RNK Products, Inc.

TR-USB
Telephonic Stethoscope
Installation and Operation Manual

TR-USB Telephonic Stethoscope Installation and Operation Manual
Revision 1.4

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This document provides the operating instructions for the TR-USB product.

This product meets the safety requirements of IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety for Type BF protection using a power source providing 5 vdc at a maximum of 500 mA via a USB cable. The device providing power should satisfy IEC 60950.

Vdc: Type BF applied part:

This product meets the EMC Emissions and Immunity requirements of IEC 60601-1-2 Medical Electrical Equipment Part 2 Collateral Standard: Electromagnetic Compatibility Requirements and Tests:

EN61000-4-2	Part 2: Electrostatic Discharge Requirements
EN61000-4-3	Part 3: Radiated Electromagnetic Field Requirements
EN61000-4-4	Part 4: Electrical Fast Transient / Burst Requirements
EN61000-4-5	Part 5: Surge Immunity Requirements
EN61000-4-6	Part 6: Conducted Immunity Requirements
EN61000-4-8	Part 8: Power Frequency Magnetic Field Requirements
EN61000-4-11	Part 11: Voltage Dips, Interrupts, and Fluctuations Requirements
EN55011 Class B	Emissions Requirements

This product may be used in continuous operation.

This product is not suitable for use in the presence of a flammable anesthetic mixture with air or with continuous oxygen or nitrous oxide.

This product 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 undesirable operation.

Normal use for this product is at an ambient temperature range of +10° to +40°C, a relative humidity range of 30% to 75%, an atmospheric pressure range of 700 hPa to 1,065 hPa. It may be transported and stored at temperatures from 0°C to 50°C.

Disposal of the device should in accordance with all federal and local laws.

For questions or comments, contact RNK Products, Inc., 4195 US Hwy 1, Suite 101, Rockledge, FL 32955

I. Introduction and Overview

The TR-USB Telephonic Stethoscope provides high quality remote auscultation with a number of valuable and unique features.

- Low bandwidth while achieving quality auscultation. The TR-USB connects to a USB port of a PC via a standard USB cable.
- The TR-USB at one location can interoperate with a TR-1/EF at another location.
- Same model can be configured for Transmit operation or Receive operation.
- Plugging in the Chest Piece Assembly automatically puts the unit into Transmit Mode and illuminates the TX Mode light.
- In Transmit Mode, the same auscultation sounds that are sent to the remote TR-USB unit are also presented at the Headset jack for local monitoring.
- Leaving the Chest Piece input jack empty automatically puts the unit into Receive Mode and illuminates the RX light.
- Volume control for adjusting the sound level delivered to the Headset jack. The Volume control works in Receive Mode for sounds received from a remote TR-USB unit or in Transmit Mode for monitoring sounds generated from the Chest Piece Assembly plugged into that local unit.
- B/D Switch for an enhanced Bell/Diaphragm selection. The Bell (B) position cuts off the high end at 250 Hz and boosts the low frequencies below 100 Hz for enhanced heart auscultation. The Diaphragm (D) position slightly reduces the very low frequency sounds and extends the high frequencies to 1,400 Hz. The B/D Switch works in Receive Mode for sounds received from a remote TR-USB unit or in Transmit Mode for monitoring sounds generated from the Chest Piece Assembly plugged into that local unit.

The TR-USB Telephonic Stethoscope is for prescription use by medical care professionals.

II. Installation

Installation of a TR-USB Telephonic Stethoscope requires TR-USB Drivers and an end-to-end data communications capability (e.g. SOIP program or equivalent) operational in the PC. The TR-USB unit will derive its power from the PC over the USB interface cable.

A. TR-USB Drivers

The TR-USB Drivers are available on a “TR-USB Stethoscope USB Driver” CD. Follow the instructions in the manual “Installation of TR-USB Drivers”. A virtual COM port will be assigned to the TR-USB unit. That COM port number should be briefly presented when a TR-USB unit is first plugged in and can be viewed at any time by going to the Device Manager in the PC.

B. End-to-End Data Communications

The PC to which the TR-USB unit is connected has the responsibility for establishing a functional data communications channel with the remote TR-USB unit.

An example of a means to establish such a channel is RNK Products' Stethoscope Over IP (SOIP) program. Detailed instructions are provided in the SOIP Operator's Manual.

If SOIP is used, then for convenience, two TR-USB units can be set up to talk to each other on the same PC. Each unit will be assigned a different virtual COM port. Open two copies of SOIP and assign one of the COM port numbers to the TR-USB unit in each of the SOIP windows. Set one copy to Receive Mode and the other to Transmit mode. Since both are on the same PC, they will use the same IP address but will be accessed on the different COM ports.

Once set up, the two TR-USB units will function as described below.

C. Mode Selection

If there is no Chest Piece Assembly plugged into the Chest Piece jack of the unit, then the unit will be in Receive Mode and the RX Mode light will be illuminated. The TX Mode light will be OFF.

If a Chest Piece Assembly is plugged into the Chest Piece jack of the unit, then the unit will be in Transmit Mode and the TX Mode light will be illuminated. The RX Mode light will be OFF.

III. Operation

For a normal remote auscultation exam, the TR-USB unit located with the patient is in Transmit Mode and the TR-USB unit with the clinician is in the Receive Mode.

A. TX Mode

To operate as an auscultation transmitting unit the TR-USB must have a Chest Piece Assembly plugged into the Chest Piece jack. That will put the unit into Transmit Mode and illuminate the TX Mode light located just over the Chest Piece jack. Sounds from the Chest Piece will be converted to digital signals and sent out over the USB data interface. The SOIP program must set that unit up in Transmit mode. At that point, it will wait indefinitely for a Receive end unit to establish a connection.

In addition to transmitting the digital signals, the auscultation sounds from the Chest Piece are looped back and presented at the local Headset jack. Thus, with an optional Headset, the local user can listen to the same auscultation sounds that the listener at the remote TR-USB (in Receive Mode) would hear.

Volume to the Headset can be increased by turning the Volume control clockwise. Increasing the volume too high can cause distortion in the Headset and will also increase the background noise. Start with the lowest volume necessary to hear the sounds, then turn up the volume as needed to focus in on specific sounds.

The B/D Switch can be used in an auscultation exam similarly to a traditional stethoscope. The Bell (B) position cuts off the high end at 250 Hz and boosts the low frequencies below 100 Hz for enhanced heart auscultation. The Diaphragm (D) position slightly reduces the very low frequency sounds and extends the high frequencies to 1,400 Hz.

Adjusting the Volume or changing the B/D Switch only affects what the local listener hears and does not affect what the remote TR-USB listener would hear. The remote TR-USB listener has independent Volume and B/D Switch controls.

B. RX Mode

Without a Chest Piece Assembly plugged into the Chest Piece jack of the TR-USB, the unit is automatically in the Receive Mode. The SOIP program must set that unit up in Receive mode. The IP address of the Transmit end TR-USB (or TR-1/EF) must be entered into the IP Address Book of SOIP. The user can select that address and initiate a connection by clicking on the Connect button.

With the data connection established and a Headset plugged into the Headset jack of the unit, the clinician is set up to hear the stethoscope sounds from the remote TR-USB (in Transmit Mode).

Volume to the Headset can be increased by turning the Volume control clockwise. Increasing the volume too high can cause distortion in the Headset and will also increase the background noise. Start with the lowest volume necessary to hear the sounds, then turn up the volume as needed to focus in on specific sounds.

The B/D Switch can be used in an auscultation exam similarly to a traditional stethoscope. The Bell (B) position cuts off the high end at 250 Hz and boosts the low frequency sounds below 100 Hz for enhanced heart auscultation. The Diaphragm (D) position slightly reduces the very low frequencies and extends the high frequencies to 1,400 Hz.

IV. Maintenance and Calibration

There is no scheduled maintenance required for the TR-USB Telephonic Stethoscope.

There is no calibration required for the TR-USB Telephonic Stethoscope.

If problems should arise with the TR-USB Telephonic Stethoscope, the table in the following section may be used to trouble shoot the problem. Any failed units should be returned for repair.

The TR-USB Telephonic Stethoscope may be cleaned with a damp cloth.

V. Trouble Shooting

Following is a chart to assist in trouble shooting problems which may arise during installation or operation.

Symptoms	Possible Causes and Solutions
Neither TX Mode nor RX Mode lights come ON	USB cable plug not inserted all the way into the USB jack of the PC. *Make sure the USB plug is fully seated.* *Try another USB cable.* If the TR-USB unit LED still does not come on, return the TR-USB unit for repair/replacement.
Chest Piece is plugged in, but the RX Mode light stays ON and the TX Mode light is OFF.	The Chest Piece Assembly is not plugged in all the way. *Make sure Chest Piece Assembly plug is fully seated.* The TR-USB unit has failed. *Return the TR-USB unit for repair/replacement.*
Nothing is plugged into Chest Piece jack, but the TX Mode light is ON and RX Mode light is OFF	The TR-USB unit has failed. *Return the TR-USB unit for repair/replacement.*
The Chest Piece is plugged in, the TX Mode light is lit, but there is no sound heard in the local Headset.	The Chest Piece Assembly is not plugged in all the way. *Make sure Chest Piece Assembly plug is fully seated.* The Headset is not plugged in all the way. *Make sure Headset plug is fully seated.* The Chest Piece Assembly and Headset are plugged into the wrong jacks. *Make sure Chest Piece Assembly and Headset are plugged into the proper jacks and are fully seated.*
The Chest Piece is plugged in, the TX Mode light is lit, sounds can be heard in the local Headset, but there is no sounds heard in the Headset of the remote TR-USB.	The remote TR-USB unit has not established an IP connection. *Initiate an IP connection from the SOIP program for the Receive end TR-USB.* Observe the status shown on the Receive end SOIP. *If it indicates that a connection has not been established trouble shoot the IP network.* *If it indicates that a connection has been established then try a different TR-USB unit at the Receive end. If the same conditions persist, then try a different TR-USB unit at the Transmit end.* *If the system works after one of the swaps, then return the failed unit for repair/replacement.*