



# Routine Follow-up CHECKLIST MODEL 1001

remedē<sup>®</sup> System

## Set Up for Visit

- Connect the programming wand to the USB port
- Connect the power supply to the tablet and connect to power source
- Press **Power** button
- Double click on **remedē 4.5.0.6** icon  on the tablet to start session; if needed
- Place programming wand over the device
- Look for a blinking green light from programming wand to signal a good telemetry connection
- Ensure programmer time matches local time in bottom right hand corner. If time does not match, go to TOOLS pull down, Set PC time.



## Initial Interrogation

- Select the **Interrogate** button
- Review any messages and select **Routine Follow-Up;** if IPG time is not correct, it will be corrected later

## Routine Follow-Up Procedures

### 1. Verify Patient Identification

### 2. Print Parameters

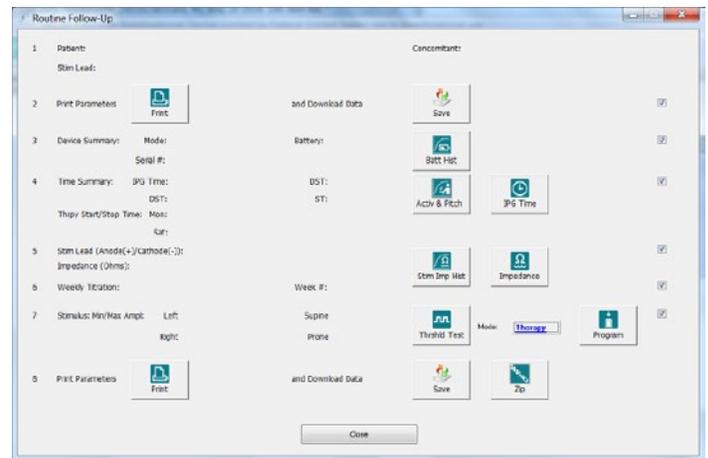
- Select **PRINT** to create pdf; save pdf to the folder desktop \respicardia\archivedpatientfiles and indicate pre-visit in file naming
- Download Data
- Select **SAVE** icon 
- Download will start automatically. If not, select **SAVE** in pop-up menu
- Close Wave & Log Data window. Click box at end of row to proceed to the next step in the follow-up window

### 3. Device Summary

- Select **Batt Hist** icon  to evaluate battery status
  - Voltage  $\geq 2.8V$  (Good)
  - Voltage  $< 2.8 V$  (Good: should decrease time between visits to assess battery)
  - Voltage  $= 2.6 V$  (ERI: schedule device change as soon as possible)
  - Voltage  $= 2.5 V$  (EOL: device no longer provides therapy)
- Close Battery Measurements window. Click box at end of row to proceed to the next step in the follow-up window

### 4. Time Summary

- Select **Activity & Pitch** icon  to evaluate activity and pitch
  - Measured pitch must be below the Pitch Threshold during patient's scheduled sleep time
- Review therapy start/stop times if pitch and activity are not consistent with therapy. Be sure to discuss with the patient. If change is needed, pitch and activity can be adjusted in the Sensor Tab and start and stop time can be adjusted in the Therapy Tab.
- Review IPG Times and DST Times: if changes are needed go to next step, otherwise to next section.



- Select **IPG Time** icon 
- Select **Get Time** and confirm time is correct. Device and PC time should be the same. If not, select "Set with PC time" (can adjust by Set time or Set with PC time); 24 hour military time used.
- Select **Get DST** (Daylight Savings Time) time adjust if a change needed before next visit (daylight savings time or travel) and press **Set DST**
- Select **Close**. Click box at end of row to proceed to the next step in the follow-up window

### 5. Stim Lead

- Select the **Stim Imp Hist** icon 
  - Review to see if impedance values are stable
    - Abnormal readings would be any readings (red or black line) in the shaded area
- Evaluate set electrode pair and all unipolar impedances. Close Stimulation Lead Impedance Chart Window
- Select **Impedance** icon 
- Select a test configuration (Anode - Can, Cathode - Electrode 1, etc)
- Select **Read Impedance**
- Repeat for each electrode
- Report any impedance abnormally high or low (any reading with a "<" or ">" value)
- Close Read Impedance window. Click box at end of row to proceed to the next step in the follow-up window



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## Routine Follow-Up Procedures (continued)

### 6. Weekly Titration

- Confirm weekly titration status or turn off under the Weekly Titration tab if no longer using. Click box at end of row to proceed to Stimulus
- Click on Full Reports icon  located on the main taskbar
- Minimize programmer screen to review reports. Review remedē Reports 1.3.0
- Return to routine follow-up window by selecting the programmer icon  on bottom tool bar



### 7. Stimulus: Min/Max Ampl:

- Disable therapy by selecting Off mode and Program
- Select Threshold Test (Threshd Test) 
- Confirm patient in typical sleep posture
- Select desired Amplitude
- Select Test Start
- Select Single Pulse
- Select appropriate response
- Select Test Stop to select new test values or to stop testing
- Repeat until weak and strong thresholds identified
- Complete testing in other postures when applicable
- Close Threshold Test window
- Reprogram mode to Therapy
- Click box at end of row to proceed to the next step in the follow-up window
- Complete all programming changes and select **Program** button to confirm

### 8. Print Parameter

- Select **PRINT** to create pdf; save pdf to the folder desktop\respicardia\archivedpatientfiles and indicate post-visit in file naming. Select Close
- Download programmer session data and compress
- Select Save icon to download final device data
- Close Wave and Log Data window. Select Zip icon to compress data for future reference and save as needed
- Select **Interrogation** button
- Ensure device is programmed to therapy mode. Exit out of patient and close remedē reports if still open

## For questions

email [customercare@remede.zoll.com](mailto:customercare@remede.zoll.com) or call 1-866-788-1109

#### Important Safety Information

The remedē<sup>®</sup> System is indicated for moderate to severe Central Sleep Apnea (CSA) in adult patients. A doctor will need to evaluate the patient's condition to determine if the remedē System is appropriate. The remedē<sup>®</sup> System should not be implanted during an active infection and patients will not be able to have diathermy (special heat therapies). The device is MR Conditional. The conditions and precautions can be found in the remedē System MRI guidelines manual. The remedē System may be used with another stimulation device such as a heart pacemaker or defibrillator; special testing will be needed to ensure the devices are not interacting. As with any surgically implanted device, there are risks related to the surgical procedure itself which may include, but are not limited to, pain, swelling, and infection. Once the therapy is turned on, some patients may experience discomfort from stimulation and/or from the presence of the device. The majority of these events are resolved either on their own or by adjusting the therapy settings. The remedē System may not work for everyone. There are additional risks associated with removing the system. If it is decided to remove the system, another surgery will be required. Be sure to understand all the risks and benefits associated with the implantation of the remedē System. For further information please visit [remede.zoll.com](http://remede.zoll.com), call 952-540-4470 or email [info@remede.zoll.com](mailto:info@remede.zoll.com). **Contraindications:** The remedē System is contraindicated for use in patients with an active infection. See the Instructions for Use for complete information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events.

**Rx Only.** The remedē<sup>®</sup> System, remedē<sup>®</sup> EL System, and remedē<sup>®</sup> EL-X System have received FDA approval. The remedē<sup>®</sup> System model 1001 has received CE Mark approval.

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