GlobalMed®

# TotalExam® 3 Camera User Manual

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| | | |

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CHAPTER 1

# About TotalExam 3

## 1.1 About TotalExam 3

The TotalExam 3 camera is a hand-held examination video camera with multiple functions. The camera has interchangeable heads, including an autofocus head and otoscope head. The TotalExam 3 allows viewing high definition freeze frame images and live images. Light settings allow for varying levels and intensities of natural white lighting. Buttons on the unit provide the ability to perform freeze frame, light control, and white balance.

USB 3.0 connectivity allows the TotalExam 3 to be easily used with laptops, tablets, as well as exam stations.

The TotalExam 3 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 3 is 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 service personnel.

## 1.2 What's Included

Items in the TotalExam 3 camera kit may be ordered separately. However, a complete kit includes the following:

- TotalExam 3 camera
- Autofocus head
- Otoscope head
- Variable Polarizing Hood (VPH)
- Derm hood
- Tongue depressor adapter
- Tongue depressors (5)
- Touch collars (5)
- 4.25 mm Specula (x5)

## 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® 3 precautions*

| Precaution Type | Description |
|---|---|
| Liquid and Moisture | • Avoid direct contact with liquids on all electrical components and devices on the telemedicine station<br>• 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 mains with protective earth<br>• Do not use if cable is damaged |
| Certifications | The TotalExam 3.0 Camera complies with U.S. FCC and EMI requirements according to FCC Part 15, ICES-001, and ICES-003 |

*Table 2 TotalExam® 3 safety symbols*

| Symbol | Description |
|---|---|
| | Type BF Applied Part<br>(IEC 60417-5333) |
| | Direct Current<br>(IEC 60417 - 5031) |
| | ON / OFF<br>(IEC 60417 - 5010) |

**Reciprocal interface:** The TotalExam 3.0 complies with U.S. FCC and EMI requirements according to FCC Part 15, ICES-001, and ICES-003.

## 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 results.**

The TotalExam 3.0 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 3 TotalExam® 3 Camera*

| Component | 3.0 Specifications | 3.1 Specifications |
|---|---|---|
| Dimensions | Camera Body: 155mm x 33mm<br>Autofocus Head: 38mm x 33mm<br>Otoscope Head: 60mm x 33mm | Camera Body: 214mm x 33mm<br>Autofocus Head: 38mm x 33mm<br>Otoscope Head: 60mm x 33mm |
| Weight of Camera Body | ~12 ozs | ~1 lb |
| Focus Type | Autofocus | Autofocus |
| Snapshot Size | 1 Megapixel | 1 Megapixel |
| Captured Video Resolution | 1280 x 720p | 1280 x 720p |
| Captured Frame Rate | Up to 60 Frames Per Second | Up to 60 Frames Per Second |

*Table 3 TotalExam® 3 Camera (Continued)*

| Component | 3.0 Specifications | 3.1 Specifications |
|---|---|---|
| Output | USB 3.0 | USB 3.0 |
| Integrated Freeze Frame | Push-button (selects the clearest frame of the last 16 frames) | Push-button (selects the clearest frame of the last 16 frames) |
| White Balance | Push-button | Push-button |
| Lighting | Autofocus Head 8 LEDs<br>Otoscope Head 2 LEDs, 5100K | Autofocus Head: 8 LEDs<br>Otoscope Head: 2 LEDs |
| Operating Temperature | 0° – 42° C (32°-107°F) | 0° – 42° C (32°-107°F) |
| Operating Humidity | Less than 90% | Less than 90% |
| Power Usage | Less than 4W | Less than 4W |
| Voltage Usage | ~ 0.800 mA @5 VDC using USB 3.0 only | ~ 0.800 mA @5 VDC using USB 3.0 only |
| Aspect Ratio | 16:9 | 16:9 |
| Lens (Aperture) | f:3.0 M12 650nM IR filter<br>f:18.0 FOV: r= 10mm DOF: 12mm – 14mm | f:3.0 M12 650nM IR filter<br>f:18.0 FOV: r= 10mm DOF: 12mm – 14mm |

## 1.6 Features

- HD video stream over USB 3.0 output
- Up to 60 fps on USB 3.0, up to 15 fps on USB 2.0
- 720p image resolution and clarity
- Powered by USB 3.0 ports (No external power supply needed)
- Integrated Freeze-Frame (FF Button)
- White Balance (WB Button)
- LED Control (Multiple levels of intensity, depending on head)
- Pivoting Head (3-Position 0°, 37.5°, 75°)

CHAPTER 2

# Using the TotalExam 3

## 2.1 Overview

This chapter provides information on the use of TotalExam 3.0 and both versions of TotalExam 3.1 cameras; where differences apply between the cameras, they are specified.

## 2.2 Installing TotalExam 3

1. Plug the TotalExam 3 cable into any Windows® based computer that has an USB 3.0 high-speed connector.
2. There are no drivers or software to install or download.
3. The TotalExam 3 does not require the use of a power supply external from the device that contains the USB 3.0 connection.
4. The TotalExam 3 camera does require that a video conferencing application, such as eNcounter®, be open on a computer when plugging in the camera for the camera to power on.

## 2.3 TotalExam 3 Controls

*Figure 1TotalExam 3.0 control locations*

**Note: Both versions of the TotalExam 3.1 have the same control locations.**

*Figure 2 Total Exam 3.1 control locations*

## 2.3.1 Autofocus (AF)

On both versions of the TotalExam 3.1 an AF button is located on the autofocus head. Press this button to turn the autofocus capabilities ON/ OFF.

### 2.3.2 Freeze-Frame Control (FF Button)

Use the FF button to freeze live video and conduct closer examination of an image. Freeze-Frame image optimization is aided by counting back eight frames and forward eight frames for analysis that automatically selects the clearest image among the sixteen buffered-frames.

1. To freeze the live video, press the FF button and release.
2. The image is frozen upon release of the button.
3. The still image remains on the screen until you press the FF button again to release the frozen image.

**Note: Unplugging the camera from the computer while still in Freeze-Frame mode causes the camera to lose power and the frozen image to be lost.**

### 2.3.3 White Balance Button (WB Button)

Use the WB button to adjust the way light affects the image and adjusts for poor contrast and color. There are two distinct white balancing methods to use. The correct white balancing method depends on if you are capturing the image from a distance of over 1 meter (Perspective Image) or within 1 meter (Micro Image) when using the autofocus head.

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

#### 2.3.3.1 Perspective Image

For images taken greater than 1 meter from the area of interest:

1. Hold a white sheet of paper in front of the subject and aim the camera at the paper.
2. Press the WB button once the view is filled with as much of the paper as possible.

**Note: If the area of interest is moved from the position where the initial white balancing took place, you may need to repeat the white balancing procedure.**

#### 2.3.3.2 Micro Image

For images that are taken less than 1 meter form the area of interest:

1. Hold a white sheet of paper about 100 mm (4 inches) away from the front of the camera and press the WB button.
2. If using the derm hood and touch collar during the white balance procedure, hold it close enough so that the entire camera's field-of-view is filled with the paper and press the WB button.

**Tip: If using the otoscope head, set the light to one of the two settings and point at a white sheet of paper with the otoscope head about 1 cm away.**

### 2.3.4 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.

1. Press the LED button to turn on the TotalExam 3 LED ring. The light intensity level is at the lowest setting.
2. Press of the button again to increase the light intensity until it reaches the highest level.
3. Press the button after the highest intensity level is reached to shut off the LED ring.

## 2.4 TotalExam 3 Heads

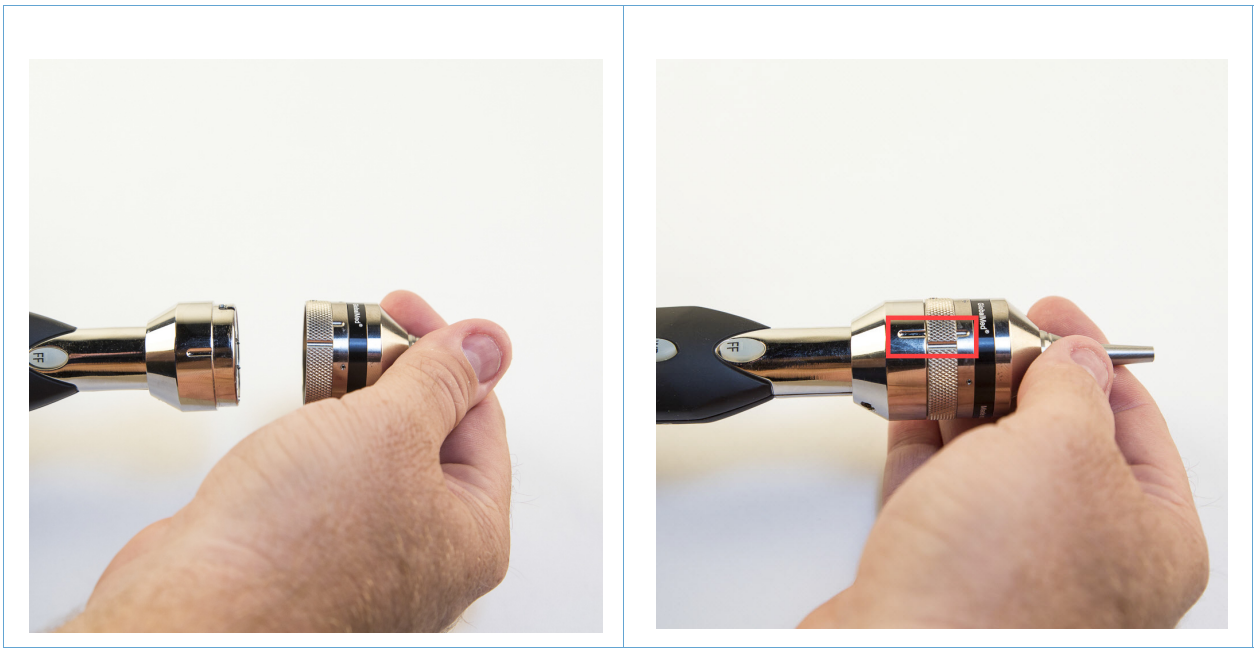
Certain TotalExam 3 camera heads can be changed as needed based on the type of consultation being conducted. Follow these instructions to change heads on the TotalExam 3.

**Note: Some TotalExam 3 camera's have fixed heads that cannot be removed. These camera's are labeled as such.**

### 2.4.1 TotalExam 3.0

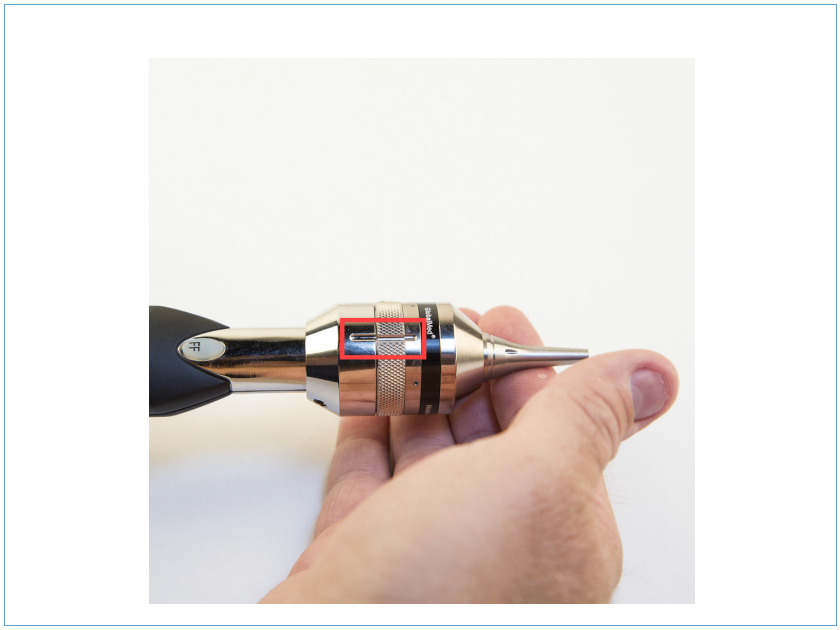
1. To put a head on, gently place the head on the camera wand, lining up the ports on each end of the camera wand and head. The alignment markers are unaligned (see *Figure 3*).

*Figure 3 Placing the head on the TotalExam® 3.0 camera wand*



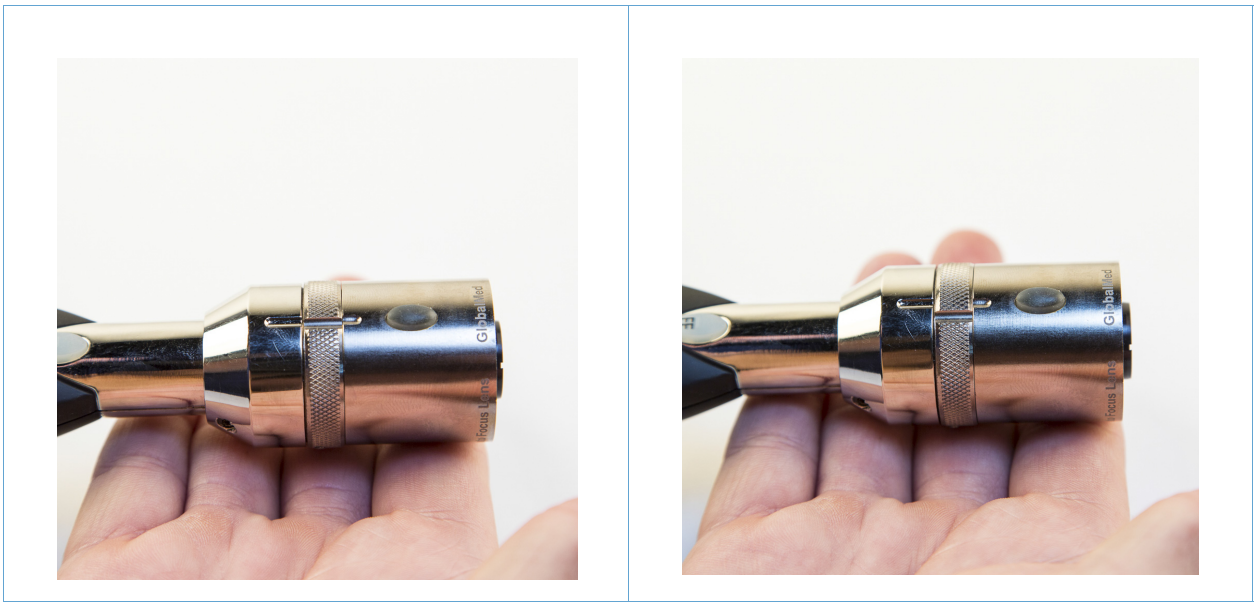
2. To lock the head on the wand, turn the middle ring clockwise until all three alignment markers are aligned.

*Figure 4 Lock the middle ring*



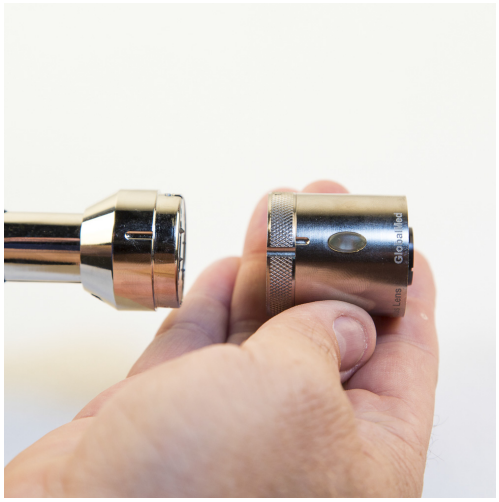
3. To take the head off the TotalExam 3.0 camera wand:
   a. Rotate the middle ring counterclockwise until the alignment markers are unaligned (see *Figure 5*).

*Figure 5 Rotate the middle ring to unalign the markers*



b. Gently pull the head away from the camera wand.

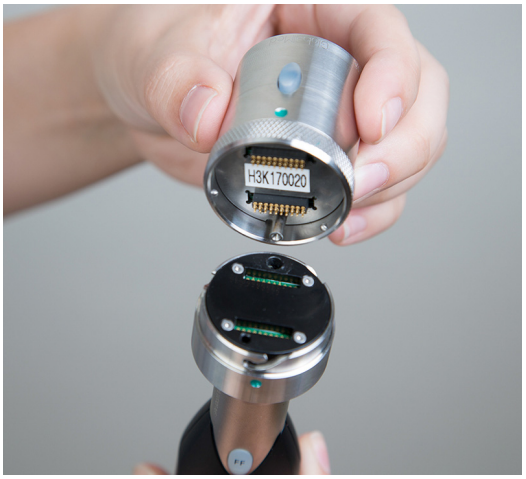
*Figure 6 Gently remove the head*



### 2.4.2 TotalExam 3.1 with alignment dots

1. To put a head on, line up the pin in the head with the hole in the camera wand. Gently begin placing the head on the wand (see *Figure 3*).

*Figure 7 Line up the pin*




2. Located the welding groove on the locking ring and align it just to the right of the green dots. See example below, *Figure 8*.

*Figure 8 Welding groove*

3. To lock the head on the wand, twist the locking ring clockwise so that the two green alignment dots are aligned and the locking ring is firmly secured.

*Figure 9 Rotate the locking ring clockwise*

See *Figure 10* for an example with the otoscope head.

*Figure 10 The otoscope head has two green alignment dots*

4. To take the head off the TotalExam 3.1 camera wand:

a. Rotate the locking ring counterclockwise until the head is loosened from the wand (see *Figure 11*).

*Figure 11 Rotate the locking ring counterclockwise*

b. Gently pull the head away from the camera wand.

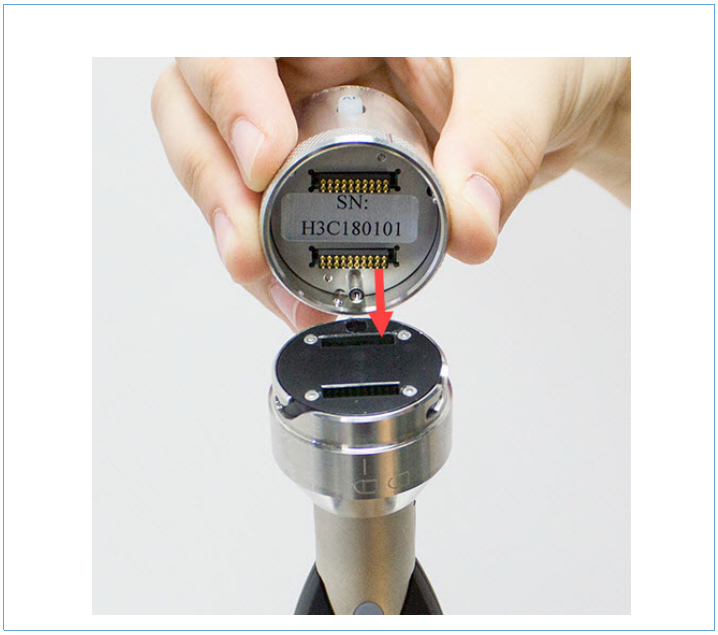
*Figure 12 Gently remove the head*

### 2.4.3 TotalExam 3.1 with locking collar

Use the following instructions for both the autofocus and otoscope heads on the TotalExam 3.1 with locking collar.

1. Line up the pin in the head with the hole in the camera wand (see *Figure 13*).

*Figure 13 Line up the pin*

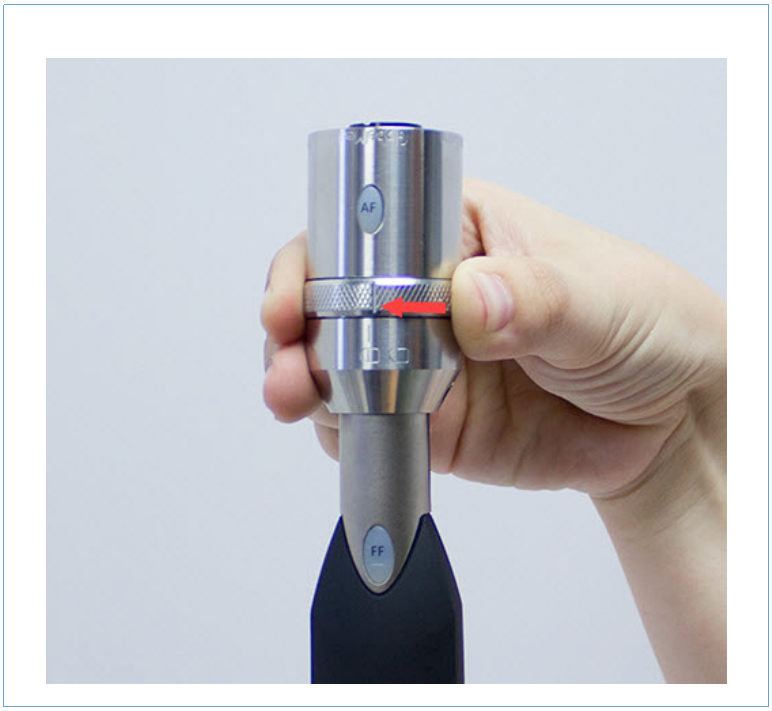



2. Gently place the head on the wand. Position the line on the locking ring above the open lock symbol (see *Figure 14*).

*Figure 14 Position line with open lock symbol*

3. Twist the locking ring to align the line on the ring with the locked symbol (see *Figure 15*).

*Figure 15 Twist the locking ring*




**Note: Do not use force to lock the head into place.**

4. To remove the head:
   a. Twist the locking ring so the line on the ring aligns with the open lock symbol again.
   b. Gently lift the head up and away from the camera wand.

## 2.4.4 Otoscope Head

Use the otoscope head to examine the pinna, external auditory canal, tympanic membrane, and middle ear in HD. The otoscope head works best

at a distance of 12-14mm from the ear drum and uses a fixed focus design. (see *Figure 16*).

*Figure 16 Otoscope head on TotalExam 3.1 with locking collar*

## 2.5 TotalExam 3 Accessories

### 2.5.1 Variable Polarizing Hood

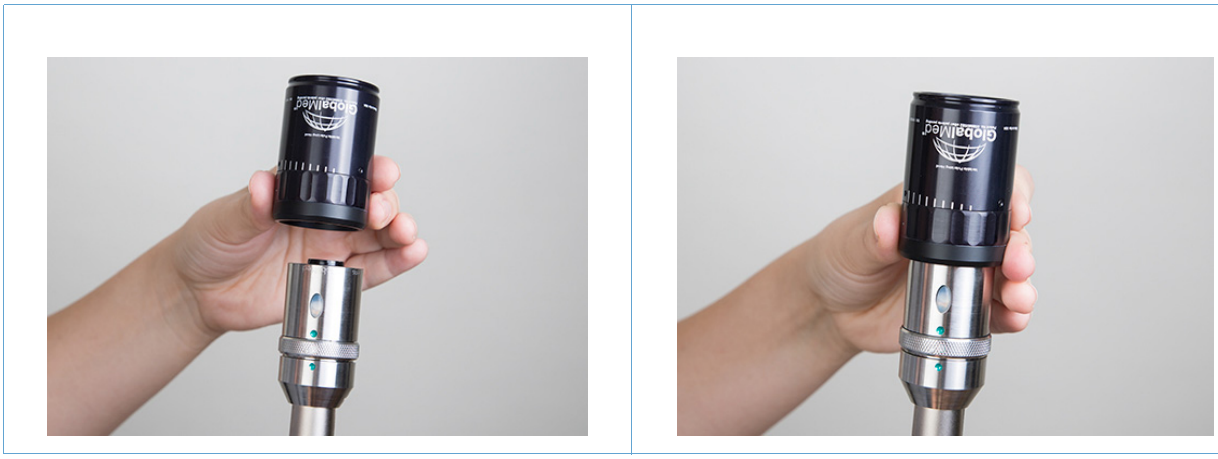
The Variable Polarizing Hood (VPH), purchased separately, is an instrument that eliminates unwanted glare from surfaces that are being examined (see *Figure 17*). It attaches to the end of the TotalExam 3 autofocus head and allows the user to control the amount of light reflecting off the area of interest. Shown below is the standard VPH and the VPH with locking collar.

*Figure 17 Standard VPH (left) and VPH with locking collar (right)*

To attach the standard VPH:

1. Place end with the polarizing ring straight onto the autofocus head (see *Figure 18*).

*Figure 18 Place the Variable Polarizing Hood on the autofocus head*



2. A touch collar can be placed on the distal end to act as a barrier between the camera and patient.

The VPH with locking collar has symbols along the blue collar to show the direction to loosen or tighten (see *Figure 19*).

*Figure 19VPH symbols*

To attach the VPH with locking collar:

1. Place the end with the polarizing ring straight onto the autofocus head (see *Figure 20*).

*Figure 20 Place the VPH with locking collar on the autofocus head*

2. Hold the top of the hood firmly and twist the blue locking collar counterclockwise until it's fully tightened (see *Figure 21*).

**Note: If the VPH loosens during use, twist the locking collar counterclockwise again to tighten.**

*Figure 21 Twist the collar to the right*

3. To remove the VPH with locking collar, hold the top of the hood and twist the blue locking collar clockwise (see *Figure 22*).

*Figure 22 Twist the collar to the left to remove*

4. A touch collar can be placed on the distal end to act as a barrier between the camera and patient.

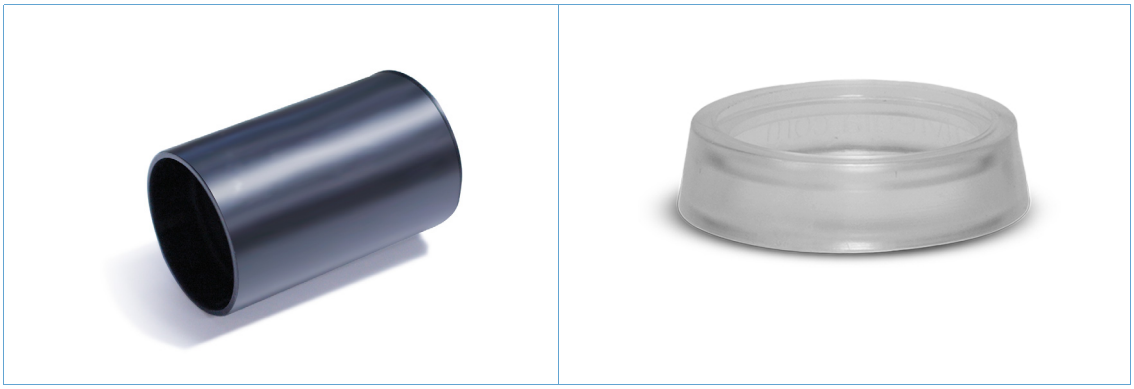
## 2.5.2 Derm Hood and Touch Collar

The derm hood is designed to fit onto the autofocus head and is utilized for up close examinations (see *Figure 23*). The purpose of the derm hood is to focus the light from the camera's LEDs down onto the surface area being examined.

The derm hood is used in conjunction with the touch collar for up close examinations of the skin's surface. The touch collar acts as a barrier to protect the derm hood and camera from becoming contaminated by contact

with mucous membranes or broken skin. The touch collar is a one-time-use only item and should be disposed of as medical/biohazard waste after use.

*Figure 23 Derm hood and touch collar*



## 2.5.3 Tongue Depressor Adapter

The tongue depressor adapter clips on to the TotalExam 3 at the narrow neck of the camera when using the autofocus head (see *Figure 24*). To use the tongue depressor adapter, the head of the TotalExam 3 must be in the upright position, not pivoted. The adapter holds a standard tongue depressor blade for examinations of the throat, mouth, or for stabilization during up-close examinations.

*Figure 24 Tongue depressor adapter*

### 2.5.4 Specula

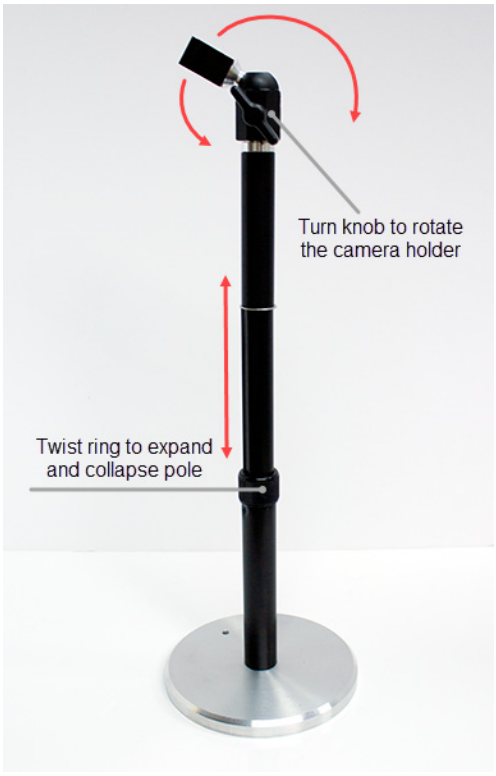
The TotalExam 3 Otoscope Head is compatible with the single use, disposable Welch Allyn Specula (Adult). After each use, the specula should be disposed of as medical/biohazard waste.

*Figure 25 Welch Allyn specula*

### 2.5.5 Total Exam 3 Stand

A camera stand can be purchased separately to hold the Total Exam 3 (see *Figure 26*).

*Figure 26 Total Exam 3 Stand*



1. Turn the knob at the top of the stand to loosen the joint, and then rotate the camera holder to the desired angle.
2. Tighten the knob again to lock in place.
3. Twist the ring on the pole to expand and collapse the pole.
4. Tighten the ring to lock the pole in place.

# 2.6 Cleaning Procedures

The TotalExam 3 Camera is an FDA registered Class I non-sterile medical device. The camera is used in conjunction with three accessories: the tongue depressor adapter, derm hood and the disposable touch collar. The Welch-Allyn specula is used in conjunction with the otoscope head.

The derm hood and the tongue depressor adapter 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 single use components.

*Table 4 Cleaning procedures for the TotalExam® 3 kits*

| Component | Procedure | Frequency |
|---|---|---|
| TotalExam 3 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 solution. | At least weekly or when contaminated. |
| TotalExam 3 Otoscope Head | Gently wipe down with cotton swabs and Isopropyl alcohol (90% or higher). | Clean after every exam of the ear or nose. |
| TotalExam 3 Camera Body ONLY | Use a lens cloth or soft cotton swab with a CDC approved lens cleaning solution. | Clean at least weekly or when contaminated. |
| TotalExam 3 derm hood and Tongue Depressor Adapter | Derm hood and the Tongue Depressor Adapter can be gently wiped down or soaked in a facility or CDC approved cleaning solution. | After each use. |
| Variable Polarizing Hood | Gently wipe down with alcohol pads (90% or higher). | After each use. |
| TotalExam 3 touch collars and Specula | N/A | Dispose after each use. |
| Tongue depressors | N/A | Dispose after each use. |