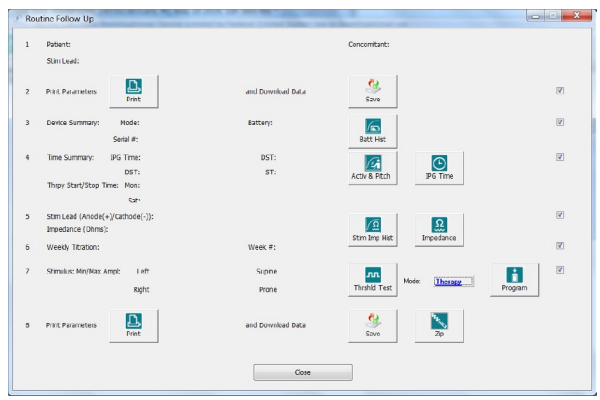
Routine Follow-up CHECKLIST

remedē® 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
- ☐ Select Respicardia **rem**edē 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
- ☐ Ensure USB memory is available for storing patient data



Initial Interrogation

- ☐ Select the **Interrogate** button
- ☐ Review any messages and select **Routine Follow-Up**

Routine Follow-Up Procedures

- ☐ 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
  - — Click box at end of row to proceed to the next step in the follow-up window
- ☐ Select **Batt History** icon to evaluate battery status
  - — Voltage ≥ 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)
  - — Click box at end of row to proceed to the next step in the follow-up window
- ☐ Select **Activity & Pitch** icon to evaluate activity and pitch
  - — Measured pitch must be below the Pitch Threshold during patient's scheduled sleep time
  - — Adjust therapy start/stop times if pitch and activity are not consistent with therapy on time and accounting for any feedback from patient
- ☐ Review IPG Times
  - — Select **IPG Time** Icon
  - — Select **Get Time** and confirm time is correct (can adjust by **Set time** or **Set with PC time**); 24 hour military time used
  - — Select **Get DST time** adjust if a change needed before next visit (daylight savings time or travel) and press **Set DST**
  - — Click box at end of row to proceed to the next step in the follow-up window
- ☐ Evaluate Stimulation Lead Impedance
  - — Select the Stimulation Impedance History icon (**Stim Imp Hist**)
  - — Review to see if impedance values are stable
  - — Abnormal readings would be any readings (red or black line) in the shaded area
  - — Every 6 months, and at Therapy Initiation, check all electrodes
    - Select **Impedance** icon
    - Select a test configuration (1-Can, 2-Can, 3-Can, etc)
    - Select Read Impedance
    - Repeat for each electrode
    - Report any impedance abnormally high or low (any reading with a "<" or ">" value)
    - Click box at end of row to proceed to the next step in the follow-up window

Routine Follow-up CHECKLIST

remedē® System

Routine Follow-Up Procedures (continued)

- ☐ Confirm weekly titration status or turn off titration if no longer using
- ☐ Evaluate Diagnostics Reports
  - — Click on **Full Reports** icon located on the main toolbar
  - — Review diagnostic report
  - — Return to routine follow-up window
  - — Click box at end of row to proceed to next step in the follow-up window
- ☐ Evaluate Stimulation Threshold
  - — Disable therapy by selecting **Off** mode and **Program**
  - — Select Threshold Test (**Thrshld Test**)
  - — Confirm patient in typical sleep posture
  - — Select desired **Amplitude**
  - — Select **Test Start**
  - — Select **Single Pulse**
  - — Select appropriate response
  - — Select **Test Stop** to stop testing or select new test values
  - — Repeat until weak and strong thresholds identified
  - — Complete testing in other postures when applicable
  - — Close 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
- ☐ Ensure device is programmed to therapy mode
- ☐ **Print** Parameter Settings Report (will include all changes made during this visit to the patient file location and indicate post-visit in file naming)
- ☐ Download programmer session data and compress
  - — Select **Save** icon to download final device data and save pdf to the folder desktop\respicardia\archivedpatientfiles
  - — Select **Zip** icon to compress data for future reference
- ☐ Select **Interrogation** button
- ☐ Ensure device is programmed to therapy mode

For questions

email **customercare@respicardia.com** or call **1-866-788-1109**

Important Safety Information

The **rem**edē® System is indicated for moderate to severe Central Sleep Apnea in adult patients. A doctor will need to evaluate the patient's condition to determine if the **rem**edē System is appropriate. Patients will not be able to have an MRI or diathermy (special heat therapies) if the **rem**edē system is implanted. The **rem**edē 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 **rem**edē 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 of the risks and benefits associated with the implantation of the **rem**edē System.

For further information, please visit www.respicardia.com, call +1-952-540-4470 or email info@respicardia.com.

Indication for use: The **rem**edē® System is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe central sleep apnea (CSA) in adult patients.

Contraindications: The **rem**edē System is contraindicated for use in patients with an active infection or patients known to require magnetic resonance imaging (MRI). See the Instructions for Use for complete information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events.

Rx Only.

MedEd 1771, Rev A

Respicardia®