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Use of ResMed bilevel ST devices as invasive ventilators: guidelines for clinicians

ResMed S9 VPAP ST Operational Checklist and Instructions for Use

Tx Link Hardware Setup Instructions

ResMed EasyCare Tx Link Software Installation and Setup

Advisory on the Use of ResMed VPAP ST

(ResMed, Australia; ResMed USA, San Diego)

Because of an automatic shut-off feature in the ResMed bilevel (S9 VPAP™ and AirCurve™), these devices should NOT be used for invasive ventilation without additional modification to the circuit unless no other options exist.

The ResMed VPAP™ ST is designed to be a *noninvasive* ventilator. Incorporation of supplemental oxygen at > 15 l/min into the circuit anywhere distal to the blower should be undertaken with extreme caution and only after modifying the circuit with a second exhalation valve close to the blower and proximal to the O_2 bleed in.

At a set CPAP or EPAP > 10 cmH_2O, oxygen flows > 15 l/min in a circuit with a single standard exhalation port can result in an unanticipated device shut-off and patient harm. This shut-off does not occur at EPAP ≤ 10 cmH_2O or when O_2 flow < 15 l/min.

At supplemental oxygen flows of 15 l/min, the maximum achievable FiO_2 will be no higher than 60%. If a patient requires FiO_2 > 60% or PEEP > 10 cmH_2O, the circuit must be modified with the addition of a second exhalation port, or the use of another brand of bilevel or a conventional invasive ventilator should be considered.

Exercise extreme caution when EPAP requirements exceed 10 cmH_2O and FiO_2 requirements exceed 60% unless 2 exhalation ports are used!

Use of ResMed Bi-level ST devices as invasive ventilators: guidelines for clinicians

Version 3.0 [Apr 27 2020]

Mount Sinai Health System

Current Working Guidelines – Subject to Revision

These current working guidelines are subject to revision. It is expected this document will be updated and re- released as additional experience is accumulated.

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For additional information and associated documents, please see below links:
Primer - Theory and Background for Bilevel Repurposing
Protocol - Repurposing of Bilevel Devices for Invasive Ventilation
Clinical Guidelines / Operating Checklist - Philips Respironics Devices
Clinical Guidelines / Operating Checklist - ResMed Devices
Monitoring and Alarm Guidelines / Construction
Construction of an Anesthesia Circuit Component Diagram
Construction of a Bilevel Circuit Component Diagram
Frequently Asked Questions

QUICK GLANCE: POTENTIAL CANDIDATES FOR USE OF BILEVEL FOR INVASIVE VENTILATION

To be followed for support of intubated ICU patients if there is a crisis shortage of ventilators

Ideal initial candidates for bilevel ventilation if there is a crisis induced shortage of ventilators are patients with either:

- Stable or improving P/F ratio

or

- Decreasing or stable ventilator requirements

We do not recommend use in newly intubated patients unless no other ventilators are available. Newly intubated patients should be reassessed and considered for transition to ResMed VPAP™ ST once they are stable, as detailed in Table 1.

Table 1: Criteria

Parameter on Conventional Ventilator	Acceptable Limit
FiO_2	<60% for ResMed VPAP™ ST or AirCurve™
PEEP*	<10 cm H_2O for ResMed VPAP™ ST or AirCurve™
Driving pressure: ($P_{Plateau}$ – PEEP) or inspiratory pressure (Pi)*	≤ 20 cm H_2O
***Driving Pressure + PEEP**	**<23**

The ResMed VPAP ™ST device can deliver a maximum pressure (Driving Pressure + PEEP) of 25 cmH_2O. For safety, given a potential increase of resistance in the bilevel circuit, we recommend that these devices are most appropriate for patients with settings on conventional ventilation as follows:

- *If patient on Pressure Control mode: check that Inspiratory Pressure (Pi) + PEEP is below 23 cmH_2O*
- *If patient on Volume Control mode: check that plateau pressure is below 23 cmH_2O*

TRANSITIONING FROM CONVENTIONAL VENTILATOR TO BILEVEL VENTILATOR

Bilevel devices provide positive pressure ventilation in a manner analogous to pressure control ventilation on traditional ventilators.

Calculate patient ideal body weight (IBW) from height and goal tidal volume (TV) of ***6 - 8 cc/kg with plateau pressure < 30.***

Device Settings:

MODE: ST (bilevel)

EPAP = PEEP

IPAP:

- If patient is on Pressure Control (AC/PC) mode:

  IPAP = PI + PEEP

- If patient is on Volume Control (VC/PC) mode:

  IPAP = plateau pressure (perform inspiratory pause maneuver)

Resp Rate: Match patient's rate

Ti Max: Based on respiratory frequency; see chart (Table 2)

Ti Min: Based on respiratory frequency; see chart (Table 2)

Rise Time: Min

Trigger: Low

Cycle: Low

Oxygen: 15 l/m via port—DO NOT exceed 15 l/m of supplemental oxygen

If an FiO_2 > 60% is required, you must use a different bi-level device

Warning: With ResMed VPAP™ ST and AirCurve™ bi-levels, supplemental oxygen > 15 l/m in a circuit with a standard exhalation port can result in an unanticipated device shut-off and patient harm

Table 2: Ti settings based on Respiratory Rate (RR):

Respiratory Rate (bpm)	Ti Max = 30/RR	TiMin = ½ TiMax
30	1	0.5
25	1.2	0.6
20	1.5	0.8
15	2.0	1.0
12	2.5	1.3

Whenever a patient is started on a bilevel ventilator or if a change in IPAP or EPAP is made, VERIFY TV reading on bilevel device display or on gas sampling/flow monitor:

- TV > 6 – 8 cc/kg IBW → lower IPAP in 3-5 cmH_20 increments until at/near goal
- TV < 6 - 8 cc/kg IBW with unacceptable hypercapnia/respiratory acidosis:
    - If not already at device maximum IPAP (25 cmH_2O), increase IPAP in 3-5 cm H_2O increments until TV at goal
    - If IPAP at maximum of 25 cmH_2O, check ABG → if unacceptable degree of hypercapnia/respiratory acidosis, increase RR to maximum of 35 bpm
    - If IPAP at maximum of 25 cmH_2O, RR at maximum of 35 bpm, with severe respiratory acidosis, decrease EPAP by 3-5 cmH_2O (if oxygenation tolerated as measured)
        - NOTE: More advanced device support may be needed if unable to achieve adequate ventilation and oxygenation despite these adjustments.
- End-tidal CO_2 readings can be used as a surrogate indicator of changes in ventilation if tidal volume readings are not available
- Check FiO_2

OXYGEN and FiO_2

The circuit is usually set up with supplemental oxygen flow at 15 l/m. A second oxygen port can be used to add additional oxygen if needed.

WARNING: the ResMed VPAP ST and AirCurve™ have a feature that will cause an unexpected shut-down of the device if the supplemental O_2 flow exceeds the leak; this appears to the software as a "tube blocked" condition. DO NOT EXCEED 15 l/m of supplemental O_2 if using these devices and the set pressure is above 10 cmH_2O.

- Check FiO_2 on gas sampling/flow monitor if possible at the start of therapy
- FiO_2 may drop slightly if IPAP or EPAP is increased without increasing oxygen flow rates (especially if using single source of O_2 at 15 l/m)
- Check for changes in SpO_2 and/or PaO_2 after increasing IPAP or EPAP
- **DO NOT increase O_2 > 15 l/m if EPAP is ≥ 10 cmH_2O**

Comments on LEAK

- The current set up of the circuitry provides the necessary degree of leak needed to prevent CO_2 re-breathing (this value cannot be displayed); this leak is filtered.
- When all tubing circuitry is connected and working properly, the ResMed VPAP ST screen should read a leak of 0 as this display is NOT the total leak, but the leak in excess of that intended and filtered. Other bilevel devices display the total leak. On other bilevel devices, the leak displayed is the total leak.
    - If reading goes above 0 on the ResMed devices, there may be an unexpected leak in the system (cuff leak, disconnected tubing, etc.). This condition can result in:
        - Loss of delivered pressure, unexplained drop in patient SpO_2, sudden change (up or down) in end-tidal CO_2, and drop in TV readings.
        - Exposure of healthcare providers to *unfiltered* leak.
- If you see this, check circuit, including all connections, ETT cuff inflation.

VPAP ST OPERATIONAL CHECKLIST AND INSTRUCTIONS FOR USE

Ensure that emergency ventilator equipment (i.e. the patient's original ventilator connected to an oxygen source, Ambu-Bag®) is readily available in the event of device malfunction.

BEFORE ROOM ENTRY:

- ❑ Have the following ready:
  - VPAP™ ST machine with power brick and cable
  - Pre-assembled "Bi-level Vent Circuit Kit" with tubing and components
  - Rolling cart or Mayo stand
  - GE CARESCAPE™ B450 freestanding monitor. **Keep this outside of the negative-pressure isolation room.**
- ❑ Connect the gas sampling line and spirometry connector to the GE monitor.
- ❑ Don appropriate PPE per institutional protocol.
- ❑ Enter the room with the VPAP™ ST, circuit kit, and rolling cart.
  - Be sure to not disconnect the gas sampling line from the GE monitor.

AFTER ROOM ENTRY:

- ❑ Move the patient so the endotracheal tube is less than 5 feet away from the door.
- ❑ Plug in VPAP ST to an outlet capable of backup generator power (this is a red outlet in most hospitals) in the event of power outage.
  - If using Tx-Link, see *Home Bi-level to Vent Modification - Tx Link Hardware Setup*
- ❑ Connect the **pre-assembled circuit** to the VPAP™ ST. **Do not disconnect the patient from the ventilator.**
- ❑ Connect O_2 line to wall regulator.
- ❑ Adjust O_2 flow to 15 l/m per clinical protocol.

- ❑ Turn the VPAP™ machine on by pressing the power button.

- ❑ To enter "Clinical Mode" on the VPAP™ ST, hold down the knob and the lower button simultaneously for about 3 seconds.

- ❑ Press the button on the knob to select a menu or field.

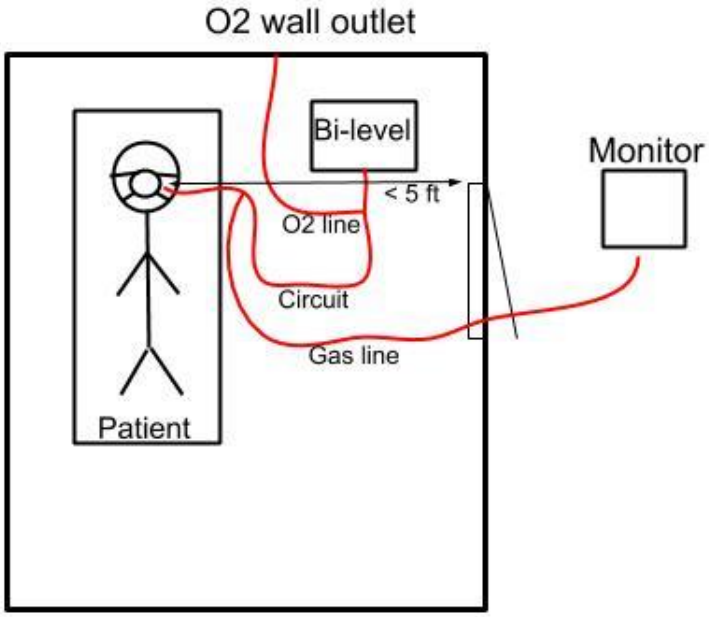
- ❑ Rotate the knob to navigate the menus

- ❑ Press the lower button to go back

Before attaching the circuit to the patient's endotracheal tube, perform final safety checks:

- ❑ Check circuit for uncapped openings
- ❑ Confirm DreamStation settings
- ❑ Confirm O_2 flow rate

- ❑ Disconnect the patient from the ventilator. **CAUTION: THIS IS AN AEROSOLIZING PROCEDURE.**
- ❑ Connect the VPAP™ ST circuit to the endotracheal tube. Confirm the the VPAP™ ST is delivering set tidal volumes.
- ❑ Leave ventilator accessible at patient's bedside, if possible. **CAUTION: DO NOT TURN OFF THE BILEVEL DEVICE ONCE THE PATIENT IS CONNECTED.**

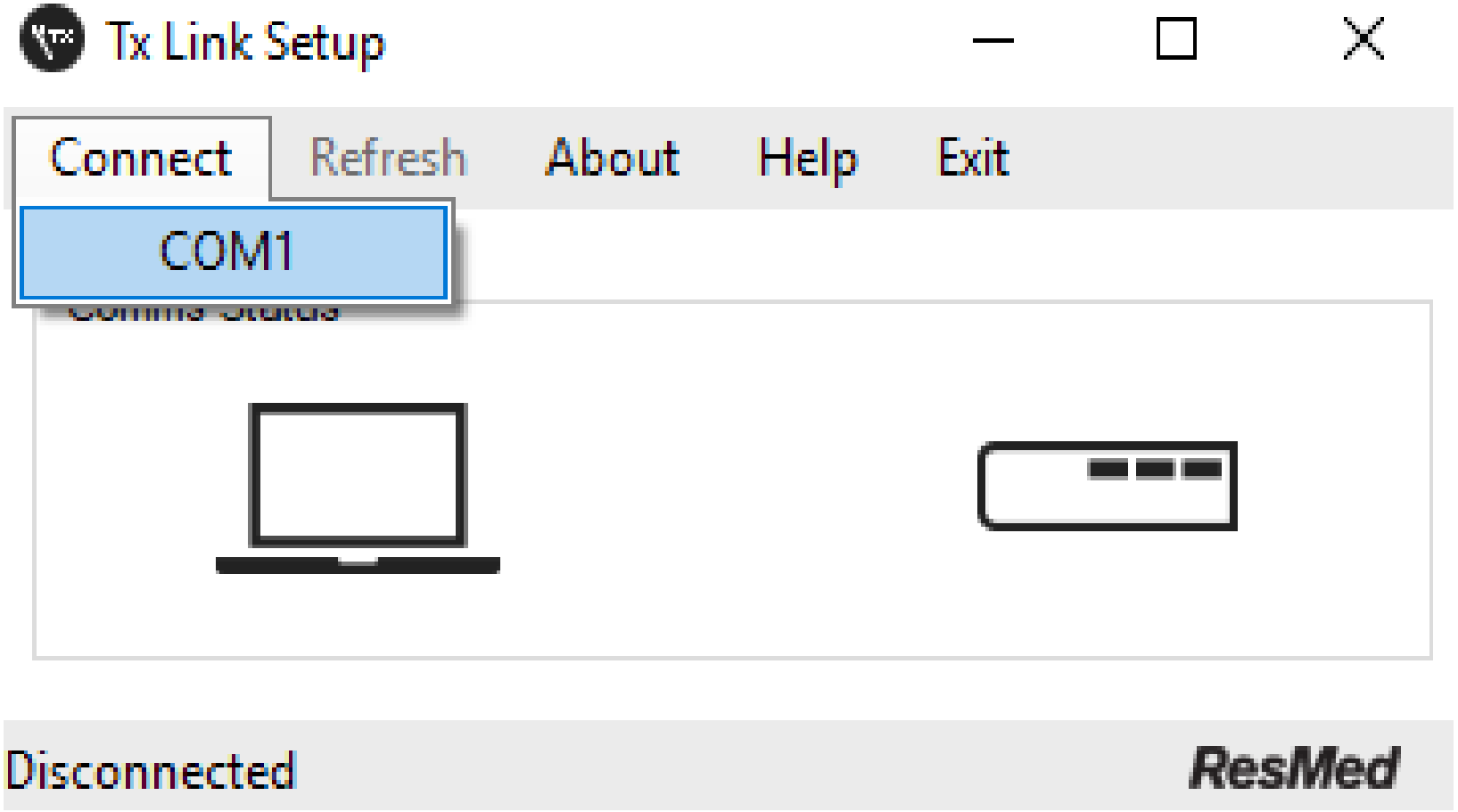


Tx Link Hardware Setup Instructions

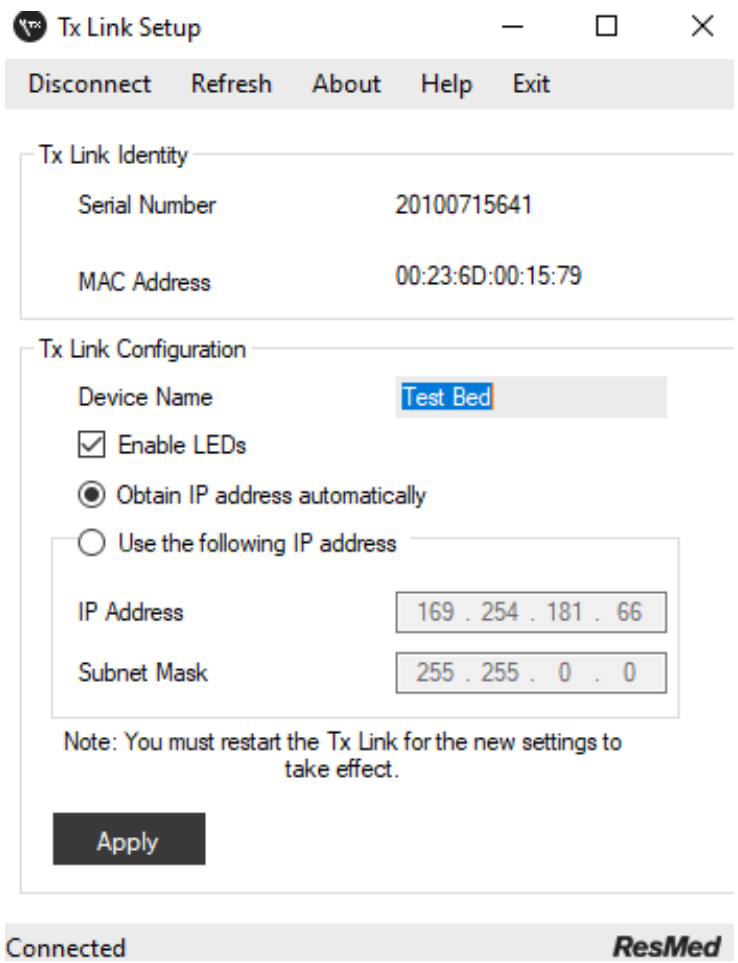
The Tx Link needs to be setup via a serial connection before connecting to the network

1. Connect the power for the Tx Link Device
2. Connect a 9 Pin Male serial connection into the Tx Link device, and connect the other end (9 Pin female) into your computer.

3. Launch “ResMed Tx Link Setup”



4. The setup screen should appear, that will show the Tx Link's serial number and MAC address, and allow you to set the name, IP Address and subnet of the Tx Link. After assigning the settings, hit "Apply"



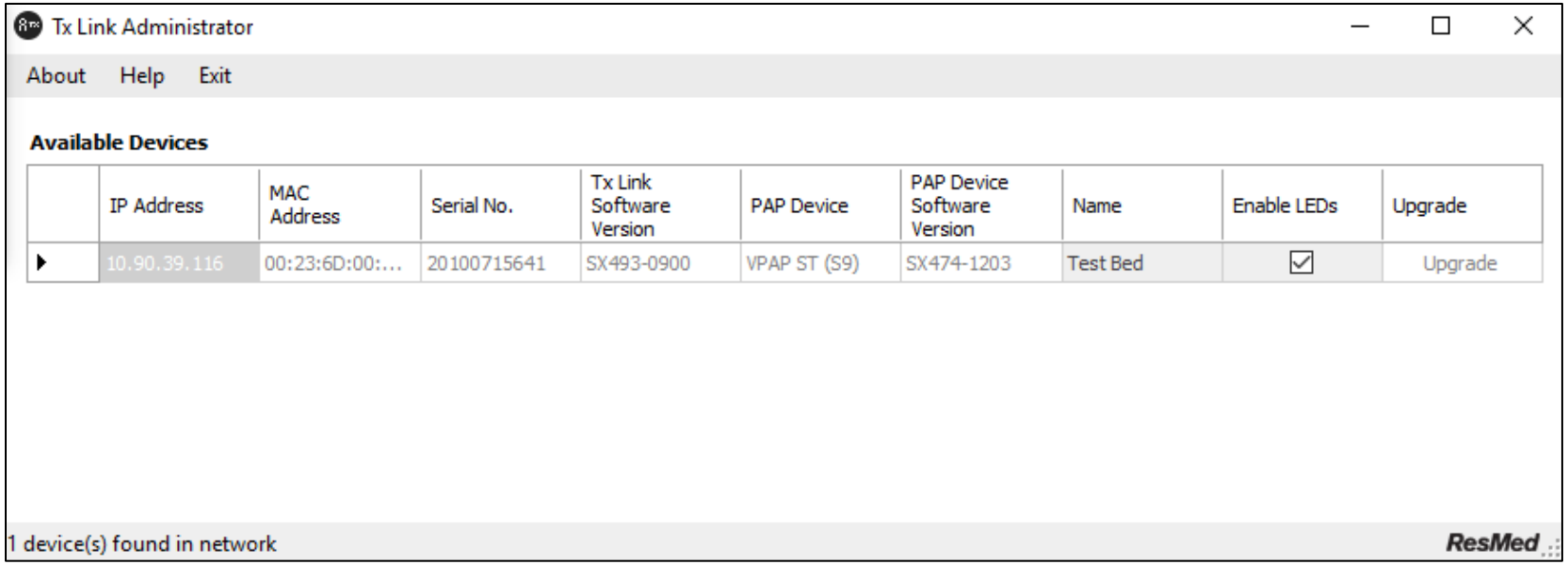
This document should be used as a clinical adjunct to the protocol "Repurposing bilevel ventilators for use with intubated patients while minimizing risk to health care works during insufficient supply of conventional ventilation for patients with COVID-19" and is shared with our health care colleagues to increase knowledge about potential solutions to increase the capacity and access to mechanical ventilation during the COVID-19 crisis. Icahn School of Medicine does not warrant the contents or effectiveness of the protocol, and the use and implementation of this protocol should be first reviewed and evaluated with each hospital's medical staff.

5. Exit Tx Link Setup. To apply the settings, disconnect the power from the Tx Link device.
6. After about 5 seconds, connect the power back in, and disconnect the serial cable.
7. Connect the USB adapters to both the Bi-level device and the Tx Link.
    a. The USB 2.0 connection connects to the Tx Link, the other end labeled “ResMed USB Adapter” connects to the Bi-level device machine.

8. Below is a screenshot of how the final setup should look like regarding connections. Circled in red shows the connection between the Tx Link and the Bilevel device.

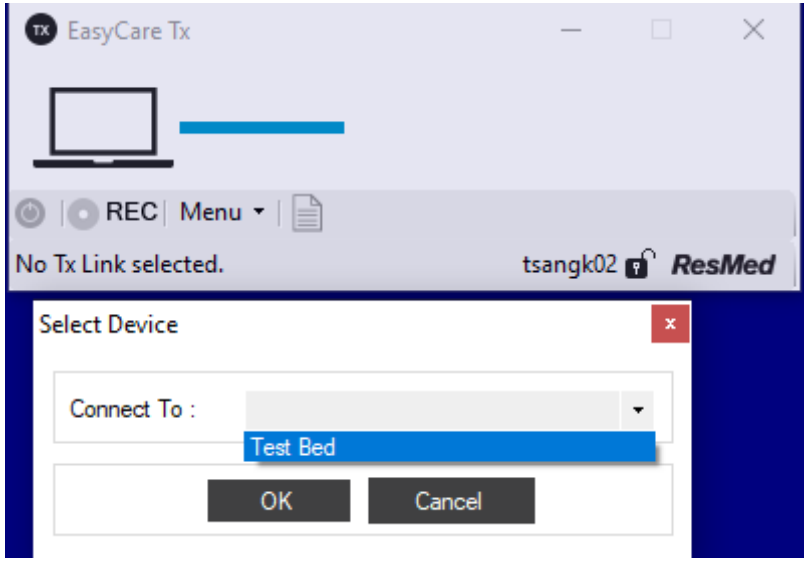
9. Connect the power to the Bilevel device.

10. If you launch Tx Link Administrator, your device should now be detected.

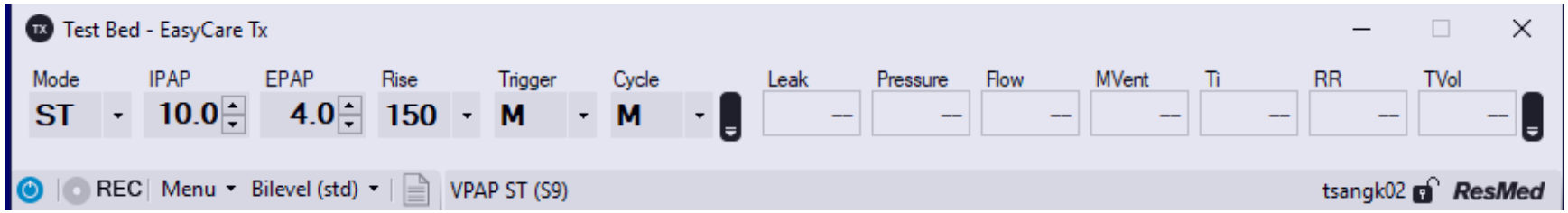


11. Launch ResMed EasyCare Tx. The username/password is normally linked to your active directory or local Windows account.

12. Hit Menu →Connect. A new window should appear with a dropdown of a list of all your Tx Link devices on your network.

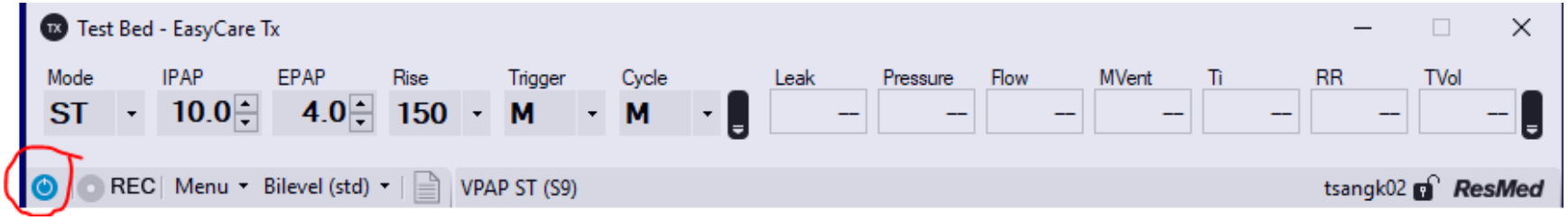


13. You should now be connected to Tx Link and able to remotely monitor the Bilevel device.

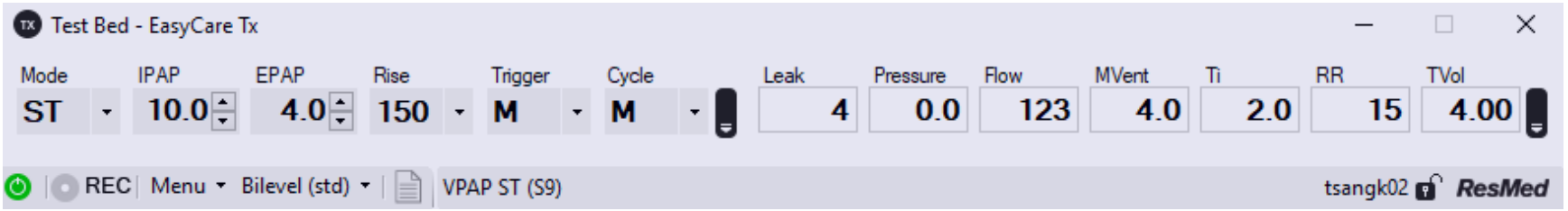


14. To enable additional displays on the toolbar, hit Menu→User Preferences→View and check the boxes with items you want to view.

15. The circled button (Turn therapy on) below will turn on the Bi-level device. **This is equivalent to pressing the power button on the bilevel device.**

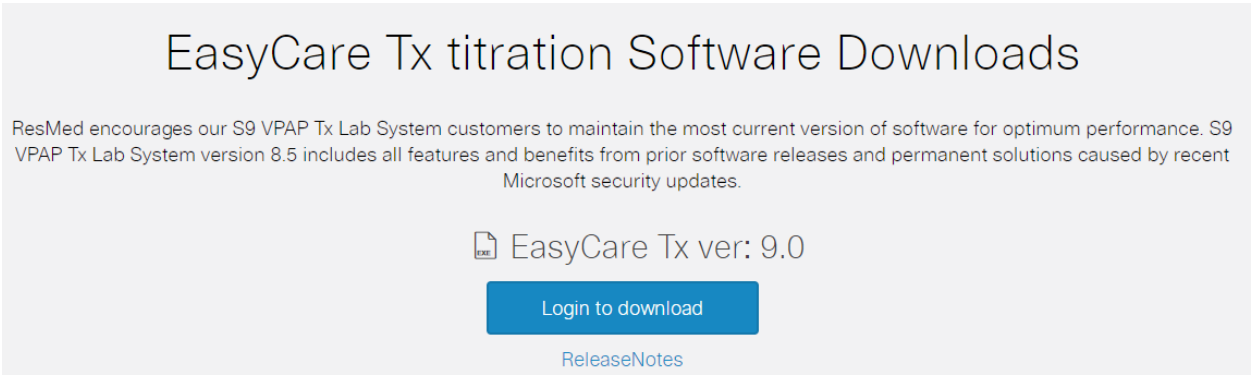


16. Example of real time data below

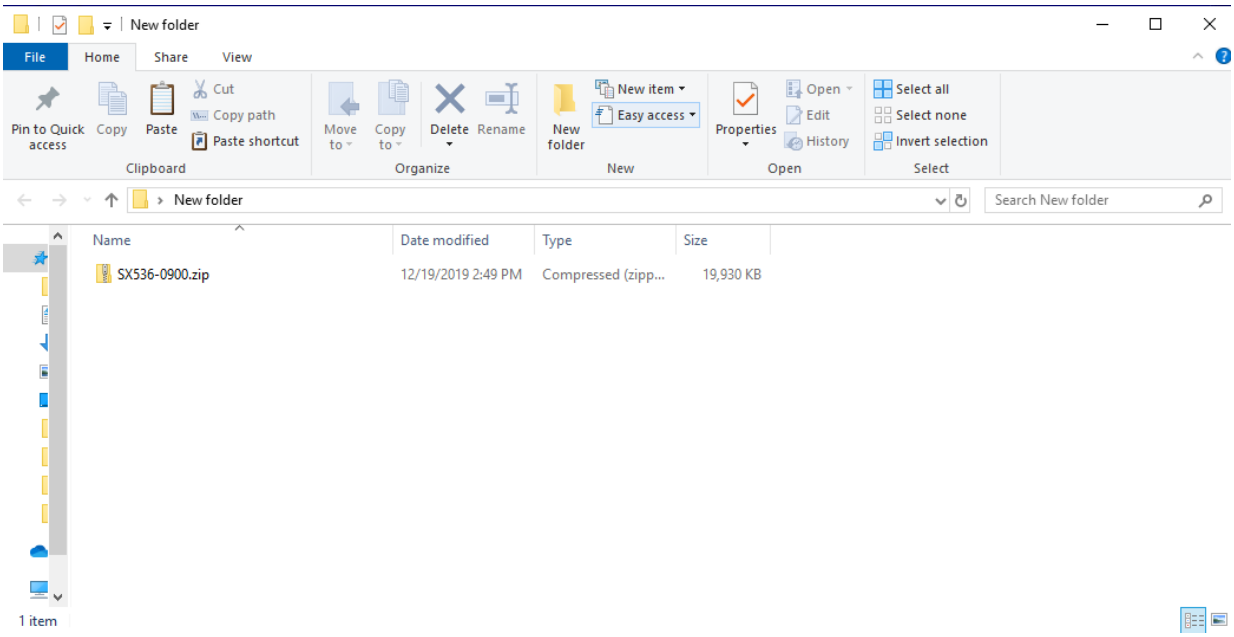


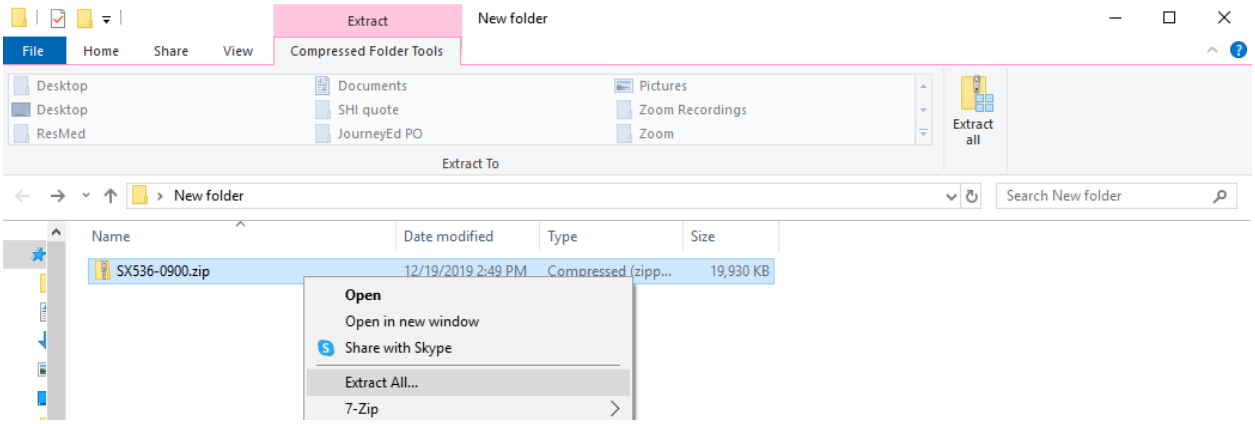
ResMed EasyCare Tx Link Software Installation and Setup

1. Navigate to the following link in an internet browser:
    a. https://www.resmed.com/us/en/healthcare-professional/support/titration/easycare-tx-titration-software.html
2. Click on the "Login to download" link
    a. You will have to create a ResMed login if you do not already have one

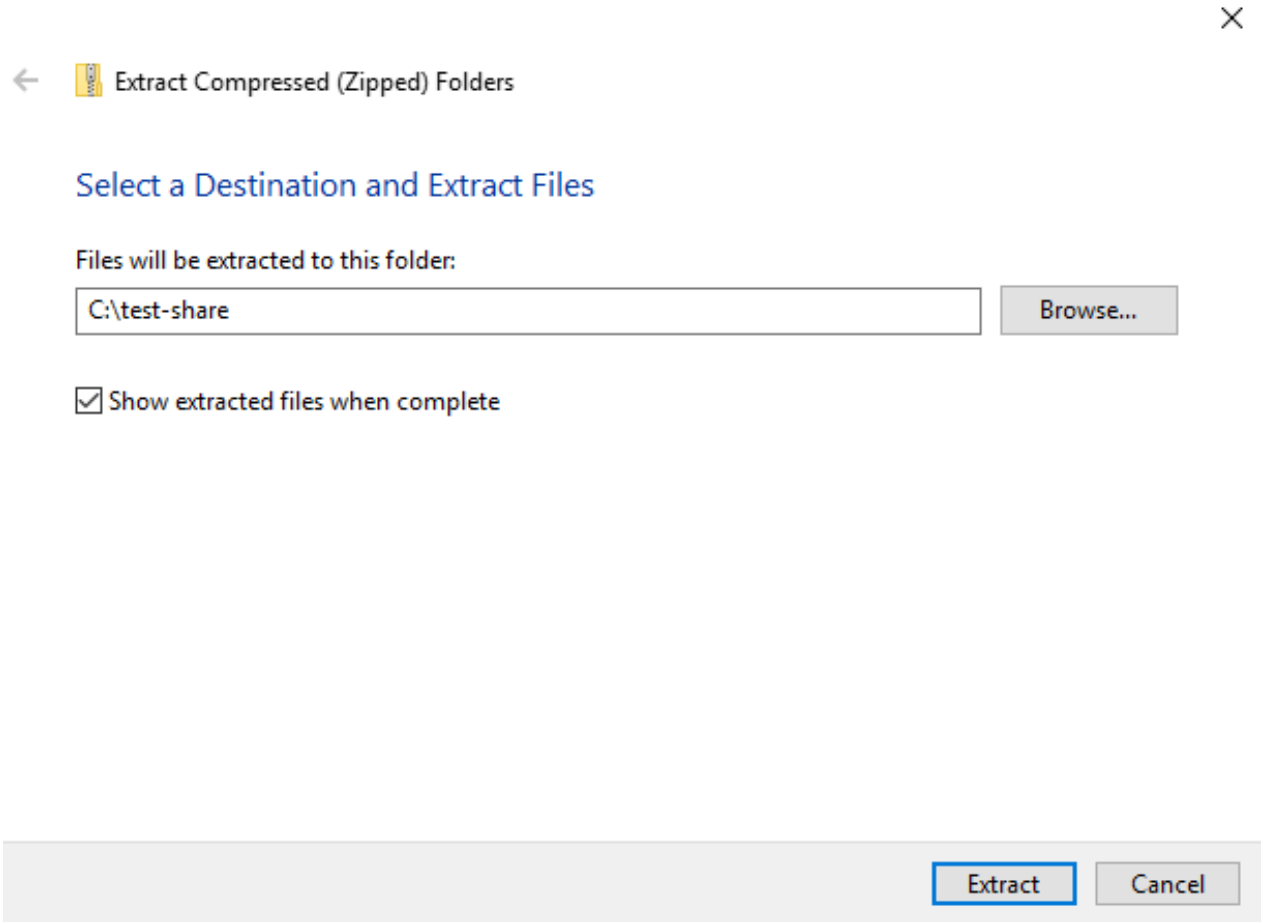


3. Once you have successfully logged in, the icon will now say "Download Zip"
4. Click on the link and download to a location on your computer that you can access
    a. Once it is downloaded, unzip the file by right clicking the zip file and selecting "Extract All"

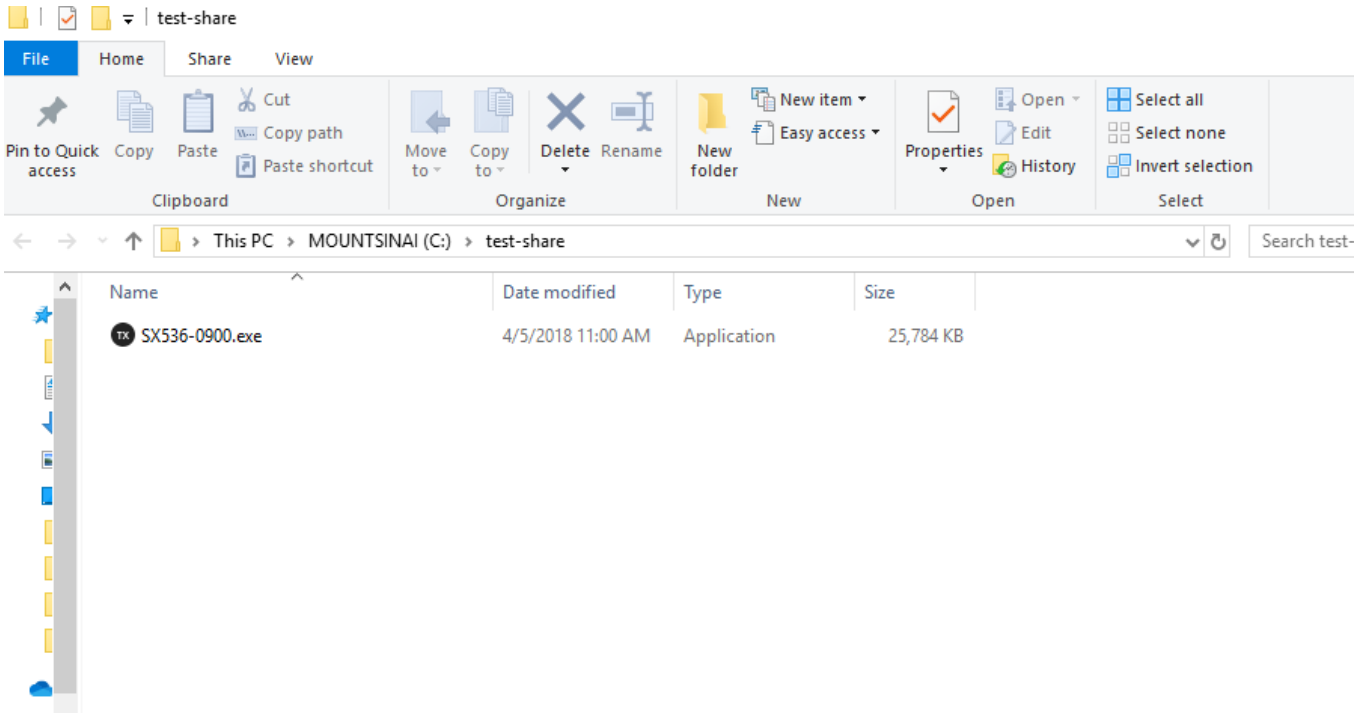


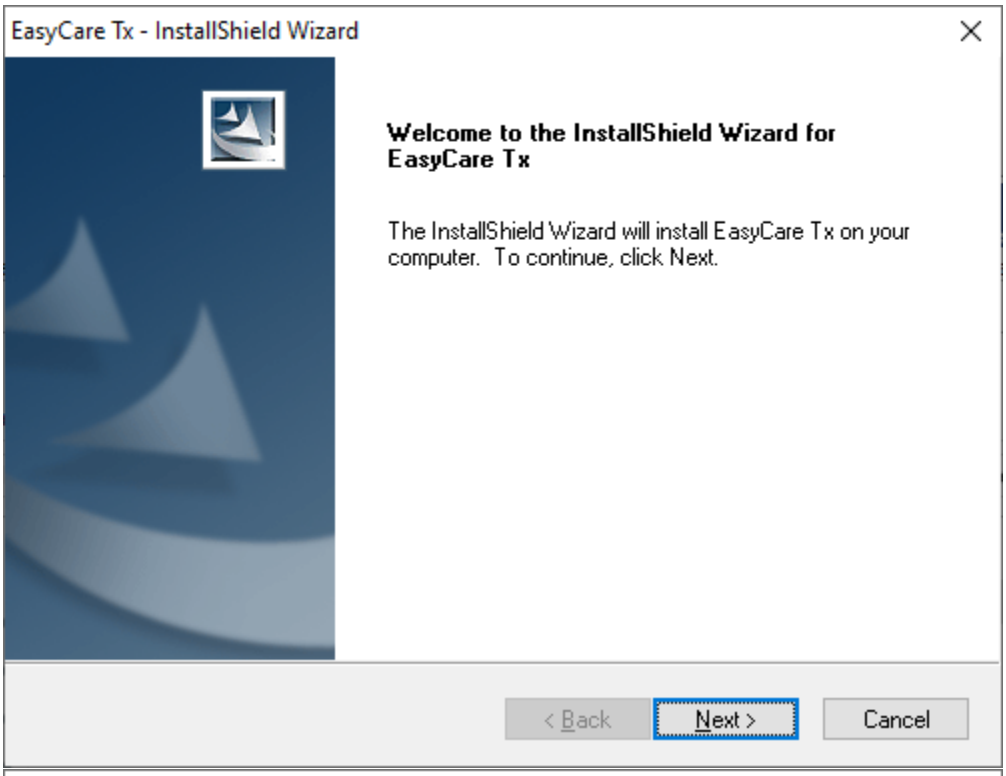


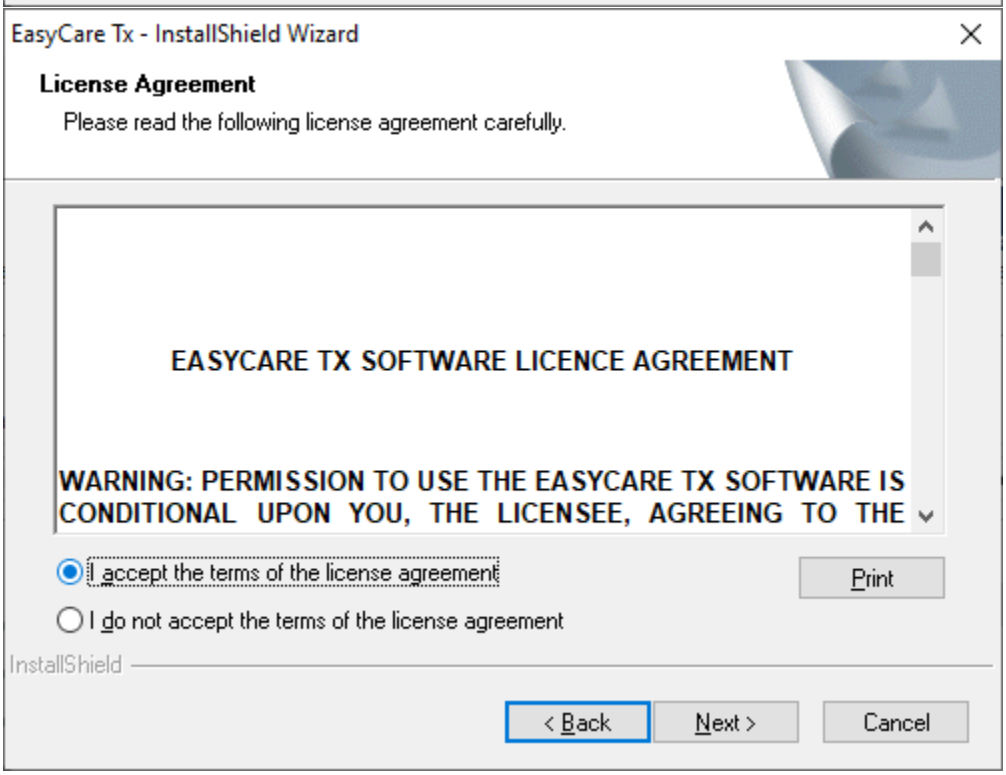
5. Select your desired location to save the extracted file, and hit “Extract”

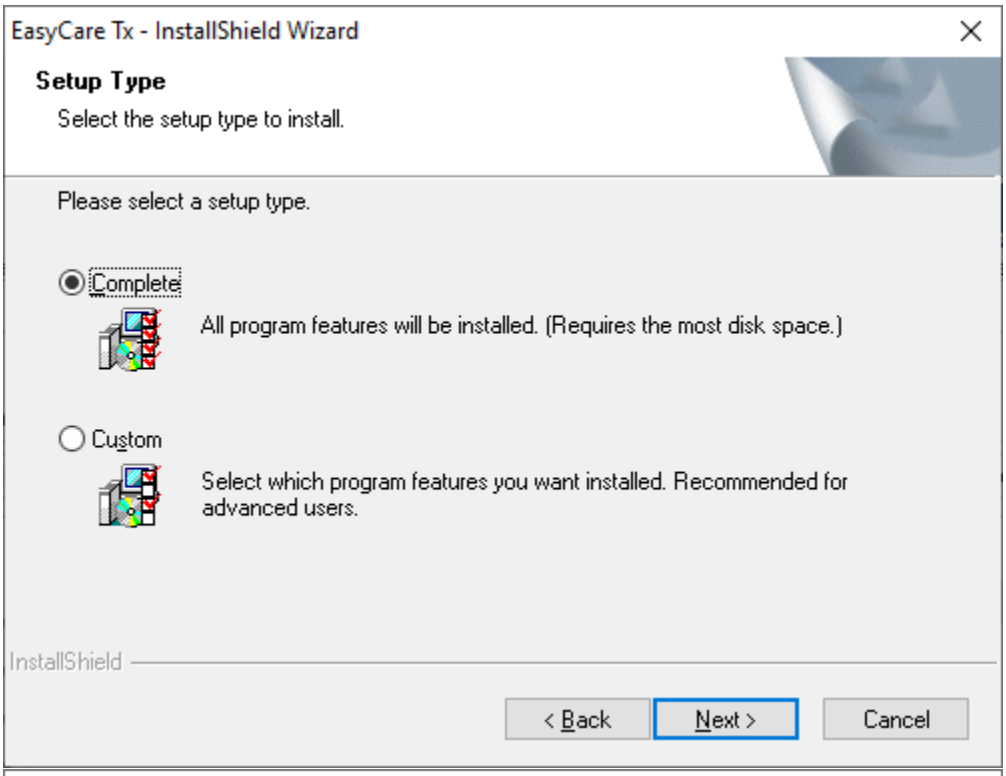


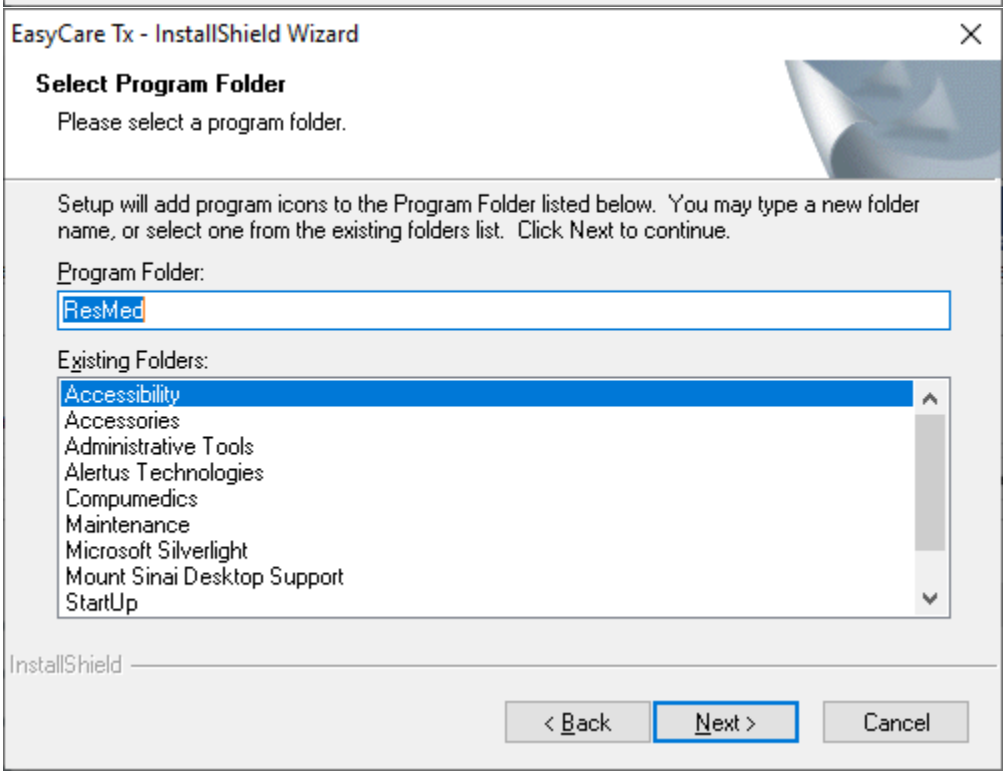
6. You should now see the extracted installation file “SX536-0900.exe”.
7. To start installation, launch the installation file “SX536-0900”, and follow the prompts to install ResMed EasyCare.

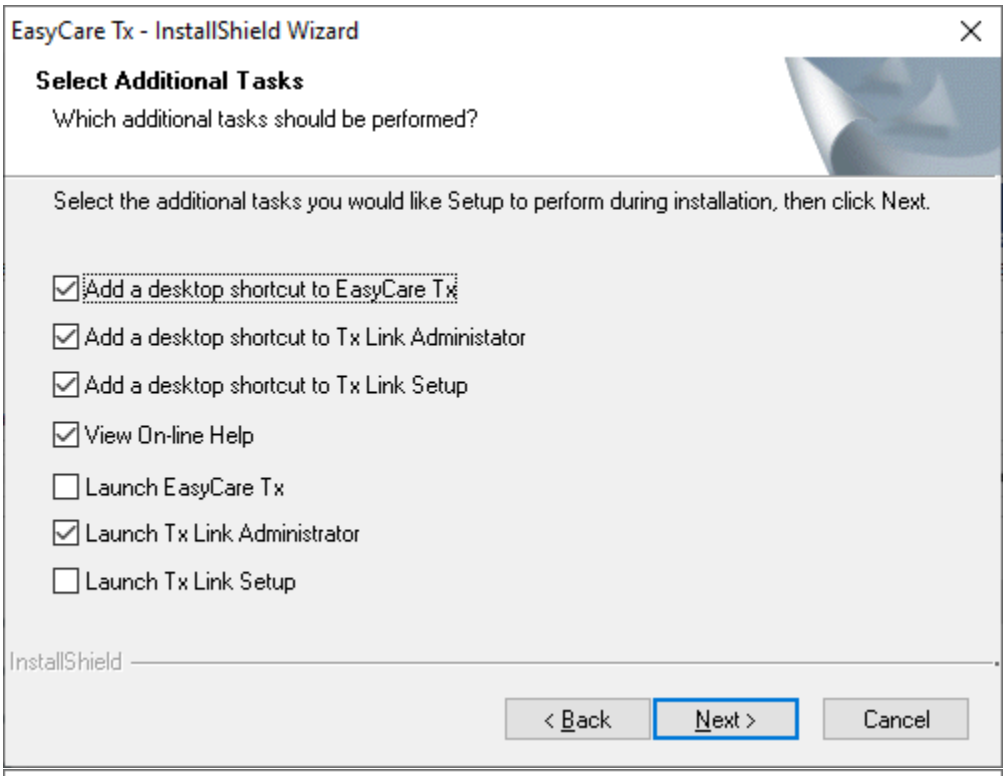


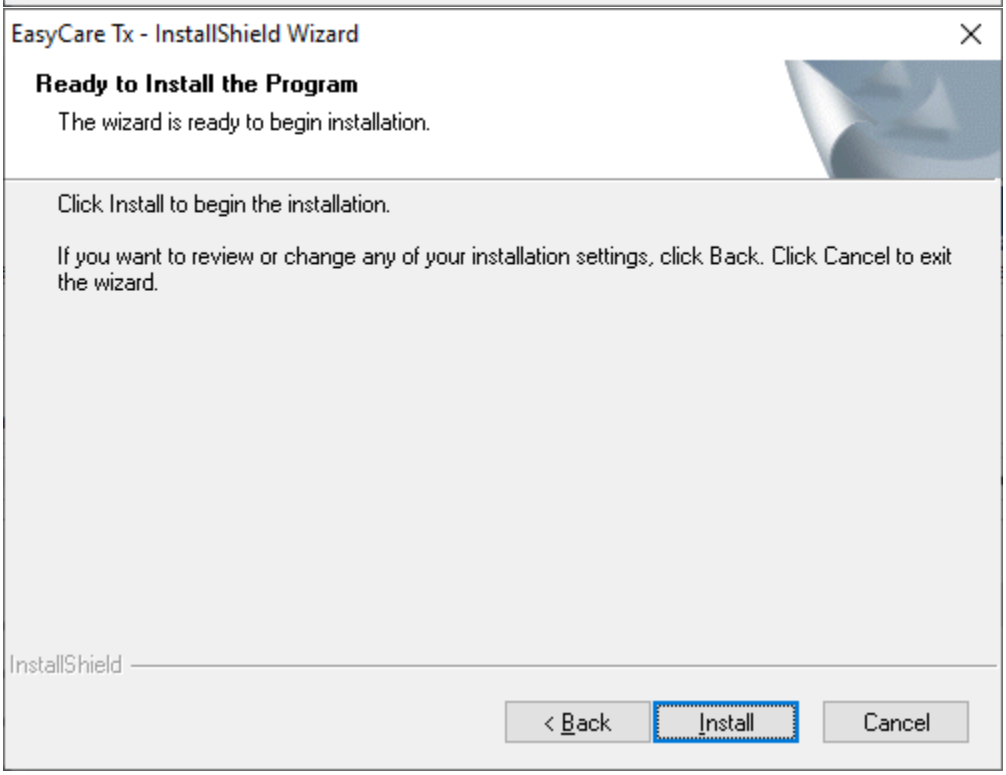

EasyCare Tx - InstallShield Wizard
Welcome to the InstallShield Wizard for EasyCare Tx
The InstallShield Wizard will install EasyCare Tx on your computer. To continue, click Next.
< Back
Next >
Cancel


EasyCare Tx - InstallShield Wizard
License Agreement
Please read the following license agreement carefully.
EASYCARE TX SOFTWARE LICENCE AGREEMENT
WARNING: PERMISSION TO USE THE EASYCARE TX SOFTWARE IS CONDITIONAL UPON YOU, THE LICENSEE, AGREEING TO THE
I accept the terms of the license agreement
I do not accept the terms of the license agreement
Print
InstallShield
< Back
Next >
Cancel


EasyCare Tx - InstallShield Wizard
Setup Type
Select the setup type to install.
Please select a setup type.
Complete
All program features will be installed. (Requires the most disk space.)
Custom
Select which program features you want installed. Recommended for advanced users.
InstallShield
< Back
Next >
Cancel


EasyCare Tx - InstallShield Wizard
Select Program Folder
Please select a program folder.
Setup will add program icons to the Program Folder listed below. You may type a new folder name, or select one from the existing folders list. Click Next to continue.
Program Folder:
ResMed
Existing Folders:
Accessibility
Accessories
Administrative Tools
Alertus Technologies
Compumedics
Maintenance
Microsoft Silverlight
Mount Sinai Desktop Support
StartUp
InstallShield
< Back
Next >
Cancel





Restart Computer