



TotalExam[®] Backpack User Manual



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1

Getting Started

1.1. Overview

The GlobalMed TotalExam® Backpack (TEB) brings a new dimension to delivering virtual care to patients in remote environments. This lightweight, USB-powered design provides a simple and organized solution, configured for in-home care or remote provider consultations with our suite of clinical devices. Our devices allow a wide array of clinical data collection, from vital signs including blood pressure, heart rate and temperature, to heart and lung sounds. Even in the most rural areas or isolated locations, a clinician can gather video evidence for an ENT consultation, and even capture ultrasound images, expanding care to patients anytime, anywhere.

This chapter describes various technical details about the TEB. The following topics are discussed:

- *"Precautions"*
- *"Technical Specifications"*
- *"Compatible Devices"*

1.2. Precautions

Note: This device is only intended for use by licensed medical professionals. Refer to all component manuals for any additional precautions before using this unit.

Table 1 TEB Precautions

Precaution Type	Warning Description
General	• Always set the TEB on a steady tabletop or flat surface. • Only use manufacturer-recommended or approved accessories to ensure compatibility. • Retain the original packaging material.
Liquid and Moisture	• Never spray or use liquid directly on components or connectors. • If any liquid penetrates any component or connector, switch it off and unplug the power cord. Contact your service provider. Continuous use may lead to further damage and/or result in electrical shock or may create a fire hazard. • Never operate or touch any electrical component with wet hands. • Do not store or operate equipment in areas with excessive moisture

1.2.1. Warnings

1. These devices are electrical; do not attempt to submerge into any kind of liquid. Doing so could result in equipment failure and/or user electrical shock.
2. The devices have been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.
3. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications.
4. Any dismantling of the devices will void the warranty and could damage the devices or cause electrical shock. If it is necessary to clean them, refer to the cleaning procedures sections for instructions on how to maintain cleanliness and thereby prevent contamination. The devices alone are not intended to be used to diagnose, treat, cure or prevent any disease and should not be used as substitute for a health professional's advice.
5. GlobalMed does not accept any liability for injury, loss, or damage by use of or reliance on the information gathered by our product.

1.2.2. Cautions

1. The TEB is delivered in non-sterile condition and is not intended to be sterile for use.
2. Modification to equipment may void your warranty or may cause damage to the unit. Consult with your service provider prior to making changes.
3. When using the TEB, position the unit in a manner that does not cause a trip hazard between the unit and the electrical wall outlet.

Table 2 Warning Symbols

Symbol	Description
	General Warning Sign (ISO 7010 – W001)
	Type B Applied Part (IEC 60601 – 1)
	Follow Operating Instructions (IEC 60878)
	Take all used batteries to a battery collection site according to your national legislation and the Batteries Directive 2006/66/EU. Do not discard in standard trash or at a trash site.
	Direct Current (IEC 60417 - 5031)
	ON / OFF (IEC 60417 - 5010)

Reciprocal interface: The TotalExam Lite/TE3 camera, otoscope, TotalVitals, and ClearSteth stethoscope comply with U.S. FCC and EMI requirements according to FCC Part 15, ICES-001, and ICES-003

1.3. Technical Specifications

Table 3 TEB Specifications

Component Specification	Description
Dimensions	18.9" x 11.8" x 6.3" – Backpack Size
Weight	18.0 lbs
Computer Minimum Requirements	• Intel i7 Quad Core 64 bit CPU • 16GB of RAM memory • 512GB Solid State NVMe Hard Drive • Laptop Format PC – for storage and mobility • 15" – 17" LCD Display
Operating System Requirements	Windows® 10 Pro or 11 Pro 64bit
Connectivity	Wi-Fi, Ethernet, Bluetooth
Ports	• 1 SuperSpeed USB 3.0 Type-A connection • 3.5mm Audio Port
Audio	Factory build in Speaker/Microphone combo
Main Camera	Computer Integrated Camera
AC to DC power supply	• Frequency 50/60 hertz • Required Voltage AC 100-240 volt
Operating Conditions	• 10° to 35°C (50 to 95°F) • 5% to 90% Relative Humidity

1.4. Compatible Devices

Below is a list of compatible devices that can be used alongside the TEB. Contact us for further details on the options presented.

Figure 1 Compatible Devices

Note: Not all devices are shown in the figures below. Devices can vary based on your LES configuration.



1. Small Blood Pressure Cuff
2. Large Adult Blood Pressure Cuff
3. Accessory Pouch
 - ECG 12-Leads
 - Klipsch In-Ear Headphones
 - 6" Tongue Depressors (x5)
 - Otoscope Specula (x5)
4. One-Touch Collars (x5)
5. TotalECG®
6. Derm & Polarizing Hood
7. White Balance w/ Scale
8. USB Digital Stethoscope
9. USB-C Interface Cable
10. TotalExam® 3.2 Camera
11. TotalExam® 3.2 Camera Cable
12. TotalVitals® Device
 - Medium Blood Pressure Cuff
 - SpO2 Sensor (Under Cuff)
 - Thermometer (Under Cuff)
13. Autofocus Head
14. Otoscope Head

2

Using the TEB

2.1. Overview

This chapter provides an overview of the fundamental features and functions of the TEB. The following topics are discussed:

- *“TEB Features”*
- *“Using Devices”*

2.2. TEB Features

The following images identify the TEB features.

Figure 2 Lightweight and Compact Bag Design

The TotalExam Backpack (TEB) is designed with comfort and efficiency in mind. Its goal is to enable care without burdening the individual, as well as being an optimal choice for care that involves travel.



Figure 3 Integrated 4-port USB hub

The TotalExam backpack has an integrated USB hub with four ports, two of which are accessible underneath the TotalVitals Insert. The TotalECG Bluetooth dongle and the USB connector for TotalVitals are pre-connected into the USB hub. To connect the hub to your laptop, use the provided USB extender.

Note: The TotalECG and the TotalVitals come plugged into the hub, to connect these devices to your laptop, use the provided USB extender.



Figure 4 USB Extender



Figure 5 Dedicated 15.6" to 17" laptop pocket

The backpack provides a dedicated laptop pocket to ensure its safety in travel.



Figure 6 Custom Foam Insert For Each Peripheral Device

All devices and their accessories are stored in custom inserts to protect the equipment during transport.



Figure 7 Additional storage pockets

The front pocket of the backpack provides ample room for any accessories needed for the devices included.



2.3. Using Devices

2.3.1. Installing the Camera

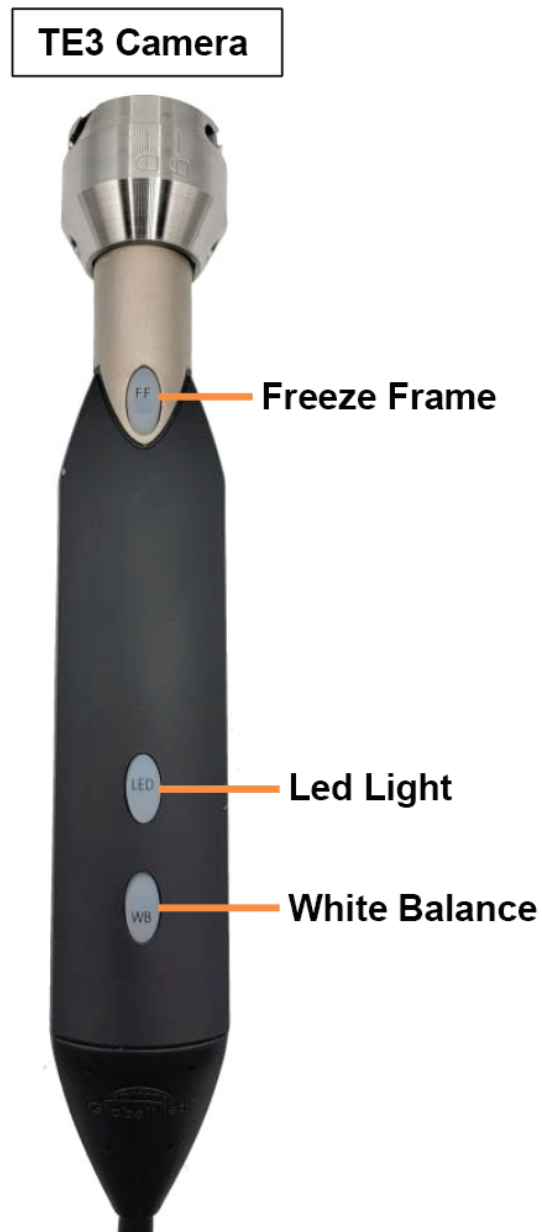
1. Connect either camera to the provided USB-C camera cable and then connect the USB hub extender to the Male to Female USB extension cable attached to your laptop.
 - a. There are no drivers or software to install or download, the camera should be automatically recognized when the USB hub extender is connected to your laptop.
 - b. The cameras do not require an additional power source apart from the USB connection to the laptop.
 - c. For further details on the cameras, please see the applicable TotalExam Lite or TE3 product manual.

Figure 8 Connecting Exam Camera



2.3.2. Camera Controls

Figure 9 Camera Controls - TotalExam® 3.2



2.3.3. Total Vitals

1. The TotalVitals device can be taken out of the backpack to give additional patient access and can be utilized up to six feet away from the back.
2. To remove the device from the backpack, lift the case by the bottom edge and pull up. To put back in the case, place the top end into the cavity first and secure in place.
 - a. For details on how to use this device and its peripherals, please see the product's user manual.

Figure 11 TotalVitals



3. After the device is out of the bag, the cable management system for TotalVitals will be accessible. Carefully wind and unwind the cable as needed.

Figure 12 TotalVitals Cable Management



2.3.4. Other Devices

2.3.4.1. ClearSteth Stethoscope

1. For details on how to use this device and its peripherals, please see the product's user manual.

2.3.4.2. Total ECG

1. For details on how to use this device and its peripherals, please see the product's user manual.

3

Cleaning Procedures

3.1. Overview

This chapter describes the cleaning procedures for the TEB.

3.2. Cleaning Procedures

The aim of these procedures is to provide clear guidance and instruction regarding the cleaning requirements for the TEB. These procedures refer to the classification scheme outlined in the Centers for Disease Control and Prevention (CDC) *Guidelines for Disinfection and Sterilization in Healthcare Facilities*, 2008. To classify the relative degree of risk for infection when using individual TEB components, the procedures are categorized into three levels. The categories and their basic definitions are as follows:

3.2.1. Risk Categorization

1. **Critical:** Items confer a high risk for infection if they are contaminated with any microorganism.
2. **Semi-critical:** Items that contain mucous membranes or non-intact skin.
3. **Non-critical:** Items that contact intact skin but not mucous membranes.

3.2.2. Cleaning Guidelines

1. **Table 8** details the component type, the CDC disinfection and sterilization procedure, and the CDC classification based on the product's use.
 - a. **ALWAYS** use approved disinfecting wipes and/or a soft cloth, lightly moistened with the approved cleaning solutions per CDC guidelines.
 - b. **ALWAYS** check with CDC guidelines and product manuals, if in doubt.
 - c. **NEVER** spray any liquids directly on the or any of the components.
 - d. **NEVER** use any abrasive cleaners or volatile solvents.
 - e. **NEVER** use any alcohol, ammonia, or abrasive products on screens or monitors as they can etch the screen surface and cause the surface to appear cloudy.

Table 4 CDC cleaning guidelines

Component	Procedure	CDC Classification
Devices	Items that may come in contact with non-intact skin for a brief period of time are usually considered noncritical surfaces and are disinfected with intermediate-level disinfectants such as phenol, iodine solution, alcohol, or chlorine.	Semi-critical
External Surfaces	Gently wipe the external with a disinfecting wipe and/or soft cloth, lightly moistened with a facility or CDC-approved cleaning solution.	Non-critical
Cables and cords	Gently wipe all the exposed cables and cords with a disinfecting wipe and or soft cloth, lightly moistened with a facility or CDC approved cleaning solution. All the electrical cords must be unplugged before cleaning. After cleaning, check that all the cables and cords are properly plugged in.	Non-critical
Laptop computer	Use a soft cloth to gently clean the screen(s). The screen(s) are fragile. Do not scrape or tap the screen(s) with any sharp objects. Upon contamination, use a soft cloth moistened with an approved spray designed for monitors and computer screens. Wipe the display with a soft, dry cloth after cleaning. Gently wipe the keyboard with a disinfecting wipe and/ or soft cloth, lightly moistened with a facility or CDC-approved cleaning solution.	Non-critical
Device storage compartments	Gently wipe the interior surfaces with a disinfecting wipe and/or soft cloth, lightly moistened with a facility or CDC-approved cleaning solution.	Non-critical