

PCP-USB Stethoscope

Installation and Operation Instructions

EC Version

Rev 1.2

This document provides the patient operating instructions for the PCP-USB Stethoscope



This product meets the safety requirements of EN 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety for Type BF protection using a power source providing 2 - 5 vdc. The device providing power should satisfy IEC 60950.

Vdc:



Type BF applied part:



Class II protection
against electrical shock:



This product is intended for use within the electromagnetic environment specified below. The user of the product should assure that it is used in such an environment. Portable and mobile RF communications equipment should be used no closer to any part of the product than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. A problem arising in usage may be resolved by relocating the other equipment so that it is farther away.

Immunity Test	IEC 60601 Test Level	Electromagnetic Environment Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz - 80 MHz	$d = [3.5/3V]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz - 2.5 GHz	$d = [3.5/3V]\sqrt{P}$ for 80 MHz to 800 MHz $d = [7.0/3V]\sqrt{P}$ for 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts according to the manufacturer and d is the recommended separation in meters. Interference may occur in the vicinity of equipment marked with the RF radiation symbol.



RF Radiation
symbol

This product may be used in continuous operation.

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

Normal use for this product is at an ambient temperature range of +10°C 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 and relative humidity of 10% to 95%.

The device contains electronic components and disposal of it should in accordance with all federal and local laws.

Local laws may take priority over the above requirements. If in doubt, consult your local representative or the technical service department.

This device is intended for use in a professional healthcare environment to listen to sounds produced within the body. There are no contraindications.

For questions or comments, contact EC Authorized Representative
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I. Introduction

The PCP-USB Chest Piece can be used with a generic PC. It is typically used as an accessory to a video conferencing software application.

II. Installation

Installation of the PCP-USB Stethoscope is comprised of plugging the PCP-USB Chest Piece into the USB port of the PC. If any software is used (e.g. video conferencing software), it should be installed in accordance with the directions provided with the software.

III. Auscultation Sessions

Typical operation is that before starting an auscultation session, a video conferencing session would be established to enable the remote Clinician to see and talk to the Patient and any local Clinicians. A stethoscope session would be initiated following the software Operation Instructions.

The chest piece will be positioned on the patient to satisfy the clinical objectives of the exam.

IV. Cleaning, Preventive Inspection, Maintenance and Calibration

The PCP-USB Chest Piece requires no preventive inspection, no preventive or routine maintenance, and it does not have to be calibrated.

The PCP-USB Chest Piece is not a sterile device and does not require sterilization or disinfection. It can be cleaned, as required, by wiping with a moist cloth, alcohol or a sanitizing towelette.

V. Trouble Shooting

If no stethoscope sounds are heard from the PC:

- Check for a failed PCP-USB Chest Piece by testing the local loop back through the PC Control Panel
- Check for a failed PCP-USB Chest Piece by substituting it with a replacement PCP-USB Chest Piece.