Amendment to hardware manual - Backup pacing

This document contains important safety information!

1 Purpose

This document contains updated instructions relating to the correct use of the "backup pacing" feature.

1.1 Applicability

The instructions contained in this document applies to all EP-TRACER hardware devices (EP-TRACER 38; EP-TRACER 70; EP-TRACER 102), and systems wherein these devices are used (Portable, Stationary, MobileCart/MobileDesk), including all systems running software versions V1.0x and V2.0.xxxx.

The instructions contained in this document supersedes any previously supplied information regarding the functioning of the backup pacing feature and is intended as an amendment to all previously released hardware manuals. This document is valid only as an amendment to the hardware manual originally provided with the EP-TRACER system and is invalidated by the availability of subsequent hardware manuals (v1.21 and above).

Amendment to hardware manual - Backup pacing

2 Backup pacing function

2.1 Use scenario

The EP-TRACER has an integrated safety feature, termed 'backup pacing', which allows for continuous pacing independent of software. This feature is intended to be used in the sole case that if, during use, the EP-TRACER software becomes unresponsive, e.g. due to a PC failure. In this scenario the backup pacing feature may be activated while the source of the unresponsive software is corrected. This also applies to the scenario whereby the software cannot control the stimulator due to a break in communication between the PC and the EP-TRACER device; i.e. if the USB cable is removed. Backup pacing may also be used to override or stop an ongoing stimulation protocol should a PC failure/software failure/communication break occur while a user defined stimulation protocol is active.

Warning!

Backup pacing is not be used while the software is fully functional! If the software is fully functional backup pacing parameters (pulse width, pulse amplitude, delay between output channels, pulse shape) may be changed unintentionally. This may be confusing to the user and lead to delayed treatment.

The backup pacing feature does not replace the need for a dedicated external pacemaker during EP procedures and must only be operated by a trained EP-TRACER user.

2.2 System setup

The backup pacing capability operates independently of software to deliver a continuous pulse of 1Hz (60bpm) to a backup pacing catheter selected by the operator. The selected backup pacing catheter must be directly connected to the OUT channels (OUT1/OUT2) located on CCB4/CCB6 or directly to the EP-TRACER device (Figure 1).
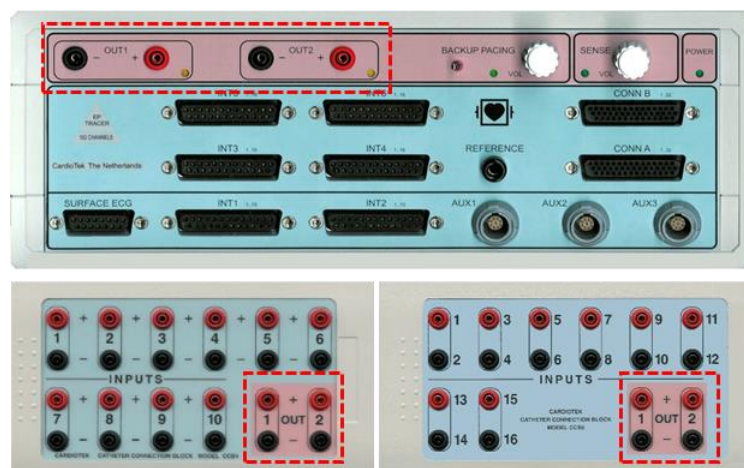

Figure 1: Backup pacing outputs, on the EP-TRACER front panel, CCB4 and CCB6

Amendment to hardware manual - Backup pacing

Warning!
The following steps are critical to ensure patient safety.

1. Remove all catheter connection pins from the 'INPUTS' of the CCBs before starting backup pacing. This ensures that stimulation cannot occur on an intracardiac channel selected by the user through the software user interface during the study.

2. Once the catheter connection pins have been removed from the INPUT section, connect only the 2 pins needed for bipolar stimulation to one of the designated OUT connections before activating the backup pacing switch.

Note:

This is to ensure that independent of the stimulation output selected in the software backup pacing functions as intended, regardless of faults in the software.

Both OUT channels are stimulated with the same frequency (60bpm), and pulse width (2mS), however the power output for each OUT channel is different (as summarized in Table 1). This offers the user the opportunity to select the appropriate power setting for the pacing location (e.g. atrium/ventricle).

	OUT1	OUT2
Power output	8mA	4mA
Pulse width	2mS	2mS
Frequency	60bpm	60bpm

Table 1: Backup pacing stimulation power output parameters

Amendment to hardware manual - Backup pacing

2.3 Activating backup pacing

Switching the backup switch to the right activates the pre-defined stimulation protocols on both stimulation channels. This will be accompanied by flashing LEDs and beeping on both OUT channels on the EP-TRACER front panel (See Figure 2).
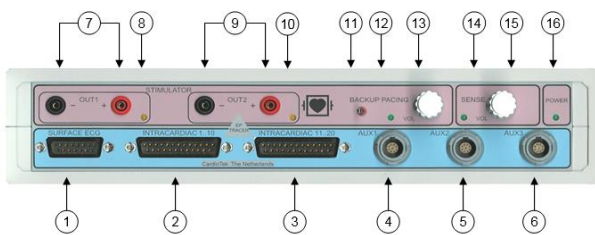

Figure 2: EP-TRACER front panel

1	Amplifier	Surface ECG input
2	Amplifier	Intracardiac inputs 1-10
3	Amplifier	Intracardiac inputs 11-20
4	Amplifier	Auxiliary inputs 1,2
5	Amplifier	Auxiliary inputs 3,4
6	Amplifier	Auxiliary inputs 5,6
7	Stimulator	Output channel 1
8	Stimulator	Channel 1 activity indicator
9	Stimulator	Output channel 2
10	Stimulator	Channel 2 activity indicator
11	Stimulator	Backup pacing switch
12	Stimulator	Backup pacing indicator
13	Stimulator	Beep volume
14	Stimulator	Sense indicator
15	Stimulator	Sense volume (optional)
16	Power	Power indicator

The non-synchronized, continuous protocol, will repeat in groups of 100 protocol lines until the backup pacing switch is turned off. If the software is active, it will display the backup pacing protocol in the stimulation protocol window (100 lines; 1000ms; both outputs).

In upcoming software versions the text "backup pacing" will be displayed instead.

Stim 100 1000 3

Warning!
Unintentional activation of backup pacing should be immediately resolved by turning off backup pacing!

If the software is started while backup pacing is active, the EP-TRACER diagnostics screen will appear to inform you that backup pacing is active; this window can be closed using the grey X in the upper right hand corner (closing the diagnostics window has no effect on the status of the backup pacing function).

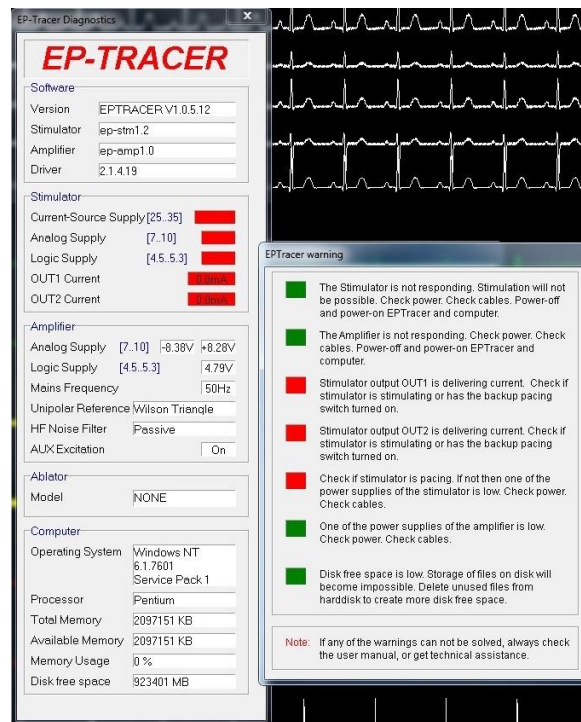# Amendment to hardware manual - Backup pacing

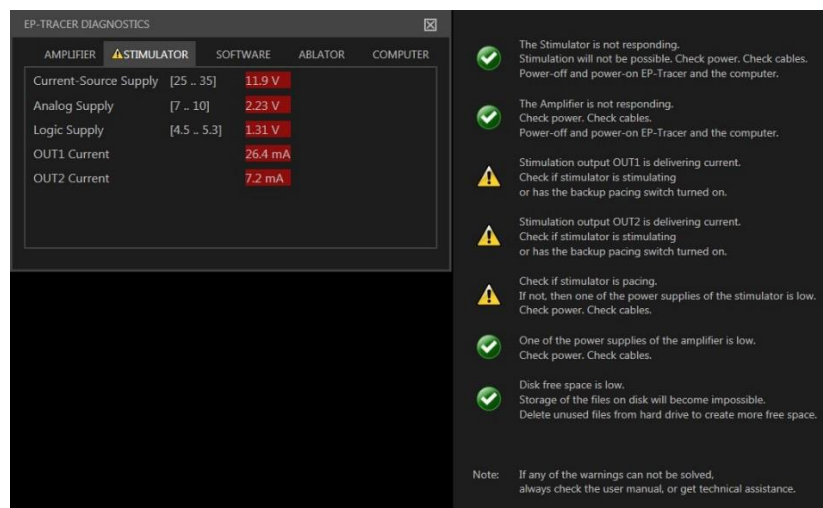*Figure 3 Diagnostics window (V1.0X) indicating backup pacing is active*

Figure 4: Diagnostics window (V2.0) indicating backup pacing is active

2.4   Deactivating backup pacing

To deactivate backup pacing, simply return the backup pacing switch to the original position (switch left). Once backup pacing is deactivated, the catheters may be reconnected to the INPUT channels of the CCBs and the procedure continued as normal.

Amendment to hardware manual - Backup pacing

2.5 Using backup pacing to override or stop a stimulation protocol

Should stimulation be active and when a PC failure occurs (software control no longer possible), backup pacing can be used to override and turn off the user-defined stimulation protocol.

The first stimulation pulse of the backup pacing protocol occurs 1s after backup pacing switch is turned ON, meaning backup pacing can be used to reset the stimulator without sending any backup pacing stimulation pulses. To do this simply flip the switch ON/OFF. In this scenario, stimulation will be stopped; i.e. the user defined protocol will not be reactivated.