

User Guide

TotalExam® Lite
Exam Camera and
Otoscope Kit

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Revision History

Revision	Changes	Date
Α	Initial Release	03-18-2021

Chapter 1: About the TotalExam Lite Camera

1.1 About the TotalExam Lite Camera

The TotalExam Lite camera is a hand-held examination video camera with multiple functions. The kit includes One Autofocus and One Otoscope camera. The TotalExam Lite camera allows viewing high definition freeze frame images and live video. Light settings allow for varying levels and intensities of natural white lighting. Buttons on the unit provide controls for freeze frame, light control, and white balance.

USB 2.0 connectivity allows the TotalExam Lite camera to be easily used with laptops, tablet PCs, as well as GlobalMed Exam Stations.

The TotalExam Lite camera kit is intended for indoor use only

Prior to use of the equipment, the operator must possess fundamental understanding of the operational processes outlined in this manual.

Following the instructions provided in this manual will enable the operator to safely utilize the camera.

The TotalExam Lite cameras are not intended to be serviced or maintained while in use. Any repair or replacement of components will be performed by GlobalMed personnel and are not to be replaced by clinical personnel.

1.2 What's Included

Items in the TotalExam Lite camera kit include the following:

- Polarizing Hood Attachment Qty 1
- Derm Hood Attachment Qty 1
- Standard 6.0" Tongue Depressor sample Qty 5
- One Touch Collar sample Qty 5
- Disposable GlobalMed 4.2 mm Adult Specula Qty 5
- Disposable GlobalMed 3.0 mm Child Specula Qty 5
- USB-C Cable Qty 2

1.3 Precautions

Please thoroughly review these safety instructions before operating the equipment. Clinical and technical personnel should adhere to warnings and precautions at all times. Equipment should be used according to operating instructions outlined throughout this manual. Only use manufacturer recommended or approved accessories to ensure compatibility.

Table 1: TotalExam Lite camera precautions

Precaution Type	Description
Liquid and Moisture	- Avoid direct contact with liquids on all electrical components of the device - Do not store or operate equipment in areas with excessive moisture
Electrical	- Warning: To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth - Do not use if cable is damaged
Cerfications	- The TotalExam Lite Camera complies to FCC, EMC, and EMI requirement according to: FCC Part 15, Class B NFPA99 EMC EN60601-1-2 IEC 60601-1 Bio Compatibility 10993-1,10993-5,10993-11 RoHS 2002/95/EC CE MDR Class I

1.4 Warnings

Warning:

This Camera is an electrical device; do not attempt to submerge into any kind of liquid. Doing so could result in electrical shock or other hazardous conditions.

The TotalExam Lite camera has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.

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.

Any dismantling of the camera will void the warranty and could damage the device or cause electrical shock. If it is necessary to clean the camera refer to the cleaning procedures sections for instructions on how to maintain cleanliness and thereby prevent contamination. This device alone is 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.

GlobalMed does not accept any liability for injury, loss or damage by use of or reliance on the information gathered by our product.

1.5 Specifications

Table 2: TotalExam Lite Camera specifications

Component	Lite Camera	Oto Camera
Dimensions	192mm x 30mm	170mm x 30mm
Weight of Camera Body	88.4 grams/3.11 oz	80.2 grams/2.83 oz
Focus Type	Autofocus	Fixed Focus
Snapshot Size	1 Megapixel	1 Megapixel
Captured Video Resolution	1280 x 720	1280 x 720
Captured Frame Rate	30 fps	30 fps
Output	USB 2.0	USB 2.0

1.6 Features

Specifically designed with the clinician and medical professional in mind, the TotalExam® Lite is our most feature complete imaging solution for telemedicine kit:

- High resolution sensor for precise exam imaging
- Extended Field of View Eliminates Need for Multiple Exam Images
- Superior Operation in Low Lighting
- Variable Illumination Levels

- Optimized Color for Truer Images
- Advanced Auto-Focus and Intelligent Frame Capture for Clearer Images
- Patent-Pending USB Cable Lock, Ergonomic Grip and Easy to Clean Surfaces

Chapter 2: Using the TotalExam Lite Camera

2.1 Overview

This chapter provides information on the use of the TotalExam Lite Camera, and the TotalExam Otoscope Camera.

2.2 Installing the TotalExam Lite Camera

The TotalExam Lite and Otoscope Cameras do not have any drivers or software to install or download. The Cameras do not require any additional power and should be recognized automatically, making it ready for use.

2.3 TotalExam Lite Camera and Otoscope Controls



Figure 1: TotalExam Lite Camera Control Locations

Figure 2: TotalExam Otoscope Control Locations



2.3.1 LED Light Control (LED Button)

The camera contains a light carousel for illuminating the viewing area. There are multiple levels of LED light intensity that can be accessed and controlled via the LED button.

- Press the LED button to turn on the TotalExam Lite LED ring. The light intensity level is at the lowest level.
- 2. Press the button again to increase the light intensity until it reaches the highest level.
- Press the button after the highest intensity level is reached to shut off the LED ring.

2.3.2 White Balance Button

The Auto Focus Camera is equipped with a white balance feature that helps ensure the overall color quality of the image. Use this feature every time the light settings are changed.

Tip: Select the LED light level prior to selecting the WB option.

- 1. Point the Camera at the included White Label (or other pure white color surface).
- 2. Double Click White Balance Button (WB button will flicker).
- 3. Press the White Balance Button once more and the image should appear warm (WB button will stop flickering).

Note: The Otoscope has automatic white balance.

2.3.3 Capture Image Button

Use the Capture Image button to capture an image.

- 1. Push the Capture Button on the Camera.
- 2. Adjust the Camera until the image is in focus.
- 3. Release capture image button, image is frozen upon release.
- 4. To store the image, click on the capture icon in eNcounter.
- 5. To resume live video stream, press the capture button on the Camera again.

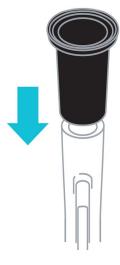
Note: Unplugging the camera from the computer while displaying a still image will cause the camera to lose power and the image to be lost.

2.4 TotalExam Lite Camera Accessories

2.4.1 Polarizing Hood Attachment - Qty 1

The Polarizing Hood helps eliminate unwanted glare from examination surfaces. It attaches to the end of the TotalExam Lite autofocus camera and allows the user to reduce the amount of light reflecting off the area of interest. Use a One Touch Collar on the Polarizing Hood when closely examining a patient's skin. The One Touch Collar acts as a barrier to protect the derm hood and camera from contact with breached or broken skin. After each use, dispose of the touch collar as medical/biohazard waste.

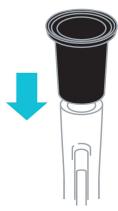
1. Attach the Polarizing Hood by firmly pressing onto the TotalExam Lite.



2.4.2 Derm Hood Attachment - Qty 1

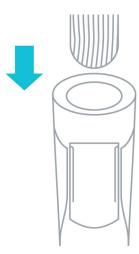
The derm hood focuses the camera's LEDs on the examination surface and helps stabilize the image. It is designed to fit onto the TotalExam Lite autofocus camera for close proximity examinations. Use a One Touch Collar on the derm hood when closely examining a patient's skin. The One Touch Collar acts as a barrier to protect the derm hood and camera from contact with breached or broken skin. After each use, dispose of the touch collar as medical/biohazard waste.

1. Attach the Derm Hood by firmly pressing onto the TotalExam Lite.

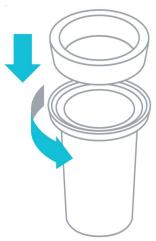


2.4.3 Standard 6.0" Tongue Depressor sample - Qty 5

The TotalExam Lite camera comes with an integrated tongue depressor adapter that holds a standard 6.0" tongue depressor for oral examinations or stabilization during close proximity examinations. The adapter will not work with either the polarizing or derm hood installed.



2.4.4 One Touch Collar sample - Qty 5



2.4.5 Disposable GlobalMed Specula

- 2.4.5.1 4.25mm Specula sample Qty 5
- 2.4.5.2 3.0mm Specula sample Qty 5

The TotalExam Oto camera is compatible with the GlobalMed's single use, child and adult size, disposable specula. After each use, dispose of the specula as medical/biohazard waste.



2.4.6 USB-C Cable - Qty 2

2.5 Cleaning Procedures

The TotalExam Lite camera and otoscope are an FDA registered Class I non-sterile medical device. The camera is used in conjunction

with three accessories: the Derm Hood, Tongue Depressor, and the Disposable Touch Collar.

The Polarizing derm hood and the tongue depressor are not intended to be patient contact components and as such are designed to be cleaned and reused multiple times. The touch collars, tongue depressors, and specula are intended for patient contact and are a one-time use components.

Table 3: Cleaning Procedures for the TotalExam Lite camera kits

Component	Procedure	Frequency
TotalExam Lite camera and cord	Gently Wipe all parts of the outer surfaces of the equipment and cord with a disinfecting wipe and/ or soft cloth moistened with a facility or CDC approved cleaning	At least weekly or when contaminated.
TotalExam Lite Otoscope	solution Gently wipe down with cotton swabs and Isopropyl alcohol (90% or higher).	Clean after every exam of the ear or nose.
TotalExam Lite Camera body	Use a lens cloth or soft cotton swab with a CDC approved lens cleaning solution.	Clean at least weekly or when contaminated.
TotalExam Lite Camera polarizing derm hood	Derm hood can be gently wiped down or soaked in a facility or CDC approved cleaning solution.	After each use.
TotalExam Lite Camera touch collar and specula	N/A	Dispose after each use.
TotalExam Lite Camera tongue depressor	N/A	Dispose after each use.

Authorized European Representative:



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