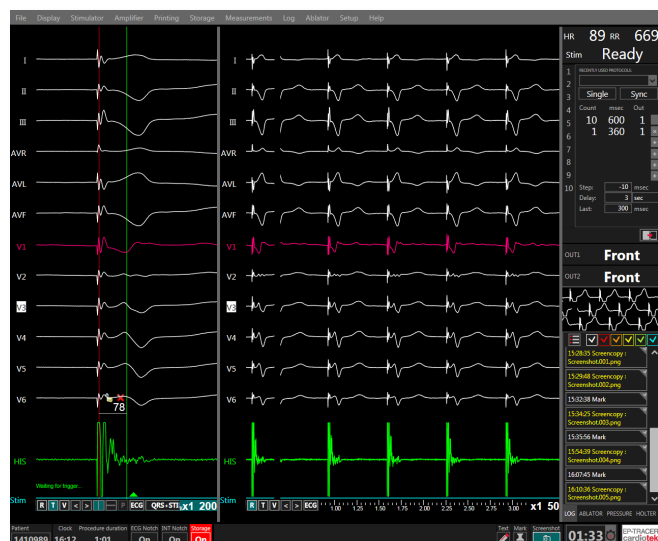
The EP-TRACER 2 amplifier allows the connection of a 12-channel surface ECG and 2 additional His-channels. If necessary, invasive blood pressure can be displayed. All signals can be displayed simultaneously. The excellent preamplifier and the intelligent filters provide sharply defined His signals - a valuable guide for the placement of the electrode.

Integrated Stimulator

The EP-TRACER 2 is equipped with a built-in 2-channel stimulator. If needed, the stimulator can be used in parallel with the pacemaker or to the programmer.

Smart Keyboard

The Smart Keyboard offers an intuitive user interface to support a streamlined workflow, combining the benefits of a digital display with the haptic feedback of a traditional keyboard. Customized stimulation protocols can be accessed via the Smart Keyboard in a short time. Additionally annotations are supported by the Smart Keyboard.



Software

The EP-TRACER 2 software has an intuitive interface that supports your requirements at every stage of the procedure.

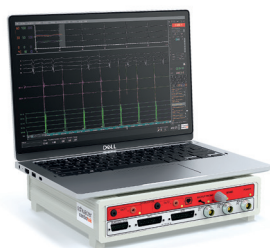
- Visible at one glance: 12-channel surface ECG and His-signals are displayed simultaneously and clearly.
- The screen can be split in a comfortable way to overlay consecutive beats. It allows the comparison of the signal's morphologies.
- In trigger mode, the response signal can be superimposed after stimulation and reproduced again at each stroke. Time and amplitude measurements can be carried out, for example to determine and evaluate the effectiveness of stimulation pulse and place.
- The excellent, noiseless signal amplification allows a better visualization of His-signals at the crucial points of the procedure.
- The 12-channel surface ECG allows immediate control of the stimulation point, for example in the His-bundle (selective vs. non-selective capture).
- The optional measurement of invasive blood pressure (IBP) supports statements about the contractility of the left ventricle.
- The software allows you to seamlessly evaluate LVAT and V1-V6-Intervall in real time or on a triggered view, to assess the conductivity during the CSP implantation.
- It offers state of the art indicators for ideal captures: Current of Injury (COI) and derivative of pressure over time (dp/dt).

Further advantages

- Fast setup: the system is ready for use in 5 minutes
- Portability: bringing freedom to perform interventions also in pacemaker labs
- Scalability: being a portable EP recording system, the usage is not only limited to CSP procedures but also can be used in common EP interventions.

EP-TRACER® 2 Portable

The portable electrophysiological measurement system to support Conduction System Pacing (CSP)-Procedures



Components

- EP-TRACER 2 Portable
 - Laptop (Windows 10 IoT, 64bit)
- Software EP-TRACER 2
 - Recording software
 - Instruction manual
 - Review software
 - Dongle license key
- EP-amplifier
 - 20, 52 or 84 intracardiac channels
 - 12 surface ECG channels
 - 6 auxiliary channels, e.g. for the invasive measurement of blood pressure
 - Integrated stimulator with 2 outputs
 - Allows custom stimulation via intracardiac channels without external wiring
 - Input mode: bipolar or unipolar
 - Isolated power supply
- Catheter connection boxes
- Power-box, 100-240 V
- Filter set with EP-TRACER 2 70 and 102
- Cabeling
 - Cable for catheter connection
 - box (approx. 3 m)
 - ECG cable with electrodes
 - Carbon-fiber cable RTBG-3605, L = 90 cm

Technical details

Medical device directive (93/42/EEC)	Class IIb
EP-TRACER 2	
Intracardiac channels	20/52/84
Sampling rate	1 kHz per channel
Amplification factor	0.1 – 25
Catheter connection box	2/4/6 × DIN DB25
	Input modes: bipolar and unipolar
ECG channels	Electrode connections: R, L, F, N, C1-C6 Standard: DIN DB15 Leads I, II, III, aVL, aVR, aVF C1-C6 Calibration equivalent to 1 mV
Additional channels	6 AUX channels Connections: 3 × 9 pin REDEL (2 channels per connection) Input mode: bipolar
Current leakage	< 50 µA
Back-up stimulation mode	60 beats per min at Out1-Out2 simultaneously current = 8 mA (Out1) current = 4 mA (Out2) pulse width = 2 msec
Stimulator	Current 0 – 25.5mA (customizable) Minimum increment 0.1 mA Maximum output-voltage: 20 V
Analog/digital converter	Resolution: 12 bit (20 bit dynamic) Bit weight: 1.25 µV/ LSB
Computer operating system	Windows 10 IoT, 64bit
Applicable standards	IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 IEC 60601-2-27: 2011 / IEC 60601-2-34: 2011 IEC 62366: 2007 + A1:2014 / IEC 62304: 2006
Patient safety	Safety class I, type CF according to IEC 60601-1; Patient connections protected against the effects of defibrillation impulses
Dimensions (h × w × d)	
Portable system in aluminium suitcase	150 × 460 × 370 mm
EP-TRACER 2 38/70/102	60 × 280 × 270 mm / 110 × 290 × 260 mm / 110 × 290 × 260 mm
Weight	
Portable system in aluminium suitcase *	approx. 10 kg
EP-TRACER 2 38/70/102	approx. 2.2 kg / 3.3 kg / 3.8 kg
Labelling	
only for EP-TRACER 2 medical device	CE 0197

Notice: The EP-TRACER Portable version is sold as a system pack while the main device, EP-TRACER, is a CE marked medical device of class IIB. Content may be subject to change. * only for EP-TRACER 2 38

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