MouthWatch Plus+

Intraoral Camera

User Guide

Version 1.0

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Safety Instructions

⚠️ This symbol is an indication to the user about important information concerning the use and maintenance of the MouthWatch Plus+ Intraoral Camera. Please read carefully.

- Please read this User Guide carefully and follow all instructions prior to installing and using the camera.

- The only permitted connection is to a USB 2.0 or higher port.

- There are no user serviceable parts within the camera housing. Do not attempt to open, modify or repair the camera.

- Prior to every use with a patient, apply a **MouthWatch OptiClear™ protective sleeve**. Sleeves can be ordered at **https://www.mouthwatch.com/product/camera-sleeves/**

- Between patients wipe the camera with a damp isopropyl alcohol wipe. Repeat, and let dry 3 minutes.

- Do not autoclave the camera.

- In case of malfunction, contact MouthWatch at **1-877-544-4342**

Regulatory Notices

⚠ WARNINGS

- No modification of this equipment is allowed.

- Using components, accessories, cables, and parts other than those specified or provided by the manufacturer of this equipment may impair the safety protection of the Plus+ camera and may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- Any other equipment not complying with IEC 60601 shall be kept at least 1.83 meters away from the patient.

- Do not stare at the LED lights when LED's are active.

- After prolonged use, surface temperatures near the aperture may exceed 43°C.
  Do not keep the LED aperture in contact with patient.

- The camera is only intended to be connected to a computer that has agency approval according to the latest edition of applicable safety and EMC standards. Connecting the camera to other equipment may be hazardous.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify normal operation. In particular, portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be closer than 30 cm (12 inches) to any part of the Plus+ camera including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- Do not immerse camera in liquids.

Device Identification

The MouthWatch Plus+ Intraoral Camera is listed with the Food and Drug Administration (FDA). The unique device identifier (UDI) is shown on the cable tag. The UDI is a combination of the Device Identifier (D937IOCPLUS0G) and the Production Identifier (serial number).

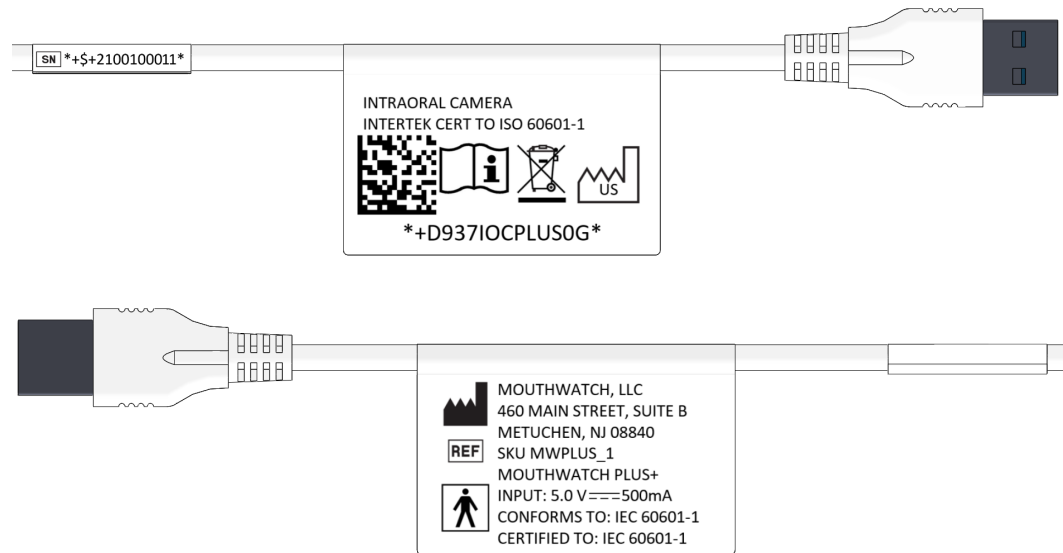| SN | Serial Number |
| Type BF Applied Part |
| Read the instructions for use |
| Assembled in the United States |
| REF | Catalog Reference Number |
| Manufactured By |
| Electronic Waste Disposal |

Each MouthWatch Plus+ Intraoral Camera is assigned a unique serial number which can be found on a tag located at the end of the USB Cable. You will need this serial number if calling for technical support.

Do not remove any tags.
Removal of tags voids the warranty.

SN *+$+2100100011*

INTRAORAL CAMERA
INTERTEK CERT TO ISO 60601-1

+D937IOCPLUS0G

MOUTHWATCH, LLC
460 MAIN STREET, SUITE B
METUCHEN, NJ 08840
REF SKU MWPLUS_1
MOUTHWATCH PLUS+
INPUT: 5.0 V===500mA
CONFORMS TO: IEC 60601-1
CERTIFIED TO: IEC 60601-1

MouthWatch Plus+ Intraoral Camera

The MouthWatch Plus+ Intraoral Camera is a High Definition dental imaging system with a unique combination of features. The camera provides true 1080p video with anatomically correct color rendering at 60 frames per second suitable for use with large monitors and high-resolution 2.1 megapixel still images using a USB 3.0 (or higher) connection to a PC. A complete list of features and capabilities is provided in this User Guide.

Intended Use

The MouthWatch Plus+ Intraoral Camera is intended only for use by health practitioners to show patients and capture images of the interior of their mouths. ⚠ THE CAMERA IS NOT A DIAGNOSTIC DEVICE AND MUST NOT BE USED FOR DIAGNOSTIC PURPOSES. It is not intended to be used near an active MRI or similar magnetic sources or in an active X-Ray field.

Features

- Comfortable, easy to use ergonomic design
  - Dual sets of camera and LED control buttons are easily located while wearing surgical gloves
  - Ergonomic light-weight design, comfortable for both left- and right-handed users

- Integrates with popular dental imaging systems including Dentrix®, EagleSoft®, OpenDental, XDR, and many more

- Anatomically accurate color rendition
  - Six adjustable LEDs provide accurate 5600K color temperature
  - 10-bit color coding enable more than 1 billion color shades to be displayed
  - High Color Rendering Index (CRI) LEDs

- Supports large video monitors
  - True 1080p HD (1920x1080) image resolution when connected to a USB 3.0 (or higher) port
  - 2.1 megapixel still images

- 60 frames per second video streaming
  - Begins automatically when camera is attached to PC
  - Eliminates blurring or lag allowing faster camera motion

- Selectable Power Saving Mode
  - Reduces energy consumption and glare
  - Automatic return to full operating mode when any button is pressed

- Fixed focus
  - Provides optimal viewing distances without the need for manual adjustment
  - Helps camera users achieve faster capture time

- Wide field of view allows capture of full arch

- Four levels of LED brightness adjustment including Off
  - With LED's off, the camera can be used to take images of a transilluminated tooth

- Clinical Grade Optical System
  - Multi-element medical grade lens
  - Optical quality glass lens protection, with anti-reflective coating
  - Medical grade 5-megapixel CMOS sensor and FPGA processor

- Compatible with MouthWatch desk mounts and wall brackets and MouthWatch OptiClear™ camera sleeves

- Two year warranty
  - Each camera is tagged with a unique serial number for quality assurance and warranty use.
  - **Labels must remain attached for warranty purposes**

Specifications

- Isopropyl alcohol disinfection may be used in accordance with CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, updated May 2019.

- 5-megapixel CMOS sensor and FPGA processor

- Optical quality glass lens protection, with anti-reflective coating

- USB 3.0 Super Speed cable is permanently and securely attached.

- 81° field of view

- Total weight in use including sleeve: 3.5 ounces (100 grams)

- Works with Windows Desktops, laptops and tablets.

Standards

Class 1
Medical Device

FDA-registered class 1 medical device; complies with FCC Part 15, Subpart 103
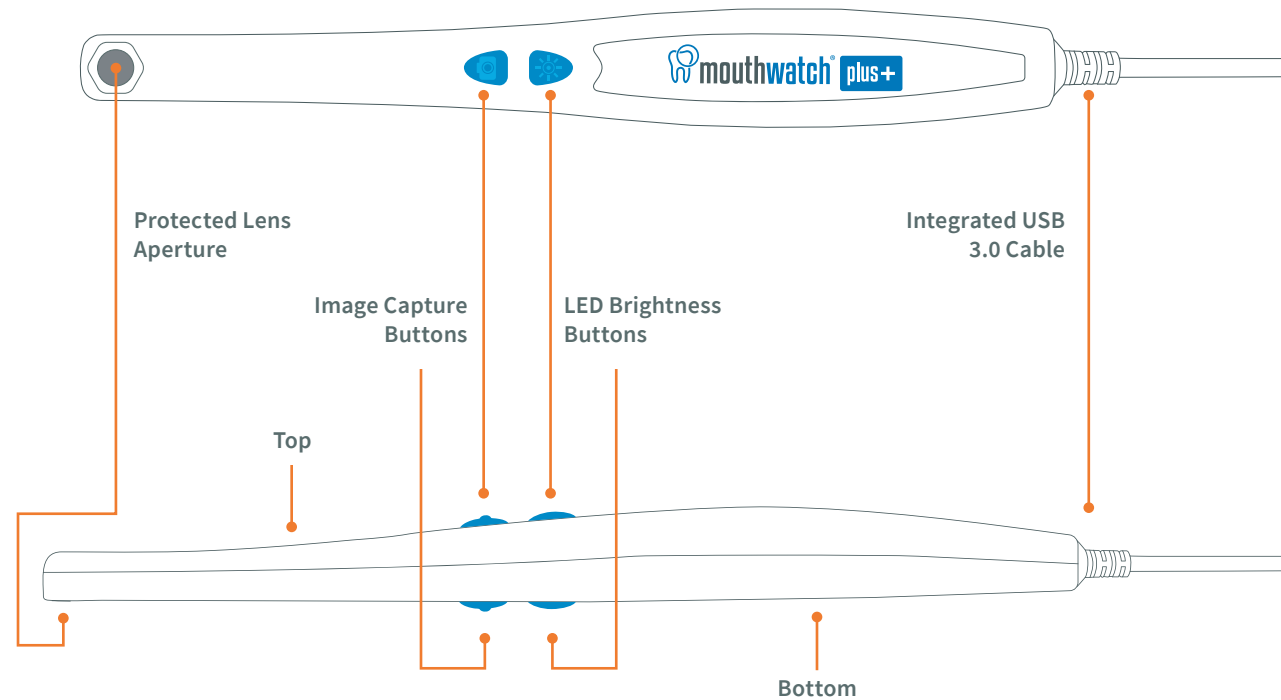
IEC 60601-1 **IEC 62304**

Meets international requirements for basic safety and essential performance of medical electrical equipment and software
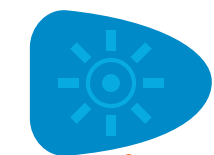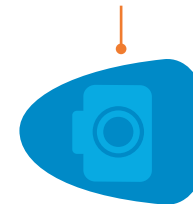
Parts & Nomenclature

Dual operating controls are provided on the top and bottom surfaces of the camera.

- Image Capture buttons are in the forward (distal) position and have a slightly raised tip which can easily be located even while wearing surgical gloves.

- LED Brightness buttons are in the rear (proximal) position and are smooth to the touch.

Protected Lens Aperture

Image Capture Buttons

LED Brightness Buttons

Integrated USB 3.0 Cable

Top

Bottom

In addition, the buttons have embossed icons to further identify Image Capture and LED Brightness.
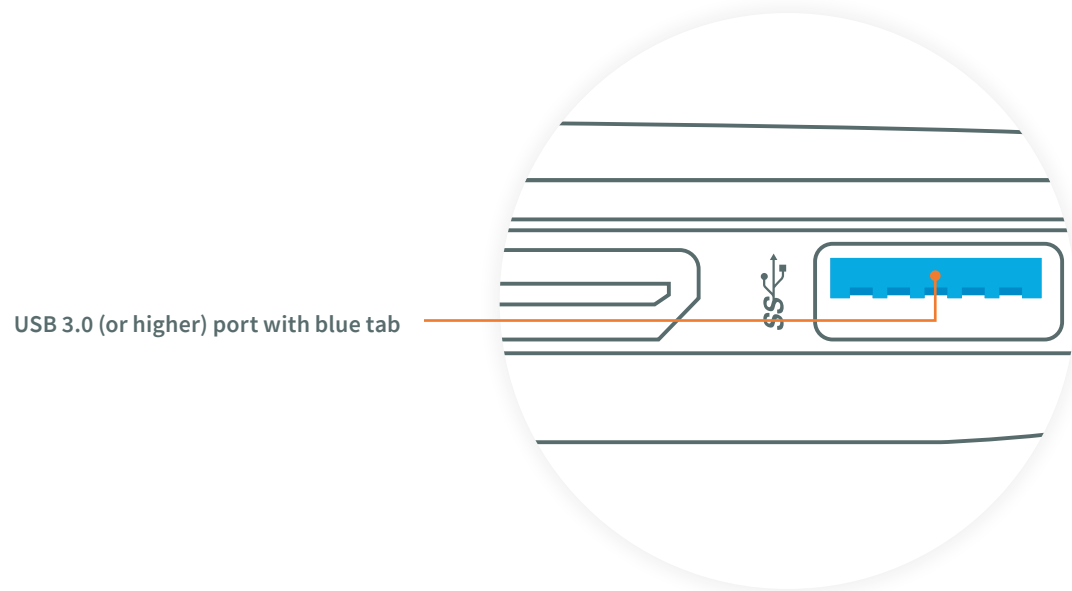
Image Capture Button

LED Brightness Button

Setup & Installation

Installation

Installation is simple. Attach the USB 3.0 connector to a USB 3.0 (or higher) port on your computer. On some computers, a USB 3 port can be identified by a blue tab. On any PC, the presence of a USB 3 port can be verified by accessing the Device Manager – Universal Serial Bus Controllers.

USB 3.0 (or higher) port with blue tab

The computer's operating system will identify the camera as a new device and will provide a message similar to "MouthWatch IOC plus+ device is ready for use".

First Steps with Your MouthWatch Plus+ Intraoral Camera

1. Attach the camera to a USB 3.0 (or higher) port on your computer. The LEDs will come on at maximum brightness.

2. If necessary, start the Windows Camera App and select the MouthWatch Plus+ Intraoral Camera.

3. If you see a full color video stream displayed through the Windows Camera App, your MouthWatch Plus+ camera is functioning correctly.

Using the 4 MouthWatch Plus+ Buttons

When connected and recognized by the computer, the MouthWatch plus+ Intraoral Camera will automatically stream full color video at true 1080p HD (1920x1280) resolution, 60 frames per second. Each time an "Image Capture" button is pressed, a 2.1 megapixel image will be stored in the computer at a location selected by the user.

When the camera is first plugged in to a PC, the LEDs will illuminate at maximum brightness. Pushing either of the LED Brightness buttons will change the brightness of the LEDs in the following cycle: Off, Low, Medium, Maximum.

Focus is preset, no manual or auto adjustment is required.

The MouthWatch Plus+ camera is preset to accurately focus on images between 10 and 50 mm from the surface of the camera. No focus adjustment is needed.

The camera can also be used to capture images beyond 50 mm, e.g., for full face pictures, although some distortion may be noticed.

Compatibility & Integrations

Compatibility with Dental Imaging Software

The MouthWatch Plus+ IOC is compatible with most imaging systems (integrated and stand-alone) including:

- ACTEON® Imaging Suite
- ABELDent
- ADSTRA
- AMCap
- Apteryx
- CADI®
- CaptureLink
- Carestream
- Centaur Media
- CLINIVIEW™
- Cliosoft
- Curve Hero
- DBSWIN
- DentalEye

- Dental Studio Plus®
- DentiMax
- Dentrix Image
- DEXIS™
- DOMx
- Eaglesoft®
- Easy Dental®
- EVASoft
- ExaminePro
- ImageXL
- Kodak
- MacPractice
- MiPACS®
- MOGO®

- Microsoft Camera
- OpenDental
- OneView
- PatientGallery®
- Patterson Imaging
- Photo Booth (Mac)
- Prof.SUNI
- Progeny®
- QSIDental®
- Romexis®
- Schick®
- Sidexis 4
- Sidexis XG

- Sopro
- Soredex™
- SOTA Imaging
- SUNI
- Tab32™
- TigerView
- TWAIN™ systems
- VISIX®
- VixWin™
- XDR
- XLDent™
- XRay Studio
- XrayVision®
- XV Lite

A complete list of software integrations and instructions can be found at:

https://support.mouthwatch.com/hc/en-us/articles/360037251333-Complete-List-of-Integrations

For information about other imaging software, please contact us at **1-877-544-4342**.

Integrate Your MouthWatch Plus+ Intraoral Camera with Imaging Software

Step 1 – Download the Button Capture Software

- Go to: **https://www.mouthwatch.com/support/intraoral-camera-support/** and download MouthWatch Button Capture Software.

- View the installation guide.

- Install the program, following all steps in the guide.

- Select your imaging software from the Button Capture Software menu

Step 2 – Plug in the MouthWatch Plus+ IOC

- Make sure that you plug the USB connector into a USB 3.0 (or higher) port. These may be identified by the blue plastic tab in the port on the computer.

- Note that the camera will also work when plugged into a USB 2.0 port, however resolution will be reduced.

Step 3 – Windows Recognizes the Camera

- Once the MouthWatch camera is plugged in, you should see a small alert on the bottom of your Windows screen saying that New Hardware "USB Video Device" was recognized.

Step 4 – Set Software Preferences

- Software specific instructions can be found at **https://support.mouthwatch.com/hc/en-us/sections/360005790634-Integrating-with-your-X-Ray-Software**

Standby Mode

If the camera detects that it has not been moved or operated for 30 seconds, it will automatically transition to a Standby mode. While in this mode, the LEDs are turned off and live video streaming is inactive, glare from LEDs is eliminated and power consumption is greatly reduced. Image processing is suspended, providing security against unintentional streaming when the camera is not being used for clinical purposes.s

The camera will transition to Standby mode if it has not been moved for a period of thirty seconds.

During Standby mode, any button press will return the camera back to normal operating mode.

Protective Measures & Cleaning

⚠ The MouthWatch Plus+ Intraoral Camera is intended for use with single-use disposable sleeves to prevent cross contamination. Your MouthWatch Plus+ will have come with a starter pack of MouthWatch OptiClear™ sleeves. Before using the camera for intraoral images:

- Disinfect the camera by wiping with an isopropyl alcohol wipe. Repeat with a second wipe and allow to air dry for three minutes. ⚠ **Do not spray the camera directly.**

- Fit the camera with a new sleeve.

Remove the sleeve after each use and dispose as biomedical waste.

Fitting an OptiClear™ Protective Sleeve

⚠ Having the right sleeve and right sleeve fit is important for best imaging. OptiClear sleeves are designed to exactly fit the Plus+ camera and come with an optically clear window to fit over the lens aperture of the camera. To fit an OptiClear™ sleeve:

- Hold the camera with the LED's facing down.

- Slide the camera end under the blue tab of the protective sleeve.

- Slide the camera all the way into the sleeve.

- Pull the sleeve wrapper away from the camera.

- Ensure that the sleeve is taut over the lens aperture.

Sleeves should not be used when taking extraoral images.

Ordering MouthWatch OptiClear™ Sleeves

Additional sleeves can be ordered from MouthWatch at

https://www.mouthwatch.com/product/camera-sleeves/.

Operational Conditions & Requirements

Ambient Operating Conditions

- **Transportation and storage temperature:** -40°C to +70°C (-40°F to +158°F)

- **Operating temperature:** +10°C to +40°C (+50°F to +104°F)

- **Relative humidity:** 10% to 90%, non-condensing

- **Atmospheric Pressure:** 700-1060 hPa (storage is 600-1060 hPa)

Computer System Requirements

The MouthWatch Plus+ Intraoral Camera is designed to interface through a USB 3.0 or 3.1 connection to a computer running the Windows with Windows XP, 7 (with Service Pack 1 or later*), 8 or 10 (preferred) operating system (32 or 64 bit) for optimal performance.

* Special requirements for WIN 7 SP1, KB 404-8957 update needed.

1. **Monitor requirement**

   - 1280 x 1024 optimum screen resolution - 32 bits color mode

2. **USB port**

   - USB 3.0 high speed, high power (500 mA) port for optimal resolution

   - USB 2.0 high speed, high power (500 mA) port (for lower resolution)

NOTE: *USB bandwidth is shared among all USB devices attached to the same port. Achieving optimal performance may not be possible if other USB devices are attached to the same port or are in use at the same time.*

Warranty

The MouthWatch Plus+ Intraoral Camera is warranted against defects in materials or workmanship for two years from the date you receive the camera **provided the serial number tag has not been removed**.

If you have any questions about the camera, please call us at **877-544-4342**.

- There is no restocking fee on intraoral camera orders returned within 60 days. After that period, a 15% restocking fee applies. We only ask that if you ordered multiple cameras, that you open one and use that to make sure you are satisfied.

- To return any MouthWatch product, please email us at **support@mouthwatch.com** with your order number, camera serial number and your contact information. We will get back to you shortly, will issue a return shipping label and will refund to your original payment method upon receipt of the returned camera with serial number tag attached.

NOTE: *International purchases are responsible for paying for the return shipping label and fees.*

This limited warranty does not cover any damage, deterioration or malfunction resulting from any alteration, modification, improper or unreasonable use or maintenance, misuse, abuse, accident, neglect, exposure to excess moisture, fire, lightning, power surges, or other acts of nature.

This limited warranty does not cover any damage, deterioration or malfunction resulting from any unauthorized tampering with this product, any repairs attempted by anyone unauthorized by MouthWatch, LLC to make such repairs, or any other cause which does not relate directly to a defect in materials and/or workmanship of this product.

Without limiting any other exclusion herein, MouthWatch, LLC does not warrant that the product covered hereby, including, without limitation, the technology included in the product, will not become obsolete or that such items are or will remain compatible with any other product or technology with which the product may be used.

mouthwatch® plus+