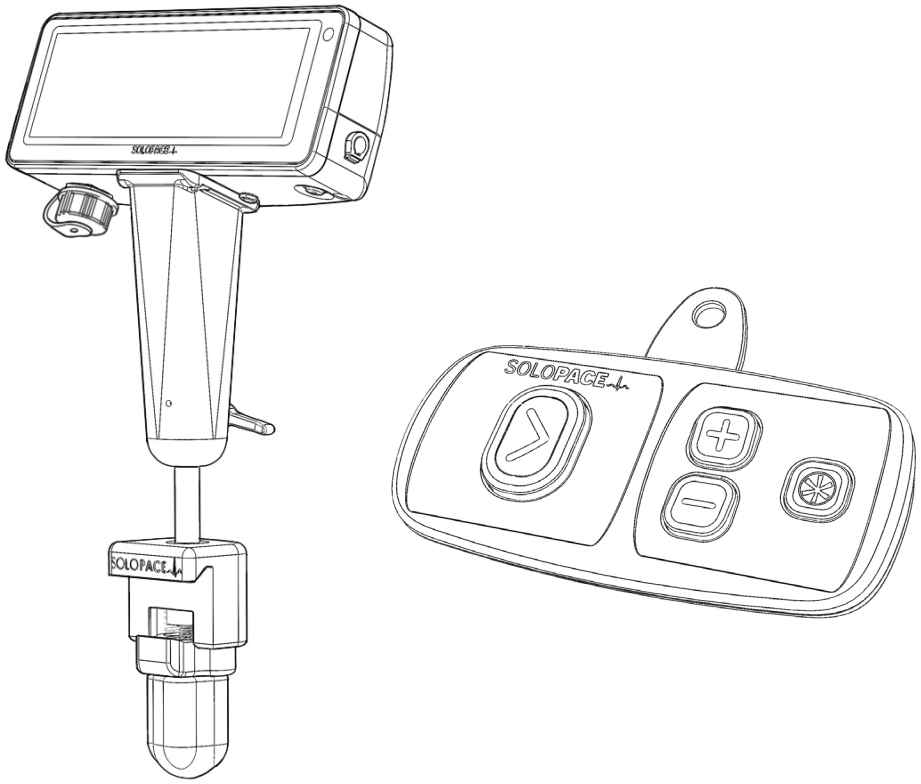
SOLOPACE Inc
CONTROL

Instructions for Use



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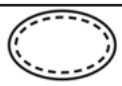
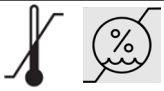
http://www.solopace.health IFU

version 104744-001 Rev D Draft

Solo Pace, Inc.
(Manufacturer)
1030 B Street
Petaluma
California, 94952

Contents

Symbols

Symbol	Symbol Name	Description
	Do Not Re-Use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do Not Re-Sterilize	Indicates a medical device that is not to be resterilized.
	Sterilized Using Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	Single Sterile Barrier System	Indicates a single sterile barrier system with protective packaging inside.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Consult Instructions For Use	Indicates the need for the user to consult the instructions for use.
	Catalog Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Caution: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Use-By Date YYYY-MM-DD	Indicates the date after which the medical device is not to be used
	Do Not Use If Package Is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened
	Manufacturer	Indicates the medical device manufacturer
	Distributor	Indicates the medical device distributor
	Date Of Manufacture	Indicates the date when the medical device was manufactured
	Temperature and Humidity Limit	Indicates the temperature and humidity limits to which the medical device can be safely exposed
	Keep Away From Sunlight	Indicates a medical device that needs protection from light sources
	Keep Dry	Indicates a medical device that needs to be protected from moisture
	Cardiac Floating	Identifies a cardiac floating power supply

1. Disclaimer

Please read all directions, warnings, and precautions prior to using the Solo Pace Control temporary external pacemaker. Failure to properly follow instructions may result in improper device function and/ or may lead to injury.

These instructions are not a substitute for appropriate training.

2. Intended Use

The Solo Pace Control external pulse generator is used with a cardiac pacing lead system for temporary single chamber ventricular pacing in a clinical environment by trained personnel. Train clinical personnel on the functionality and use of the external pulse generator prior to initial use of the device, as needed, and per clinic procedures. Contact your Solo Pace representative to schedule training.

The external pulse generator can be used where short-term pacing is indicated for therapeutic purposes. The external pulse generator must be used in an environment where the patient is monitored continuously to ensure that it is operating properly and delivering appropriate therapy to the patient.

Specific indications for temporary cardiac pacing include, but are not limited to, the following:

- Complete heart block
- Sinus bradycardia
- Sick sinus syndrome
- Bradycardia with congestive heart failure
- Support, management, and evaluation of a patient before permanent pacemaker implantation
- Support during permanent pacemaker replacement
- Cardiac complications during invasive or surgical procedures
- Interventional cardiology procedures where pacing is required.

3. Contraindications

There are no known contraindications for the use of temporary pacing as a means to control heart rate. However, the patient's age and medical condition may dictate the type of external pulse generator and lead system that the physician uses.

4. System Components

- External Pulse Generator (EPG) with cath lab table mount (Solo Pace PN 301377-001)
- Power Supply (2m cord Solo Pace PN 103571-001; 3m cord Solo Pace PN 104950-001)
- Instructions for Use (See front cover)

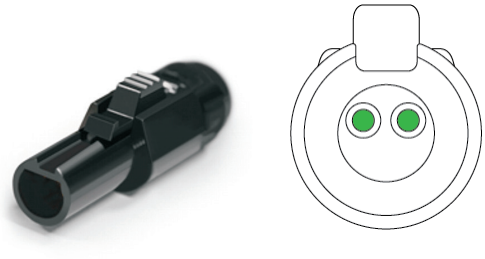
Single Use Components

Remote Control Module (RCM). Sterile, packaged separately from EPG. (Solo Pace PN 301374-001)

Compatible Accessories

(Not included with the Solo Pace Control system.)

- Sterile cardiac pacing patient cables that use 2-pin Smiths Interconnect D01 series plugs.



- Temporary cardiac pacing leads (applied parts).

5. UL Section

MEDICAL – APPLIED CURRENT/ENERGY EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH AAMI ES60601-1:2005/(R)2012 and A1:2012/(R)2012 and A2:2021

6. Warnings

Defibrillation – The Solo Pace Control temporary external pacemaker (EPG) is designed to withstand direct exposure to internal defibrillation discharge energies of to 50 J without damage. External defibrillation energy reaching the heart (and potentially carried to the EPG via pacing leads) is lower than with internal defibrillation.

Defibrillation paddles should be placed as far away from pacing leads as possible. Excessive energy from defibrillation may damage the EPG.

For patient safety, the EPG should be disconnected from the implanted pacing leads prior to defibrillation to prevent the possibility that defibrillation energy intended to be delivered to the heart is reduced.

AC mains – An indwelling pacing lead with an extension cable constitutes a direct, low-resistance current pathway to the myocardium. Extreme caution must be taken to properly ground all line-powered equipment used on or in the vicinity of the patient due to the danger of tachyarrhythmias resulting from alternating current leakage.

Cautery – Electrosurgical cautery can induce a current on pacing leads, which can cause pacemaker inhibition or tachyarrhythmias. Do not use such devices within 6 inches of the EPG or pacing leads.

RF or microwave ablation (high-frequency surgical equipment) – Ablation used in conjunction with the Solo Pace Control system may result in ventricular tachyarrhythmias, inhibited pacing, unintended tissue damage, damage to the EPG, and other adverse effects. Pacing leads are particularly vulnerable to induced currents from nearby pulse modulated ablation.

Using RF Ablation in conjunction with the Solo Pace Control system is not recommended. If RF Ablation is used, take precautions including:

- Maintain a backup temporary pacemaker in the event of damage to the Solo Pace system
- Ensure defibrillation equipment is readily available
- Do not allow ablation catheter to contact pacing leads
- Take care to position the ablation return electrode such that the return current path is kept away from pacing leads
- Closely monitor the patient during ablation

Electromagnetic interference (EMI) – The Solo Pace Control EPG operates primarily in synchronous demand (VVI) mode, which inhibits pulse generation based on sensed electrical signals such as small signals generated by cardiac activity. Excessive levels of EMI in the presence of the Solo Pace EPG or connected pacing leads may cause oversensing and inhibit pacing.

Sources of EMI that may temporarily inhibit the EPG should be kept at least 12 inches away from the system and its components. Potential sources of EMI include:

- High-frequency electrosurgical equipment
- Transcutaneous electrical nerve stimulators (TENS) devices
- Communication transmitters used in hospitals such as cellular phones, push-to-talk radios, and transmitters in emergency transport vehicles
- Magnetic resonance imaging (MRI) equipment
- Other diagnostic and monitoring equipment when used near the EPG or pacing leads

Pacing cable and leads connections – The patient cables should be connected to the EPG before the implanted lead is connected to the patient cable.

Implanted pacing leads – Terminal pins or exposed conductive portions of implanted pacing leads must not be touched nor allowed to contact electrically conductive or wet surfaces.

Electrostatic discharge (ESD) – Implanted pacing can carry ESD energy directly to the patient's heart. Touching a grounded metal or conductive surface is recommended before touching the EPG, patient cable, pacing leads, patient. Static charge on the patient may be neutralized by touching the patient, taking care not to touch near the pacing leads.

Cybersecurity – Device firmware is authenticated to protect firmware from tampering by unauthorized personnel. The firmware is not accessible to the user. Any changes to firmware must be made by Solo Pace qualified technicians. If any cybersecurity vulnerability or incident is detected, contact Solo Pace, Inc. or the distributor for immediate assistance.

7. Precautions

Backup battery – The EPG backup battery is not user serviceable. If the date is more than 8 years from the date of manufacture indicated on the device label, the backup battery may not provide the duration of pacing therapy [published herein] in the event that AC mains are lost or disconnected during a procedure. If [battery status unknown indicator] is displayed or the backup battery fails to charge completely, contact Solo Pace for service.

Cleaning and disinfection – Follow cleaning instructions in this manual and the sanitizing product manufacturer's instructions to avoid damage to the EPG.

Patient monitoring – The patient should be monitored continuously while the Solo Pace Control system is in use. Special care should be taken following defibrillation to ensure that the temporary external pacemaker system is functioning properly and delivering appropriate therapy to the patient.

Operating condition – Before each use, evaluate the EPG for damage or defects. Do not use the EPG if the enclosure or display are cracked, touchscreen is not responsive, connectors are damaged, rail or mast clamps fail to secure the EPG in position, or if there is any other apparent defect. Contact Solo Pace for service.

Pacing leads and cables – Ensure patient cable and pacing leads are sound and properly connected before use. Faulty leads, cabling or connections may result in failure to deliver appropriate therapy.

Capture check – Use the Capture Check Workflow Stage to ensure EPG settings are appropriate to capture and pace the patient's heart.

Sensitivity threshold – Maximum sensitivity settings (lowest setting in terms of mV) in patients with atrial flutter or fibrillation can result in pacemaker inhibition.

8. Use Environment Precautions

- The EPG is designed to be kept affixed to a cath lab table rail and to be connected to AC mains at all times. The backup battery may take up to 24 hrs to fully charge upon initial installation or following discharge.
- Do not drop or mishandle the EPG. Device damage may not be immediately evident. Carefully evaluate the EPG for damage before returning it to service.
- Do not spill fluids on the EPG. While the enclosure is designed to withstand limited spills, it is important to promptly wipe away any spilled fluids with a soft cloth to avoid damage from fluid ingress.
- Drape the EPG during procedures to minimize to avoid contamination with blood or other bodily fluids.
- Do not sterilize the EPG.

Other environmental factors may impact EPG function. The Solo Pace Control EPG is designed to be stored and used in a climate controlled hospital environment.

9. Adverse Effects

Temporary external pacemakers – Potential adverse effects include:

- Asystole in the event of sudden discontinuation of pacing
- Pacemaker inhibition in the presence of electromagnetic interference (EMI)
- Onset or exacerbation of tachyarrythmia
- Inappropriate pacing therapy, if sensing and pacing parameters don't provide sufficient margin for safety

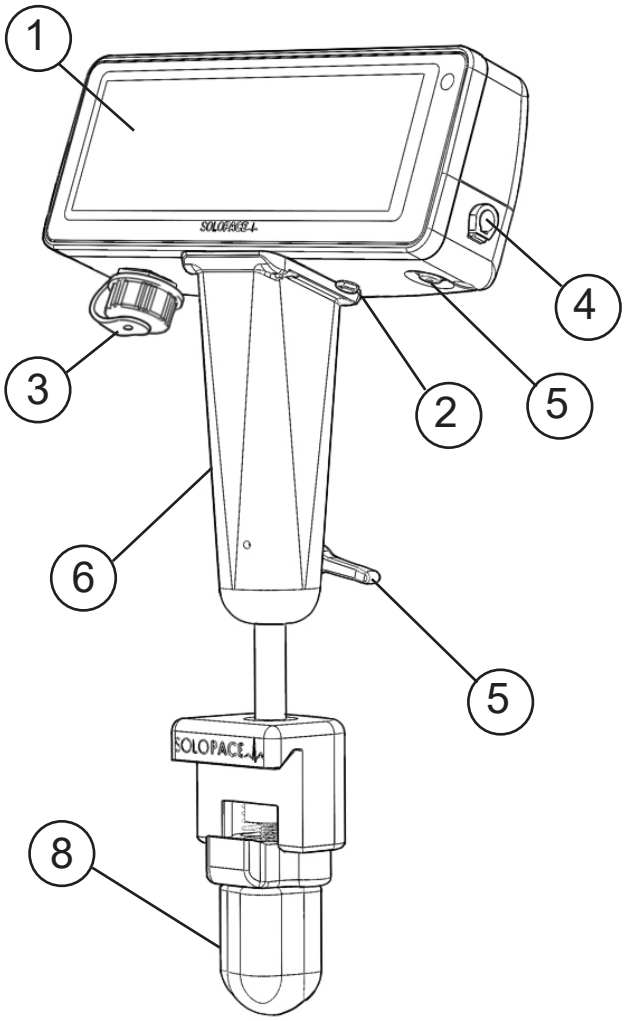
Patient cables and pacing leads – The Solo Pace Control System does not include patient cables or pacing leads. Take care to use only compatible cables and leads. Adverse effects from cables and leads include:

- Incompatible cable or lead connections, preventing initiation of pacing therapy
- Broken or intermittent conductors or connections, leading to sudden loss of sensing and/or pacing
- Perforation or tamponade
- Myocardial irritation leading to fibrillation
- Infarction
- Pericarditis
- Local tissue reaction/rejection
- Unintended muscle and/or nerve stimulation
- Infection

10. Device Specifications

Pacing Modes	VVI, VOO (Rapid Pacing mode only)		
Rate	Range [/minute]	Increments [/minute]	Tolerance
	30-200	10	± 2%
Pulse Output current	Range [mA]	Increments [mA]	Tolerance
During Capture Check	1-25	1	± 10% (200-1000 Ω)
Other Than Capture Check Mode (Fixed)	25	N/A	± 10% (200-1000 Ω)
Pulse Width (Fixed)		1.5ms ± 10%	
Sensitivity	Range [mV]	Increments [mV]	Tolerance
VVI mode	0.8-1.0 1.0-3.0 3.0-10 10-20	0.2 0.5 1.0 2.0	± 55%
Sense Blanking in VVI Mode		200ms +5/-30ms following pulse generation	
		150ms ± 15% following sensed event	
Runaway Pacing Rate Limite (rate limit for each EPG will fall within this range)			
Limit [min^{-1}]	Tolerance [min^{-1}]		
230	+10 / -20	If the pacing rate somehow exceeds the EPG's Runaway Pacing Limit (due to software malfunction, e.g.), pacing pulse output is disabled until the commanded rate falls below 200 min^{-1}.	
Backup Battery Specifications			
Backup Battery Performance Tolerances		Pulse Rate	Unchanged. Tolerances same as when operating on AC mains power.
		Pulse Output current	
		Pulse Duration	
		Sensitivity	
Backup Battery Operation Duration		45 minutes (under the follwing conditions)	
Condition	Value		
Pulse Rate	80/minute		
Display Brightness	10% (minimum setting)		
Date	Less than 8 years elapsed from date of manufacture shown on label		
Interference Reversion		VVI Mode: In the presence of electromagnetic or electrical energy sources, sensed interference may cause the EPG to become inhibited.	
		VOO Mode: In the presence of electromagnetic or electrical energy sources, the EPG will continue to produce pacing pulses at the commanded rate.	

11. EPG Components



1. Touchscreen Display
2. DC Power Input
3. USB Port (for manufacturer use only)
4. Pacing Patient Cable Port
5. Power Button
6. Mast
7. Mast Clamp Lever
8. Rail Clamp Knob

AC Mains Supply and Disconnection

The EPG power supply is rated for connection to single phase AC Mains supply voltage between 100 V and 240 V with an alternating frequency between 50 Hz and 60 Hz. It is rated for an input current of 0.6 A. The power supply outputs 2.5 A at 5 VDC.

To disconnect AC Mains, either remove the power supply plug from the AC wall outlet, or remove the power supply cord from the EPG DC Power Input (2, above). When mounting the EPG, take care that the DC Power Input (2) and cord remain accessible to allow for disconnection.

12. Storage

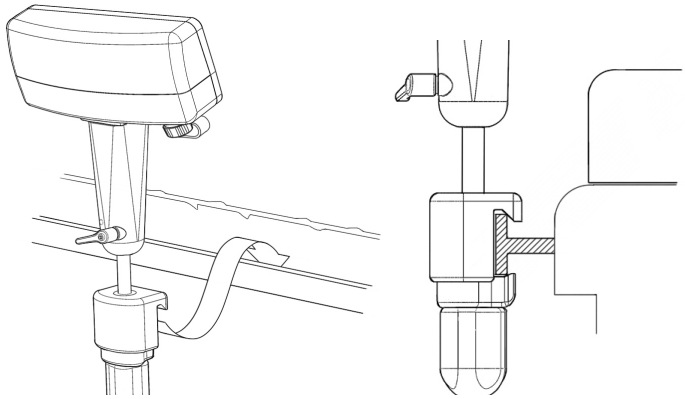
The EPG is intended to remain mounted to a cath lab table rail and plugged into AC mains between uses. This device is intended to be used and stored indoors in a typical hospital environment.

13. Initial Device Set-up

Mounting the EPG to the cath lab table rail

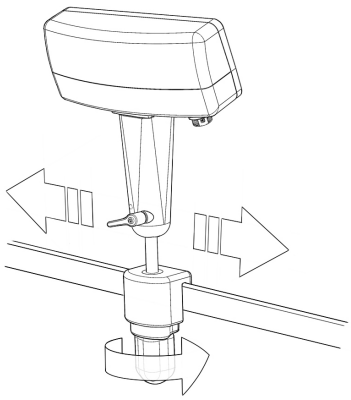
Open the rail clamp jaws by loosening the rail clamp knob (8). Fit the rail clamp jaws onto the table rail. Tighten the rail clamp knob to secure the EPG to the table rail.

Note: Turning the rail clamp knob (8) will also rotate the EPG head. It is recommended that the mast clamp lever (7) be loosened before opening/closing the rail clamp jaws to allow the mast post to rotate freely along with the rail clamp knob without also causing the EPG head to rotate.



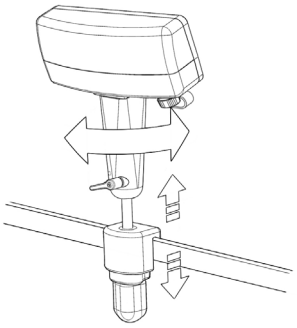
Moving the EPG position

To move the position of the EPG along the table rail, loosen the knob and hold the mast (6) of the device to slide it into the desired position. Tighten the rail clamp knob (8) to lock the EPG into position.



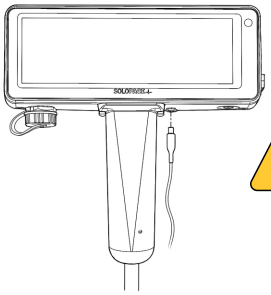
Adjusting the height and viewing angle

To adjust the height and viewing angle, loosen the lever at the top of the mast. Move the screen to the desired position. Hold the EPG in place while tightening the mast clamp lever to fix the position.

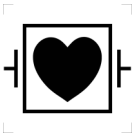


Connecting the power cord

The power cord receptacle is located on the bottom face of the EPG housing. Plug in the cord and route it behind the table rail. The cord will plug into a standard US 120-volt outlet.

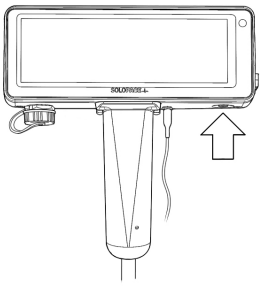


Only use a Solo Pace Control power cord that is demarked as “cardiac floating” with this symbol:



Powering on the EPG

To turn on the EPG, press the power button located on the bottom of the EPG. It is located to the right of the mast. When the power button is pressed to turn the EPG on, a ring around the button will light green indicating that the system is booting up. It may take a minute or two for the display to turn on and show a splash screen as the software finishes loading and the system is prepared for use.



Powering off the EPG

The EPG may be turned off by pressing the power button.

The EPG should not be turned off while pacing is active. If in the main pacing screen, terminate the procedure (see “End of Use”) and then press the power button to power the EPG off.

Turning off the EPG without exiting an active procedure requires pressing and holding the power button. Pressing and holding the power button during a procedure will cause a tone to sound for about ten seconds before powering off.

Potential power-related indications

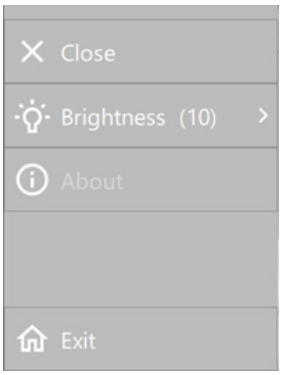
AC power disconnected
Reconnect AC power immediately. Displayed when AC Power is disconnected at any time while the device is operational. When the AC power is disconnected, initiation of a new procedure is not allowed

Battery depletion indicator
When the battery depletion indicator is lit, the system’s backup battery may not provide the operational duration indicated “Battery Backup Operation” section.

Battery status unknown
Ensure that AC Power is connected, and power cycle the system. If Battery Status Unknown indicator persists, remove the EPG from service and contact Solo Pace for repair.

14. Device Configuration

Navigation Menu



Navigation Menu shown in Procedure active mode

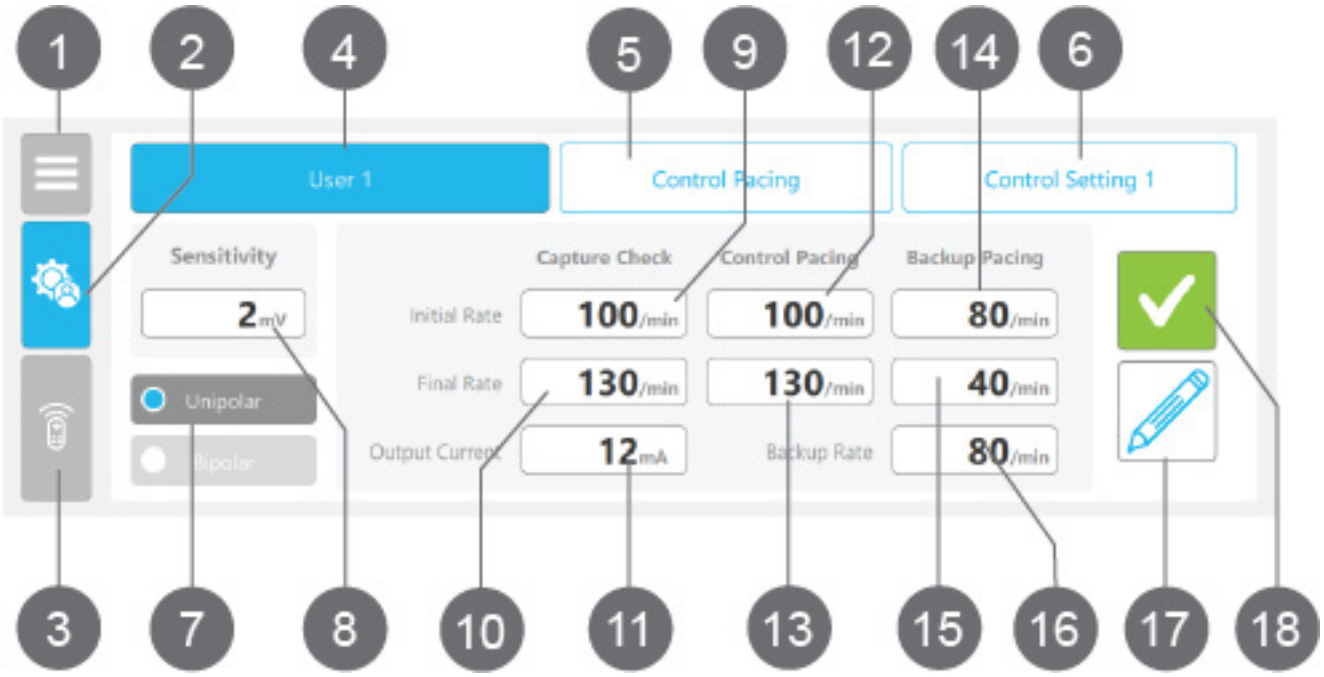
Close
- Closes the Navigation Menu
- Touching outside of the drawer also closes the Navigation Menu

Brightness
- Displays brightness setpoint
- Allows brightness setpoint adjustment (while AC Power is connected)
- Note: Brightness control is disbled while operating on backup battery power and brightness is set to minimum to conserve battery.

About
- Displays the About dialog
- Disabled during a procedure

Exit
- Displayed only during a procedure
- Exits a procedure following display and confirmation of the Procedure Exit Confirmation Dialog

15. Setting Selection Screen



1. Navigation Menu Button
This button accesses brightness settings and device information.

2. User Setting Button
Navigates to this User Setting Screen. No function here. See Main Procedure Screen (Sec. 21) for information.

3. RCM Status Indicator
Displays wether the RCM is:
- Disconnected (gray)
- Connecting (light green)
- Connected (green)
- Reconnecting (yellow)
- Disabled (red)

NOTE: When the User Profile Selection Screen is accessed while a procedure is active, touching the RCM Status Indicator brings up the RCM Status Menu as described in the Main Procedure Screen section.

4. User Profile Selection
Displays the User Name of the selected User Profile. Touching the User Name opens a User Profile Menu which lists the following:
- The unselected User Profiles (if more than one exists)
- The “Add User” option (if less than five User Profiles are Created)

While the User Profile Menu is displayed, touching the Add User option will create a new User Profile with default name, one default Rapid Pacing Workflow Preset, and one default Control Pacing Workflow Preset.

While the User Profile Menu is displayed, swiping left on an unselected User Profile exposes a delete button, which upon press will delete that unselected User Profile.

5. Pacing Strategy Selection
Displays the selected Pacing Strategy Name.
Touching the Pacing Strategy allows selection of either “Rapid Pacing” or “Control Pacing”. When Pacing Strategy is changed, the first Pacing Workflow Preset for the selected Pacing Strategy is loaded.

Touching the Pacing Strategy allows selection of either “Rapid Pacing” or “Control Pacing”. When Pacing Strategy is changed, the first Pacing Workflow Preset in the selected Pacing Strategy is loaded.

6. Pacing Workflow Preset Selection
Displays the selected Pacing Workflow Preset Name. Touching the Pacing Workflow Preset Name opens a Pacing Workflow Preset Selection Menu which lists the following:
- The unselected User Profiles (if more than one exists)
- The Add User option (if less than five User Profiles are Created)

While the Pacing Workflow Preset Selection Menu, touching an unselected Pacing Workflow Preset will make it the selected Pacing Workflow Preset for the displayed Pacing Strategy.

7. Unipolar/ Bipolar Selection
Selecting lead configurations sets a default Capture Check Output Current preset (11) appropriate for that configuration. The default Output Current (11) is higher for the Unipolar configuration to compensate for the increased impedance between the pacing electrodes.

- Unipolar: Default Output Current = 12 mA
- Bipolar: Default Output Current = 3 mA

Default values applied by this selection may be overridden by changing the Capture Check Output Current (11) to suit user preference.

8. Sensitivity Setting
Sets the threshold, above which an input signal is detected as a Sensed Event.

9. Capture Check Initial Rate
The pacing rate that is initiated at the beginning of the Capture Check stage. During a procedure, this preset value will be overridden and set equal to the Background Rate any time the Background Rate is changed.

10. Capture Check Final Rate
The maximal pacing rate that is achieved automatically during the Capture Check workflow in response to premature beats.

If the Background Rate exceeds this preset value at any point during a prcedure, this preset value will be temporarily overridden and set equal to the Background Rate until the Background Rate is reduced below this preset value.

11. Capture Check Output Current
The pacing output pulse amplitude in mA when Capture Check is active.

12. Control Pacing / Rapid Pacing Initial Rate
The pacing rate that is initiated at the beginning of the Control / Rapid Pacing stage.

13. Control Pacing / Rapid Pacing Final Rate

a. Control Pacing
The highest autonomous pacing rate allowable during Control Pacing in response to premature beats.

b. Rapid Pacing
The pacing rate set that the device quickly ramps to while Rapid Pacing is active.

If the Background Rate exceeds this preset value at any point during a prcedure, this preset value will be temporarily overridden and set equal to the Background Rate until the Background Rate is reduced below this preset value.

14. Backup Pacing Initial Rate
The pacing rate that is initiated at the beginning of the Backup Pacing stage.

15. Backup Pacing Final Rate
The pacing rate setpoint that the EPG decrements down to during the Backup Pacing workflow to test if pathological bradycardia is present.

16. Backup Rate
The pacing rate set to support presumed pathologic bradycardia if the patient fails the backup pacing workflow. If the Backup Rate is applied, the Background Rate will be set equal to the Backup Rate.

17. Edit Button
Touching the Edit Button allows the selected Pacing Workflow Preset to be edited.

18. Accept Button
Touching the Accept Button loads the settings for the Pacing Workflow Preset and displays either:

- The RCM Search Screen (if a procedure has not yet been initiated)
- The Main Procedure Screen (During a Procedure)

16. Backup Pacing

A workflow to immediately support the patients heart rate after interventional device therapy, which slowly decrements the pacing rate in order to determine if the patient is in heart block or another form of pathological bradycardia. If the patient's intrinsic heart rate is above the Backup Pacing Final Rate (15) and the EPG is inhibited, the system will navigate to Rapid or Control Pacing Ready state. If the EPG is not inhibited at the Backup Pacing Final Rate (15), then the Backup Rate (16) is applied.

17. Background Pacing

Background Rate is the pacing rate applied during Capture Check Ready, Control Pacing Ready, and Rapid Pacing Ready stages.

The default Background Rate at the start of each procedure is 50 min^{-1}, and may be altered through the course of a procedure by two different means:

1. Manual: (+) or (-) button press while in Ready state changes the Background Rate.

2. In the Backup Pacing Workflow Stage, a) if the system is uninhibited and the Backup Rate (16) is applied, that Backup Rate (16) becomes the new Background Rate, OR b) if a manual rate adjustment is made using (+) or (-) at any time during the Backup Pacing Workflow Stage, the manually adjusted Rate becomes the new Background Rate.

Preset override with background rate adjustments

Overridden Presets are indicated by a color change where those Presets are displayed below the associated Workflow Stage tile on the Main Pacing screen.

Capture Check Initial Rate (9): Any time the Background Rate is changed by any means, the Capture Check Initial Rate (9) is overridden. For the remainder of the procedure the Capture Check Initial Rate (9) will be equal to the Background Rate.

Capture Check Final Rate (10), Control / Rapid Pacing Initial Rate (12), Control / Rapid Pacing Final Rate (13): While the Background Rate is higher than any of these preset rates, that rate will be temporarily overridden and set equal to the Background Rate.

Once the Background Rate is reduced below a temporarily overridden rate, that rates preset value will once again be applied normally.

The preset parameters shown in blue below indicate a user override state

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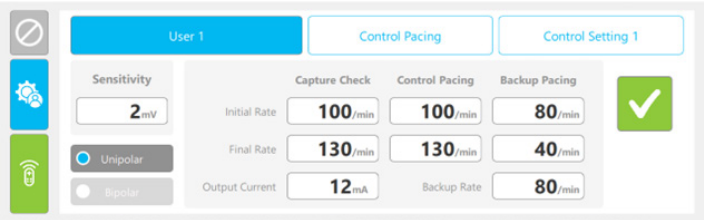
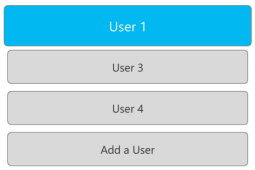
18. User Profiles

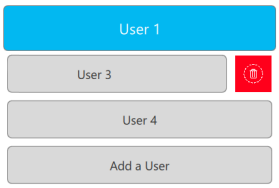
When the EPG is activated for use the device will display the User Profile Selection screen. The settings will default to the last Pacing Workflow Preset used. Confirm this selection by pressing the green box with the check mark on the touchscreen.



Example: User profile selection menu - During a procedure

To select a different user, press the User Profile Selection (4) to expand the popup.

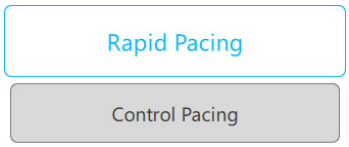


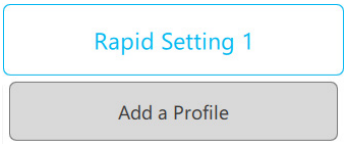


If there is more than one profile, swiping left on an unselected user allows deletion

***Note:** If there are less than 5 users, the last option allows adding a user profile. with a default User Name, one default Rapid Pacing Workflow Preset, and one default Control Pacing Workflow Preset..*

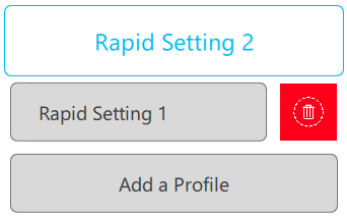
To select different Pacing Strategy, press the “Control” or “Rapid” pacing value to show popup





To select a different Pacing Workflow Preset, select “Control Setting 1” to expand popup.

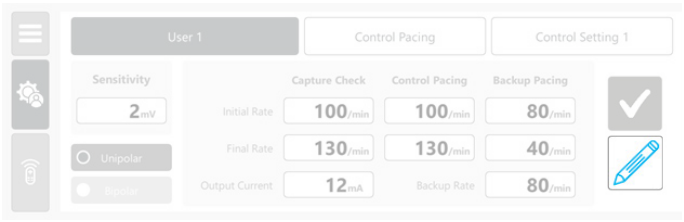
If there are less than 3 of these (per Control or Rapid Pacing), the last option allows adding.



If more than one Pacing Workflow Preset, swiping left on a profile allows deletion. Press the delete button to confirm.

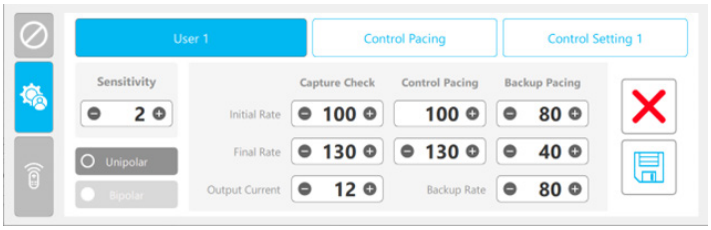
Pressing the Pencil Icon allows you to change the settings for the displayed User, Pacing Strategy, and Workflow Preset.

***Note:** Profile editing is disbled during a procedure.*



User profile edit button

The User profile edit screen allows the workflow presets for the current Pacing Workflow Preset Selection (6). Touching the Save Button saves all User Profile changes and displays the User Profile selection screen.



User profile edit screen

An on-screen keyboard appears when entering User Names, Pacing Strategy names, And Pacing Workflow presets.

User profile edit screen with keyboard

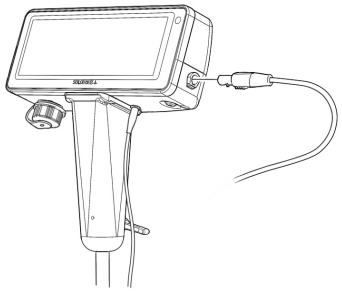
19. Preparation for Use

Shroud the EPG with the clear margin of a sterile drape. Make sure that the display screen is clearly visible from under the drape and the drape is flat on the touchscreen to allow for touch input.

Connecting leads to the patient cable

Refer to the “Compatible Accessories” section for information about patient cables.

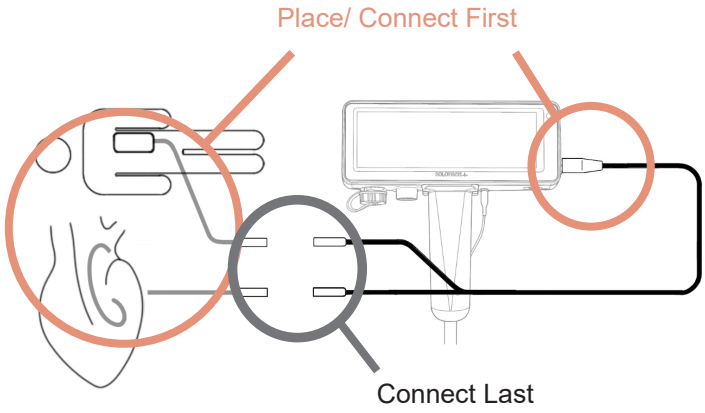
Connect the patient cable connector into the port on the right side of the EPG housing before making any connections to the pacing lead(s).



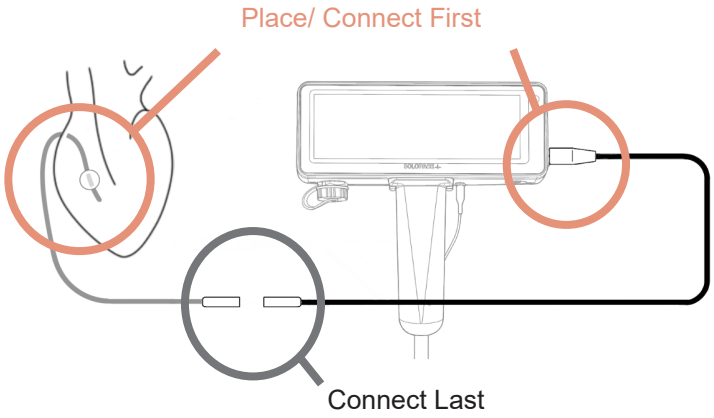
Place bipolar or unipolar ventricular pacing leads according to manufacturer instructions before making connection between patient cable and pacing leads.

Always connect patient cable to EPG before connecting pacing leads to patient cable.

Unipolar connection



Bipolar connection:

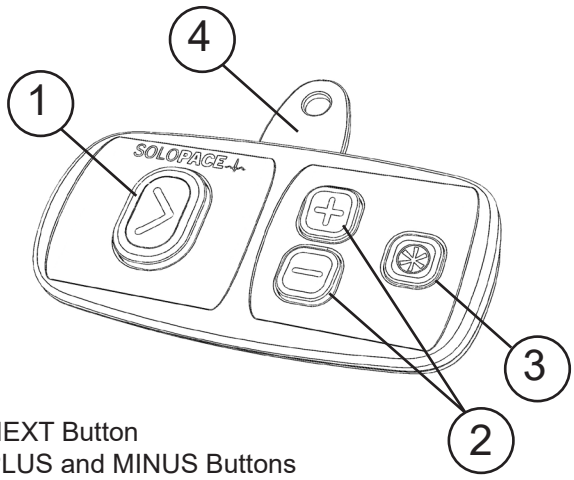


20. The Remote-Control Module (RCM)

Overview
The RCM is a streile, single-use controller that connects to the EPG via Bluetooth. A new sterile RCM must be paired to the EPG with each new application of the EPG.

The RCM will automatically disconnect from the EPG and disable itself after use.

During an extended procedure the button backlights on the RCM may dim, but RCM's ability to control the EPG will not be affected.



1. NEXT Button
2. PLUS and MINUS Buttons
3. ACCESSORY Button
4. Silicone Tag for clipping to drapes

RCM button function

Workflow Stage	Stage Status	Next (1)	Accessory (3)
Capture Check	Ready	Activate Capture Check	N/A
	Active	Proceed to Control / Rapid Pacing Ready	Increase pulse output current (mA)
Control Pacing	Ready	Activate Control Pacing	Begin Capture Check
	Active	Proceed to Backup Pacing	N/A
Rapid Pacing	Ready	Activate Rapid Pacing	Begin Capture Check
	Active	Proceed to Backup Pacing	N/A
Backup Pacing	Active	Proceed to Control / Rapid Pacing Ready	N/A

RCM +/- button function

Workflow Stage	Stage Status	Function
Capture Check Rapid Pacing Controlled Pacing	Ready	Adjust background pacing rate
Capture Check Rapid Pacing Controlled Pacing	Active	Adjust pacing rate Rate adjustment while Stage is Active interrupts and prevents any automated rate adjust-ments for the duration of that phase
Backup Pacing	Active	Adjust Rate Manual rate adjustment will stop automated ramp and prevent the Backup Rate from being applied in response to lack of inhibition (see Backup Pacing Workflow diagram). Manual rate adjustment will also change the Background Rate (see Background Rate section).

Pairing the remote-control module (RCM)

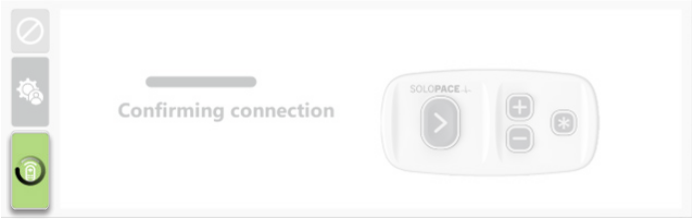
Ensure the EPG is on and is displaying the message Scanning for RCM before attempting to pair the RCM.

Carefully inspect the sterile packaging for damage. Do not use an RCM with damaged packaging. Remove the RCM from the sterile packaging. The pairing may be done prior to the patient's arrival.

Use standard aspectic practices to maintain RCM sterility

Power on the RCM by pressing any button. The Next button on the RCM should be flashing.

Press and hold the "Next" button until "Confirming Connection" is displayed on the screen.



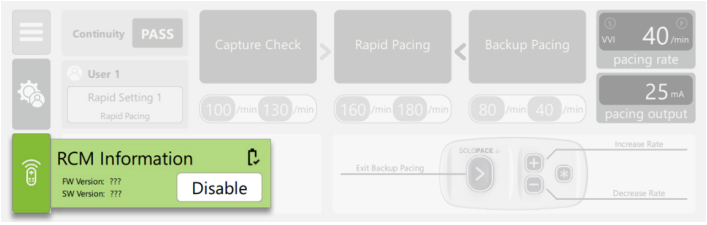
Blinking green screen when RCM is connecting

RCM has connected succesfully

RCM status

During a procedure the RCM Status Indicator also operates as a button which exposes the RCM Status Menu, which provides the following:

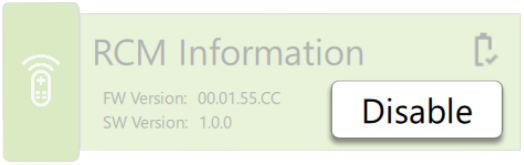
- RCM Version information
- RCM Good/Low indicator of the RCM battery
- Disable Button which, following user confirmation of the Confirm RCM Disconnect Dialog, disconnects the RCM and enables backup controls.

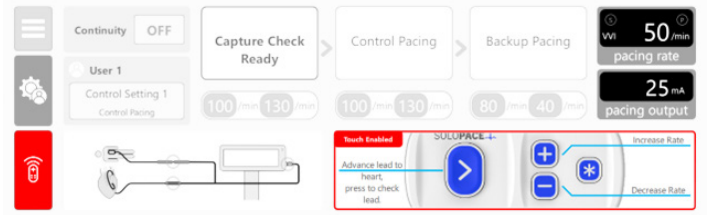


RCM Status Menu

Disabling the RCM

If the RCM becomes contaminated or otherwise unusable, the operator can disable it through the Solo Pace Control touchscreen. This step permanently disables the RCM and can be removed from the field. A new RCM cannot be paired during an active procedure.

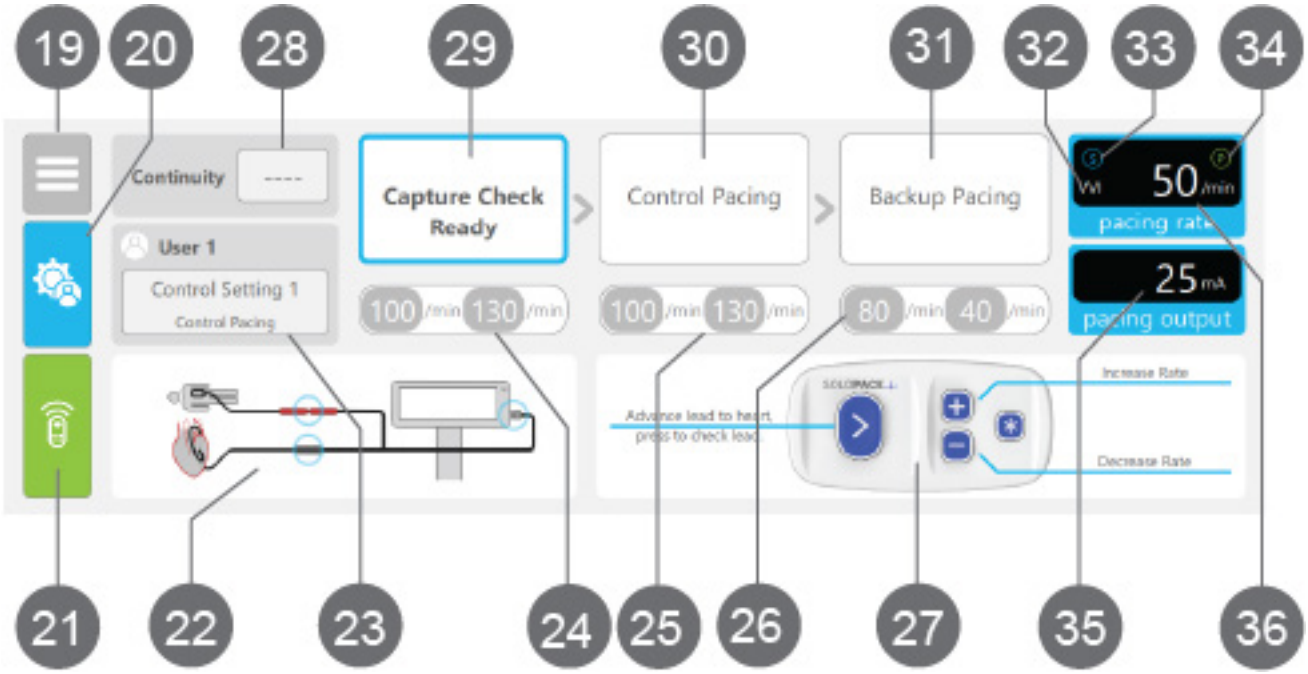




Back up controls enabled for the remainder of the procedure. RCM style controls will appear on the screen after the RCM has been disabled.

The EPG is not sterile. Any touchscreen interaction will require that sterile draping be present.

21. Main Procedure Screen



19. Navigation Menu Button
The navigation button menu provides access to brightness setpoint control and procedure exit.

20. User Settings Button
The user settings button allows selection of a different pacing workflow preset. See User Profile Screen for more information.
NOTE: User Profile Selection is only allowed when Capture Check, Control Pacing, or Rapid Pacing indicate "Ready.

21. RCM Status Indicator
The RCM status indicator displays the connection status of the RCM. Touching the RCM Status Indicator brings up the RCM Status Menu. See Section 20 for more information.

22. Instruction Panel
The instruction panel displays contextual information during a procedure.
NOTE: The instruction panel is blank when there are no information messages to display.

23. User Profile Selection Panel
The User Profile Selection Panel displays the current User Profile Selection (4), Pacing Strategy Selection (5), and Pacing Workflow Preset Selection (6).
Use the User Settings Button (2) to change selections during a procedure.

24. Capture Check Presets Indicator
The Capture Check Presets Indicator displays the Capture Check Initial Rate (9) and Capture Check Final Rate (10) for the current Pacing Workflow Preset Selection (6).

25. Control Pacing / Rapid Pacing Presets Indicator
The Control Pacing / Rapid Pacing Presets Indicator displays the Control Pacing / Rapid Pacing Initial Rate (12) and Control Pacing / Rapid Pacing Final Rate (13) for the current Pacing Workflow Preset Selection (6).

26. Backup Pacing Presets Indicator
The Backup Pacing Presets Indicator displays the Backup Pacing Initial Rate (14) and Backup Pacing Final Rate (15) for the current Pacing Workflow Preset Selection (6).
NOTE: The Backup Pacing Presets Indicator displays the Backup Pacing Backup Rate (16) if the Backup Pacing Backup Rate is applied during the Backup Pacing Workflow Stage.

27. RCM Instruction Panel
The RCM Instruction Panel displays the available RCM button functions based on the current Workflow Stage and Stage Status.

If the RCM becomes disconnected or the RCM is manually disabled, this panel enables touch capability to provide control of the EPG.

28. Continuity Status Indicator
The continuity status indicator displays whether the EPG detects electrical continuity on the pacing lead.

NOTE: Continuity indication may be unreliable below 2 mA.

29. Capture Check Indicator
The capture check indicator displays the status of the Capture Check Workflow Stage. See Capture Check Section 22 for more information.

30. Control Pacing / Rapid Pacing Indicator
The control pacing / rapid pacing indicator displays the status of either the Control Pacing Workflow Stage or the Rapid Pacing Workflow Stage based on the Pacing Strategy Selection (5)

31. Backup Pacing Indicator
The backup pacing indicator displays the status of the Backup Pacing Workflow Stage. See Backup Paing for more information.

32. Pacing Mode Indicator
Displays the pacing mode of operation, either VVI or VOO. The EPG operates in VOO mode only while the Rapid Pacing Workflow Stage is active.

33. Sense Indicator
The sense indicator flashes each time the EPG detects a sensed event.
NOTE: The sense indicator is removed when the pacing mode is VOO.

34. Pace Indicator
The pace indicator flashes each time the EPG delivers a pacing pulse.
NOTE: The pace indicator does not provide confirmation that the delivery of a pacing pulse results in a cardiac response.

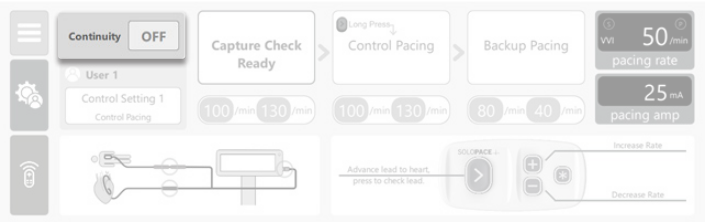
35. Pacing Rate Setpoint Indicator
The pacing rate setpoint indicator displays the current pacing rate (30 – 200 min-1) of the EPG.

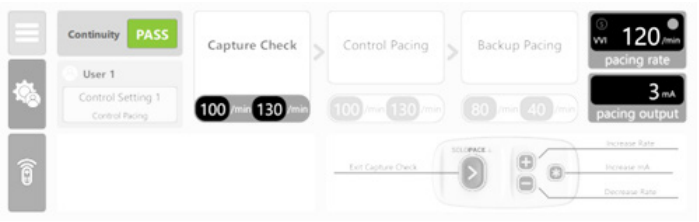
36. Pulse Amplitude Setpoint Indicator
The pulse amplitude setpoint indicator displays the current pulse amplitude of the EPG.

NOTE: The pulse amplitude setpoint can only be manually adjusted while the Capture Check Workflow Stage is Active.

Continuity status indicator

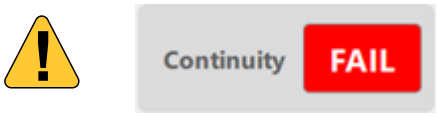
Once the RCM is paired, the EPG will automatically move to the Main Procedure Screen where the EPG is waiting and Ready to initiate Capture Check. Initially the Continuity indicator will display “----”. Pressing Next on the RCM will initiate Capture Check and and the Continuity inidcator will display PASS or FAIL for the remainder of the procedure.





Continuity is confirmed

Continuity Fail



If the continuity indicates “FAIL” then the operator should check all pacing circuit connections.

When the continuity test status indicator is FAIL for more than 30 minutes, the Timeout Pending dialog will be displayed.

NOTE: Continuity indicator may be unreliable when pacing at Output Currents below 2 mA.

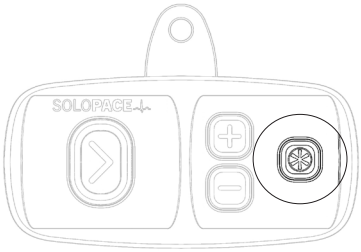
22. Capture Check

The Capture Check workflow stage is designed to support evaluation of pacing capture.

Ready
Prior to activation, while in Capture Check Ready state, the EPG will pace in VVI mode at the Background Rate.

While Ready pressing the User Settings button will allow changes to the User Profile Selection (4), Pacing Strategy Selection (5), and/or Pacing Workflow Preset Selection (6).

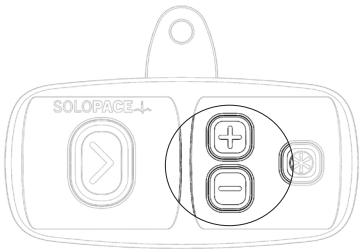
Active
Press the “Next” button to activate Capture Check. Upon activation of Capture Check, the pacing pulse amplitude is reduced from 25 mA to the Capture Check Output Current (11) preset and pressing the RCM ‘accessory’ button (3) will increase the amplitude in increments of 1 mA.



Accessory button increases pulse output current

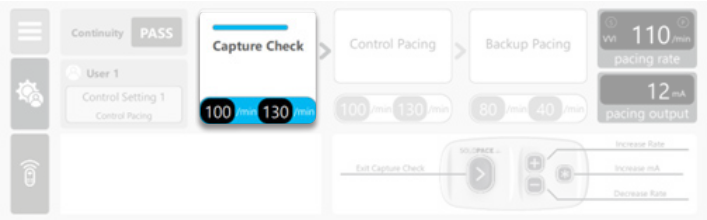
Activation of Capture Check also sets the pacing rate to the Capture Check Initial Rate (9). If inhibited, the EPG will increase the rate in increments of 10 min^{-1} until uninhibited or until the Capture Check Final Rate (10) is reached.

The rate may be manually changed by pressing the 'plus' or 'minus' buttons. Manual adustments to the pacing rate during Capture Check will disable the automated inhibition based rate increases.

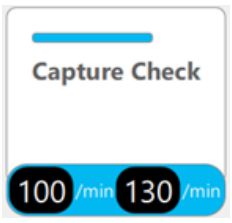


Plus and Minus button adjust pacing rate

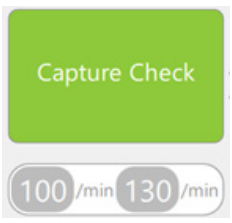
Confirmation period



Once uninhibited, a short timer will begin counting down. If the EPG becomes inhibted, the timer will pause until the EPG is once again uninhibited.



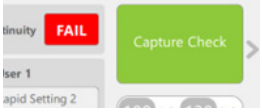
Confirming



Complete

Upon completion of the confirmation period, the EPG will progress to the Control or Rapid Pacing Ready Stage, depending on which Pacing Strategy (5) is selected.

NOTE: Capture Check may still indicate "Complete" with no continuity

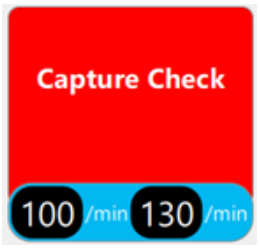


Inhibition during Capture Check

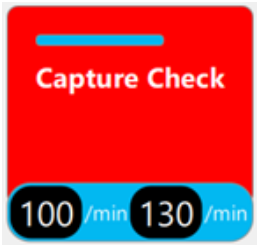
If the EPG remains or becomes inhibited after reaching the Capture Check Final Rate, the Capture Check tile will turn red.

If the pacing rate is manually adjusted via the RCM, automated rate incrementation will be disabled. If the EPG remains or becomes inhibited in this scenario, the same red tile indication will be diplayed.

To resolve, determine why the EPG is inhibited.



Inhibited



Confirmation resumed

Once the EPG is uninhibited, the confirmation period will resume.

If capture is not established, check for

- Pacing circuit continuity
- Sufficient pulse output current
- Pacing rate above intrinsic rate
- Effective pacing lead positioning

The Capture Check stage can be skipped without successful confirmation by pressing the 'Next' button to proceed to Control or Rapid Pacing Ready.

23. Rapid Pacing

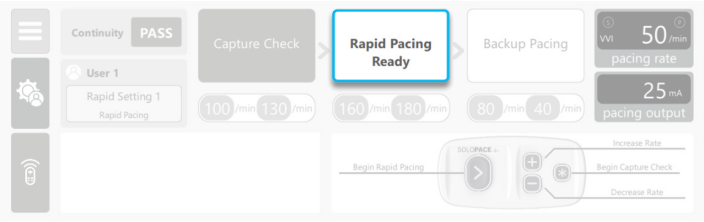
The Rapid Pacing workflow is designed to optimize maximally hypotensive hemodynamics for accurate interventional device placement.

Ready

Prior to activation, while in Rapid Pacing Ready state, the EPG will pace in VVI mode at the Background Rate.

While ready pressing the Accessory button will reactivate Capture Check.

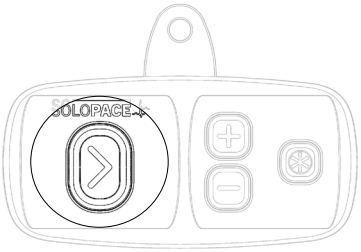
While Ready pressing the User Settings button will allow changes to the User Profile Selection (4), Pacing Strategy Selection (5), and/or Pacing Workflow Preset Selection (6).



The blue border will pulse to emphasize where the user is in the Workflow

Active

Press the “Next” button to activate rapid pacing. Activation changes the pacing mode to asynchronous (VOO) pacing and quickly ramps from the Rapid Pacing Initial Rate (12) to Rapid Pacing Final Rate (13).

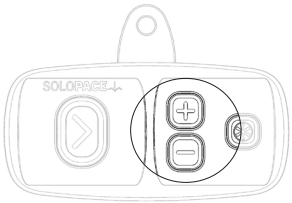


Next button activates Rapid Pacing

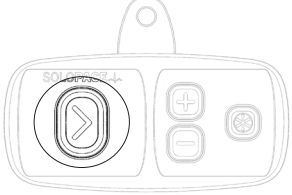
Rapid Pacing tile will flash green and white when:

- Rapid Pacing Final Rate (13) has been reached, or
- Pacing rate has been manually adjusted

Press the ‘Plus’ or ‘Minus’ button to manually adjust the pacing rate. Each button press will increase or decrease the pacing rate by 10 min^{-1}. Manual adjustment following activation will disable automated ramping to Rapid Pacing Final Rate (13).



Press the ‘Next’ button To exit the Rapid Pacing stage and proceed to Backup Pacing.



24. Control Pacing

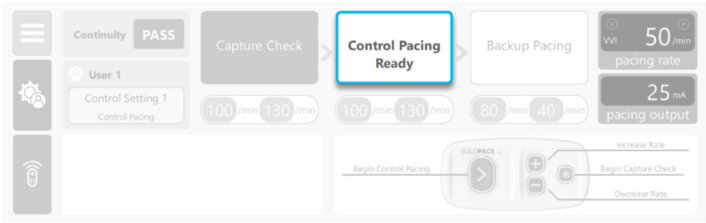
The Control Pacing workflow is designed to supress premature beats by automatically incrementing the pacing rate when a premature beat is sensed, up to a preset limit, in order to optimize the stability of interventional device placement. Use Control Pacing in situations where Rapid Pacing-induced hypotension isn’t required.

Ready

Prior to activation, while in Control Pacing Ready state, the EPG will pace at the Background Rate.

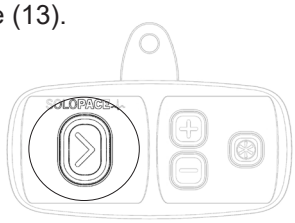
While ready pressing the Accessory button will reactivate Capture Check.

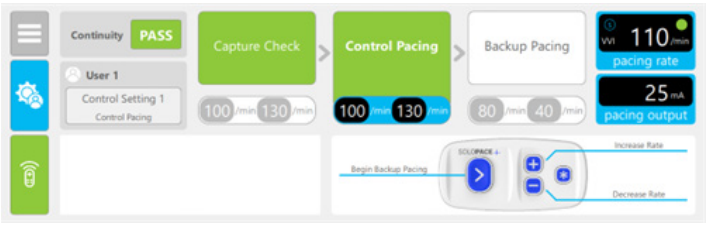
While Ready pressing the User Settings button will allow changes to the User Profile Selection (4), Pacing Strategy Selection (5), and/or Pacing Workflow Preset Selection (6).



Active

To apply Control Pacing when in control pacing mode press the “Next” button. The EPG will set the pacing rate to the Control Pacing Initial Rate (12). The EPG will then increase the rate in increments of 10 min^{-1} in response to sensed events, up to the limit established by the Capture Check Final Rate (13).



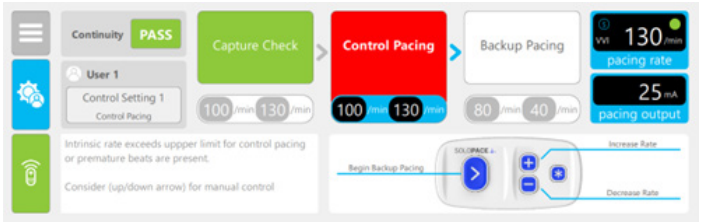


Indication when the Control Pacing Workflow Stage is Active and still ramping to the Control Pacing Final Rate. Ramping only increments the rate if a PVC/cardiac event is sensed

Active (PVC indicate)
Indication when the Control Pacing Workflow Stage is Active and the pacing rate is lower than the Control Pacing Final Rate, but an inhibition was detected.

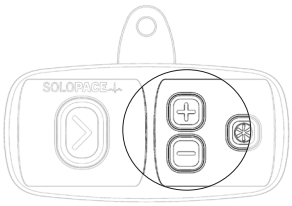
NOTE Manually adjusting pacing rate while Control Pacing is Active will no longer indicate.

Upper limit reached or manual control and inhibited

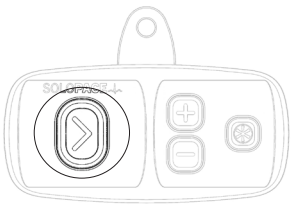


NOTE: This is an indication to use Manual Control.

If the pacing rate requires adjustment while Control Pacing is active, press the “Plus” or “Minus” buttons. Each button press will increase or decrease the pacing rate by 10 pulses per minute.



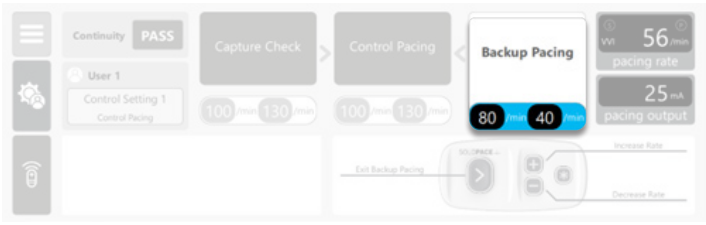
To stop controlled pacing press the “Next” button



25. Backup Pacing Mode

The EPG defaults to Backup Pacing Mode when control or rapid pacing has been deactivated.

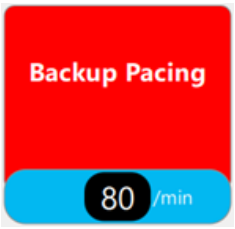
Active
Indication when the Backup Pacing Workflow Stage is Active and still ramping to the Backup Pacing Final Rate.



Complete
Indication when the Backup Pacing Workflow Stage is Active and has reached the Backup Pacing Final Rate while being consistently inhibited for the required dwell time.

NOTE: Once this status is reached, the system will automatically transition to Rapid Pacing or Control Pacing Ready following a 10 second timed delay (whether inhibited or not).

No inhibition at backup pacing
Indication when the Backup Pacing Workflow Stage is Active and has reached the Backup Pacing Final Rate but has not been inhibited for the required dwell time.



In this example the new background rate will be 80/min

NOTE: When backup pacing fails the rate at which the failure occured will become the new background rate.

26. End of Use

Bipolar
To end all pacing when in bipolar mode, disconnect the lead from the patient cable connector.

Unipolar
To end all pacing for unipolar, disconnect the guidewire from the patient cable connector.

In both cases the EPG will display a continuity failure.

Once therapy has ended, disconnect the sterile patient cable and discard. Exit the procedure by selecting Exit from the Navigation Menu (1) on the Main Procedure Screen. When the User Profile Selection Screen is displayed, confirm the RCM is flashing LEDs in a circular pattern and then discard the Remote-Control Module (RCM).

The EPG should remain connected to AC mains between uses to maintain battery life and battery charge level.

27. Backup Battery Operation

In order to maintain a fully charged backup battery, the Solo Pace Control EPG should remain connected to AC mains at all times.

The Solo Pace Control EPG is designed to operate on AC mains power and will not permit a procedure to begin without AC mains connected. Take careful note of any power related notifications (see alert indicators section).

If AC Mains power is disconnected or otherwise lost during a procedure, a fully charged backup battery will automatically engage to provide power to continue delivering pacing therapy. Following disconnection or loss of AC Mains power, when the Battery Depletion Indicator lights, the backup battery will provide energy to continue pacing for 45 minutes under the conditions described in Sec. 10 Delvice Specifications.

The backup battery in the Solo Pace EPG, like all rechargeable batteries, has a limited life. After 8 years from the date of manufacture shown on the device and packaging labels, the battery should not be relied upon to provide the duration of backup operation described herein. Contact Solo Pace for service.

If either the Battery depletion or Battery status unknown indicators are displayed prior to the disconnection or loss of AC mains power, the backup battery charge may not provide backup power to continue pacing.

28. Device Maintenance

Cleaning
Clean and disinfect the EPG whenever visibly soiled or when required by the cleaning protocols established at the facility where the system is being used.

1. Disconnect patient cable.

2. Wipe down device (excluding display screen) with Super Sani-cloth Germicidal Disposable Wipes or equivalent following cleaning product manufacturer instructions.

3. Wipe down display screen using a 70% isopropyl alcohol solution.

- Do not immerse the EPG in water or cleaning agents.
- Do not use automated machine washers.
- Do not sterilize the EPG by ethylene oxide, gamma radiation or steam-sterilization (autoclave).

Damage to the EPG may occur using these methods.

Keep device plugged into AC power between uses.

If fluid spills directly onto the EPG it should be wiped with a clean dry towel.

Always unplug the power adaptor from the EPG before performing any maintenance tasks.

Do not attempt to open or modify the EPG or RCM devices as it would pose a safety risk.

The Remote-Control Module is for single use only. Discard the device after treatment.

29. Disposal

Dispose of RCMs and EPGs in accordance with local and site guidelines. Take note of the following when disposing:

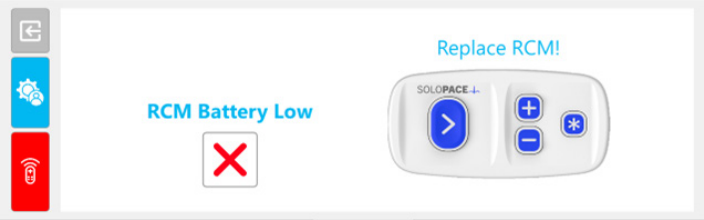
- EPG and RCM may be contaminated with blood or other potentially infectious materials after use.
- The EPG contains both lithium metal (coin cell) and lithium ion batteries.
- The RCM contains litium metal (coin cell) batteries.

30. Troubleshooting

Remote control module

RCM battery low

If the “RCM battery low” screen comes up during pairing, discard the RCM. A new RCM will need to be retrieved and the pairing process started again. Make sure to check the expiration date of the RCM before pairing.



RCM failed to connect

If the “RCM Connect Failed” screen comes up during pairing, retry connection by selecting the back button in the upper left hand corner.

If RCM Connect Failed screen is displayed again, power cycle the EPG and attempt connection again.

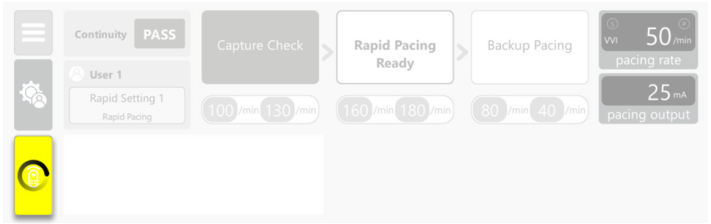
If the RCM is still unable to connect, discard the RCM. A new RCM will need to be retrieved and the pairing process started again. Make sure to check the expiration date of the RCM before pairing.

Multiple RCMs found

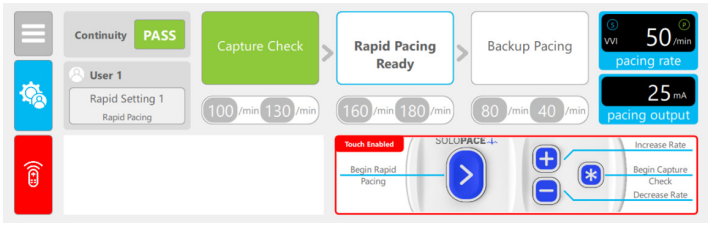
If the “Multiple RCMs found” screen comes up during pairing, release the Next button on the RCM and wait for at least 20-30 seconds before holding the Next button again.

RCM connection interruption

The RCM Status Indicator indicates whether it is connected and active. Should the RCM become disconnected, the EPG will try to re-establish a connection within five seconds. No user action is required during this attempt. After five seconds without a successful reconnection, the EPG will automatically disable the RCM. The RCM will not be functional for the remainder of the procedure and can be discarded. The operator will be prompted to use the on-screen control interface



Lost connection indicator. Device attemting to re-connect



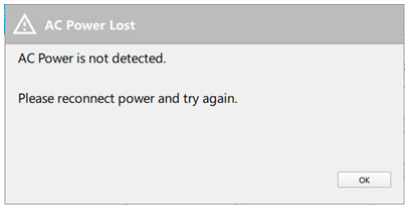
Connection lost. Backup controls appear on the EPG screen.

The EPG is not sterile. Any touchscreen interaction will require that sterile draping be present.

31. Dialogs and Popups

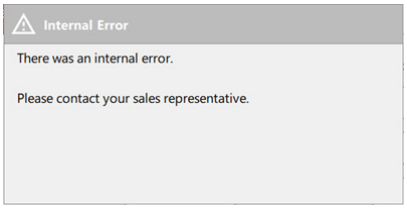
AC power lost

While AC Power is lost and the EPG is not operating as a pacemaker, i.e. the pacemaker is in its Idle State, the EPG will display the AC Power Lost Dialog upon click of the Accept Button while on the User Profile Selection Screen.



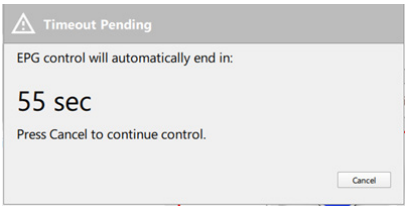
Internal error

The Internal Error Dialog is displayed when there is an internal error. When this dialog is displayed, the EPG will continue operating in its last commanded state. This error requires a power cycle of the EPG to clear.



Timeout pending

While a procedure is Active and the Continuity Test Status Indicator has been in the failed state for 30 consecutive minutes, the EPG will display the Timeout Pending Dialog. The dialog will count down an additional 5 minutes. If the Cancel button is pressed, the 30-minute timeout period is restarted. If not canceled, the Procedure Timeout Reached Dialog will be displayed.



Timeout reached

When the Timeout Reached Dialog is displayed following timeout of a procedure, the EPG will remain in its last functional operating state, that is, it will continue to operate as a pacemaker. Upon user confirmation, the dialog is dismissed, and the EPG returns to the idle state.

NOTE: Continuing to operate as a pacemaker until user confirmation is to ensure pacing continues until the user acknowledges the issue.

Alert indicators

AC power disconnected indicator
Reconnect AC power immediately. Displayed when AC Power is disconnected at any time while the device is operational. When the ac power is disconnected, initiation of a new procedure is not allowed

Battery depletion indicator
When the battery depletion indicator is lit, the system's backup battery may not provide the operational duration indicated "Battery Backup Operation" section.

Battery status unknown indicator
Ensure that AC Power is connected, and power cycle the system. If Battery Status Unknown indicator persists, remove the EPG from service and contact Solo Pace for repair.

USB device present indicator
Indicated when a USB device is inserted into the USB port.

Power down alert

If the power button is pressed and held while a pacing procedure is active, a tone will sound for about 10 seconds before powering down.

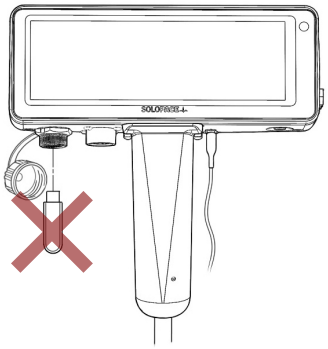
32. Appendix

USB - For manufacturer Use Only

Firmware updates

The Solo Pace EPG has a USB port that is only used for firmware updates. These updates are only done by a qualified Solo Pace representative.

Do not insert a USB device into the Solo Pace Control USB port.



Indicated when a USB device is inserted into the USB port.

33. Technical Information

Electromagnetic Compatibility

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Solo Pace System is intended for use in the electromagnetic environment specified below. The user of the Solo Pace System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
Radiated Emissions CISPR 11	Group 1 Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment, this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Conducted Emissions CISPR 11	Group 1 Class A	
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Solo Pace System system is intended for use in the electromagnetic environment specified below. The user of Solo Pace System system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±2, ±4, ±6, ±8 kV Contact, ±2, ±4, ±8, ±15 kV Air	IEC 60601 - B	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, humidity should be at least 30%. Unit may require power cycle to clear disturbances caused by ESD.
Electrical fast transient/ burst IEC 61000-4-4	± 2kV, AC Power	IEC 60601 - A	Mains power quality should be that of a typical hospital environment.
	± 1kV Signal and I/O Cables	IEC 60601 - A	
Surge IEC 61000-4-5	± 2 kV Line 1 to Earth Neutral to Earth	IEC 60601 - A	Mains power quality should be that of a typical hospital environment.
	± 1 kV Line 1 to Neutral	IEC 60601 - A	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	100% reduction for 0.5 cycles	IEC 60601 - A	Mains power quality should be that of a typical hospital environment. To use during power outages, ensure the internal battery is fully charged.
	100% reduction for 1 cycle	IEC 60601 - A	
	30% reduction for 25/30 cycles	IEC 60601 - A	
	100% reduction for 250/300 cycles	IEC 60601 - A	

Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	100% reduction for 0.5 cycles	IEC 60601 - A	Mains power quality should be that of a typical hospital environment. To use during power outages, ensure the internal battery is fully charged.
	100% reduction for 1 cycle	IEC 60601 - A	
	30% reduction for 25/30 cycles	IEC 60601 - A	
	100% reduction for 250/300 cycles	IEC 60601 - A	
Proximity magnetic fields IEC 61000-4-39	8 A/m 30kHz Continuous	N/A	Magnetic fields from hospital equpiment are not expected to affect the system.
	65 A/m 134.2kHz, Pulse Modulation 2.1kHz	IEC 60601 - B	
	7.5 A/m 13560 kHz, Pulse Modulation 50 kHz	IEC 60601 - A	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	IEC 60601 - A	Magnetic fields from hospital equpiment are not expected to affect the system.
Conducted immunity IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	IEC 60601 at 6Vrms - A	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Solo Pace System system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Field strength from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
	6 Vrms 1.9, 3.75, 5.35, 6.798825, 7.15, 10.125, 13.56, 14.1, 18.12, 21.2, 24.94, 27.12, 28.82, 40.68, 52 MHz	IEC 60601 - A	
Radiated RF immunity IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	IEC 60601 - A	
	28 V/m 450, 810, 831.5, 870, 897.5, 930, 1720, 1845, 1970, 2450 MHz	IEC 60601 - A	
	27 V/m 385 MHz	IEC 60601 - A	
	9 V/m 680.6, 710, 719.5, 745, 780, 782, 793, 831.5, 847, 1702.5, 1747.5, 1882.5, 1965, 2310, 2535, 3625, 5240, 5500, 5785 MHz	IEC 60601 - A	
	13 V/m 1965, 2350, 2595 MHz	IEC 60601 - A	
	18 V/m 2593.01, 3500, 3600, 3800 MHz	IEC 60601 - A	
	20 V/m 1747.5, 1882.5 MHz	IEC 60601 - A	

Radiated RF immunity IEC 61000-4-3 (continued)	9 V/m 680.5, 719.5, 782, 793, 847, 1702.5, 2310, 2535, 3625 MHz 10 V/m 5935 MHz 13 V/m 1965, 2350 MHz 18 V/m 2593.01, 2595, 3500, 3600, 3800, 3840 MHz 20 V/m 1747.5, 1882.5 MHz 28 V/m 831.5, 897.5 MHz	5G &Wi-Fi 6E	(Continued from previous page. See RF compatability, guidance, and interference note above)
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Solo Pace System System is used exceeds the applicable RF compliance level above, the Solo Pace System System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Solo Pace System System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

FCC Caution

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. The end user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
The device is designed to meet the requirements for exposure to radio waves established by the Federal Communications Commission (USA) RF Exposure Guidelines. The System was tested by a certified test lab and found to be safe under these limits.

Wireless Communications

Guidance and Manufacturer's Declaration - Wireless Communication	
The Solo Pace System uses BLE v5.0 for wireless communication between the EPG and RCM.	
Transmission Power	RCM: 6 dBm (peak) EPG: 10 dBm (peak)
Data Rate	Up to 1 Mb/s
Frequency Band	2400-2483.5 MHz, 40 channels, 2 MHz Bandwidth
Modulation	Gaussian Frequncy Shift Keying

34. Essential Performance

The Solo Pace Control System adopts the following Essential Performance characteristics described by IEC 60601-2-31:

- Per subclause 201.11.8, the Solo Pace Control System provides power-related indications to clearly indicate when AC mains power is to be restored.

- Per subclause 201.12.1.101 and 201.12.1.102, the Solo Pace Control System instructions for use specifies the tolerances for pulse amplitude, pulse duration, pulse rate, sensitivity, and blanking periods.

- Per subclause 201.12.4.101, deliberate action is required to change system settings

- Per subclause 201.12.4.102, the Solo Pace Control System pulse rate, pulse amplitude, pulse duration, and sensitivity remain within specified tolerances upon onset of the Battery Depletion Indicator

- Per subclause 201.12.4.103, the Solo Pace Control System is equipped with a runaway protection feature as described in the Specifications section

35. IEC 60601-1 Classifications

- EPG is Class II when connected to AC Mains / Internally Powered when not connected to AC Mains

- RCM is Internally Powered

- Applied Parts are Type CF, Defibrillation-Proof

- Ingress Protection is per IEC 60601-2-31, subclause 201.11.6.5

- System is classified for Continuous Operation

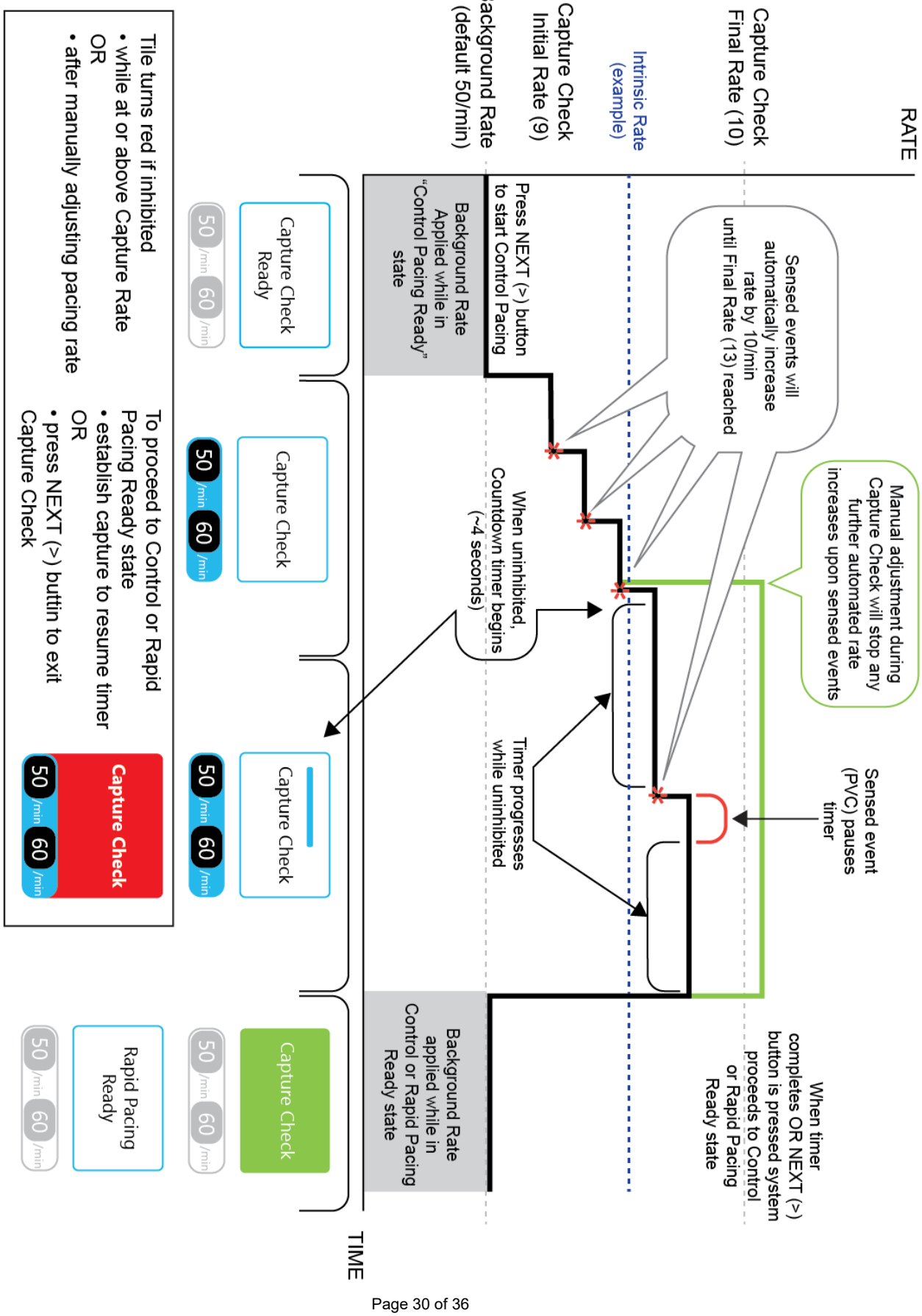
- RCM is sterilized by exposure to ethylene oxide gas (may not be resterilized)

36. Use, Storage, and Shipping Conditions

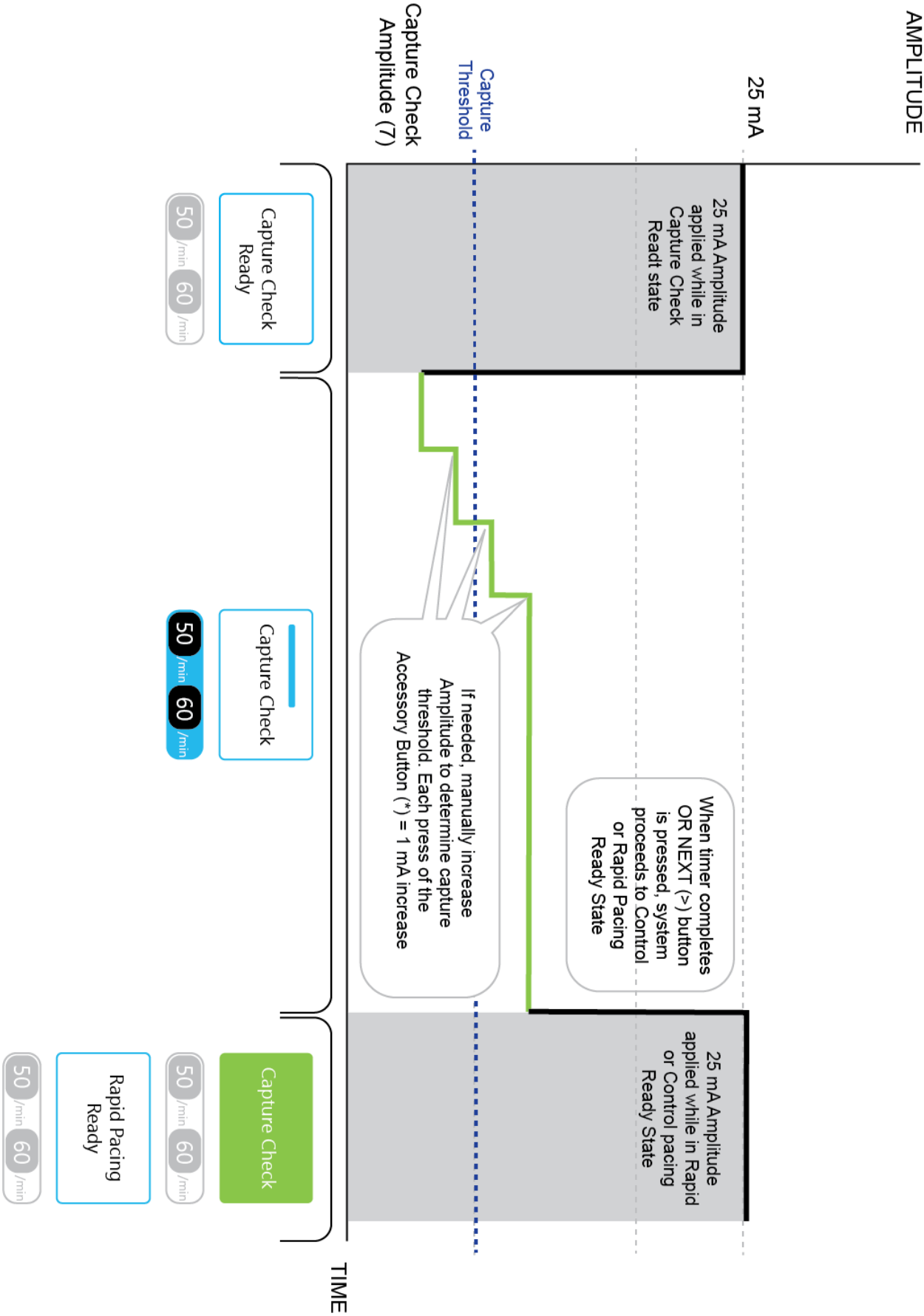
	EPG	RCM
Use	Temperature: 5°C to 30°C Pressure: 70 kPa to 110 kPa Relative Humidity: 10% RH to 90% RH	Temperature: 5°C to 30°C Pressure: 70 kPa to 110 kPa Relative Humidity: 10% RH to 90% RH
Storage	Temperature: 5°C to 30°C Relative Humidity: 10% RH to 90% RH	Temperature: 5°C to 28°C Relative Humidity: 40% RH to 60% RH
Shipping extremes (up to 72 hrs)	Temperature: -18°C to 60°C Relative Humidity: up to 90% RH	Temperature: -18°C to 60°C Relative Humidity: up to 90% RH

37. Function Diagrams

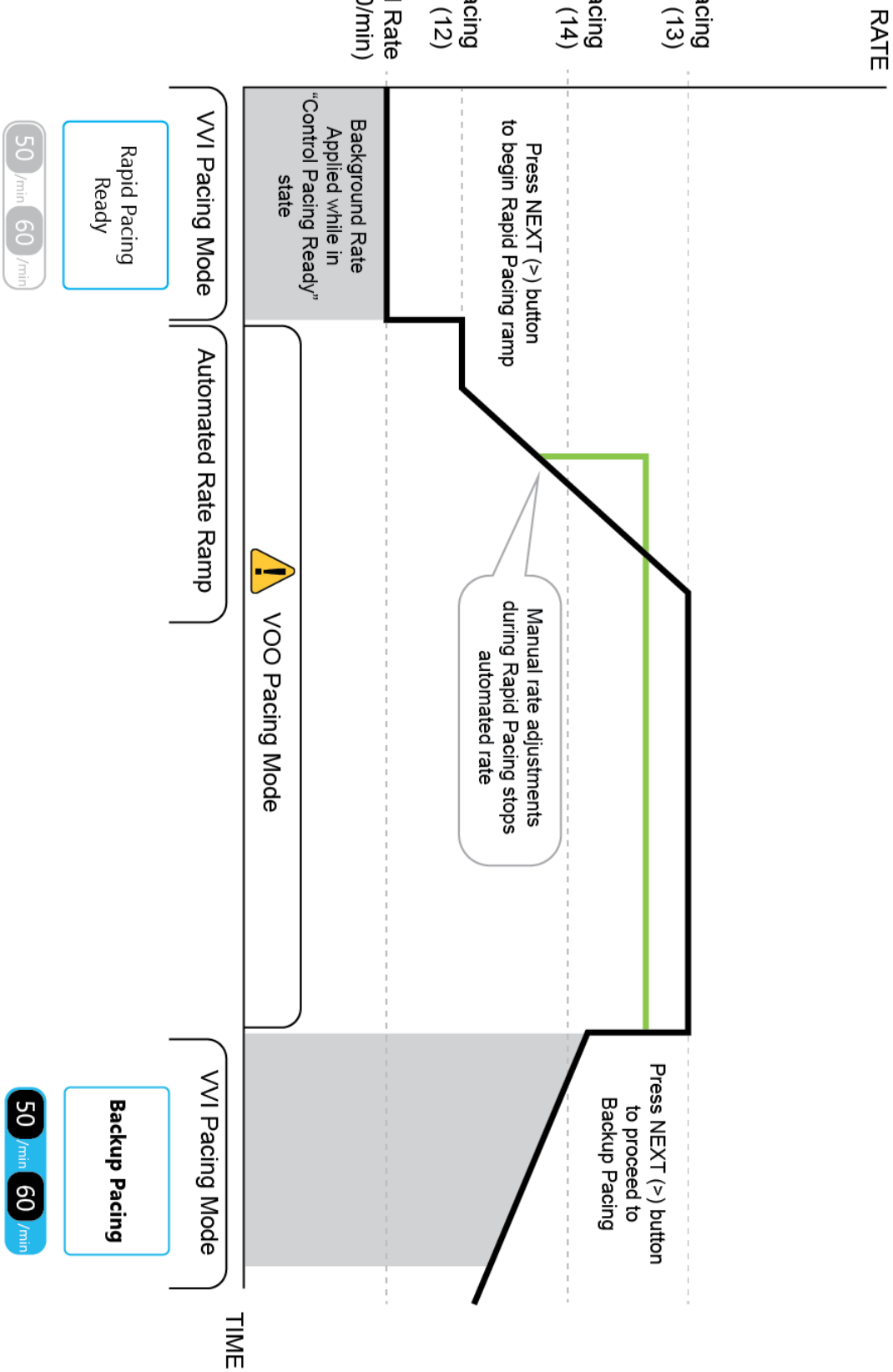
Capture Check (Rate)



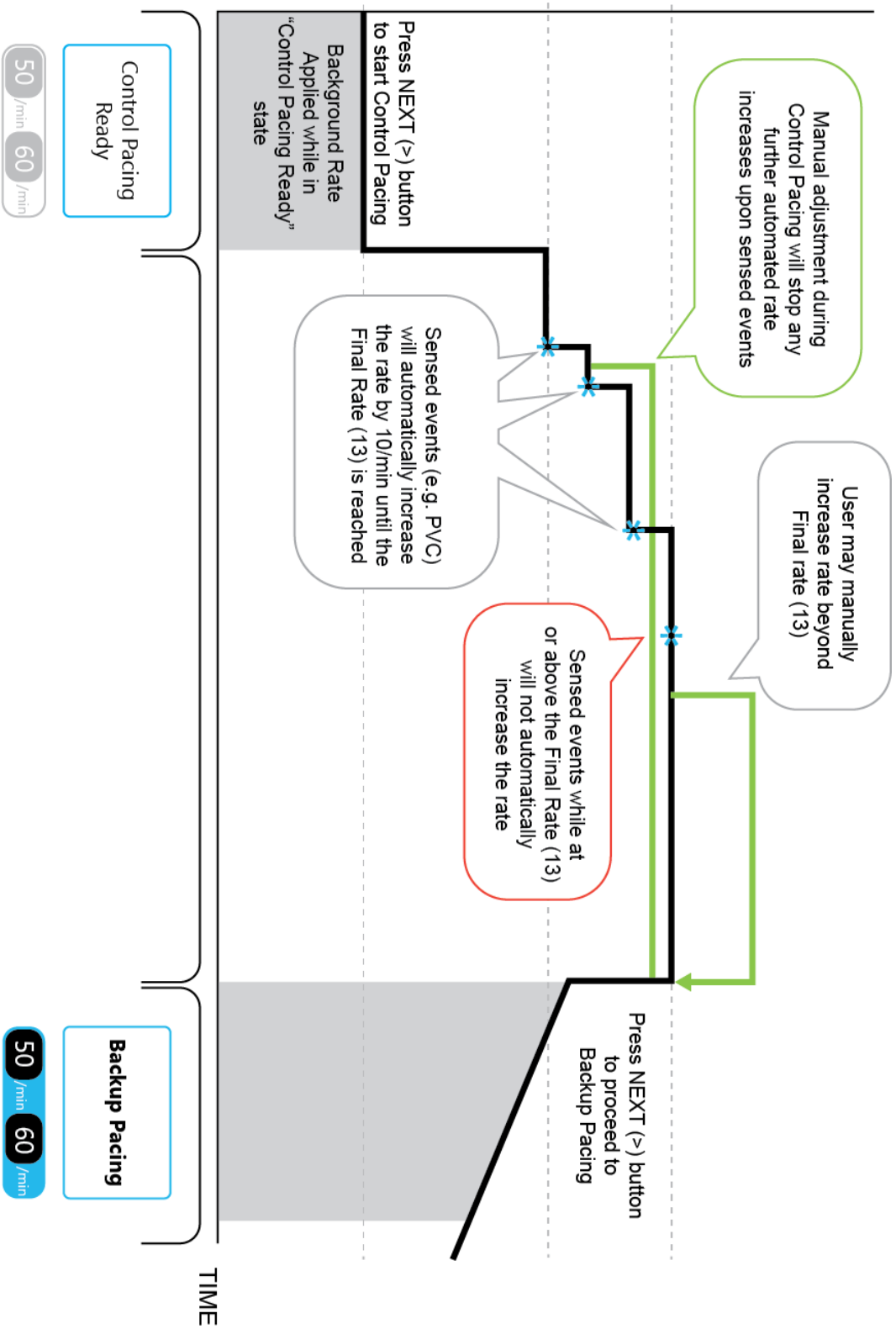
Capture Check (Amplitude)



Rapid Pacing



Control Pacing



Backup Pacing