ENT 3.6FP30

Nasopharyngoscope

Manufactured by:

Optim LLC
64 Technology Park Road
Sturbridge, MA 01566-1253 USA
USA Tel: 1.800.225.7486
Tel: +1.508.347.5100
Fax: +1.508.347.2380
www.optim-llc.com
sales@optim-llc.com

Table of Contents

Introduction 2
Precautions 2
Endoscope Description
Endoscope Diagram & Description 3
Specifications 4
Accessories Listing 4
Endoscope Function
Preparation 4
Endoscope Operation 5
Use of the Endoscope with Video 5
Care & Maintenance
I - Methods of Endoscope Reprocessing 6
II – Endoscope Reprocessing Protocol
1) Pre-Cleaning 7
2) Leak Testing 7
3) Enzymatic Cleaning and Rinsing 8
4) High-Level Disinfection or EO Sterilization
a) 2% Glutaraldehyde Solution Disinfection 8
b) EO Sterilization 8
III - Endoscope Storage 9
Troubleshooting 9
Repair Service 10
Endoscope Warranty 10

Introduction

Optim LLC's ENT 3.6FP Nasopharyngoscope is designed for examination of the upper airway from the nasal passage to the vocal cords. With proper use, the endoscope provides a thorough examination for more accurate diagnoses while minimizing patient discomfort.

Please be sure to handle the fiberoptic instrument with care at all times. The fiberoptics are comprised of thin glass fibers that can easily be damaged by physical trauma, extreme temperatures, high humidity, or fluid invasion of the endoscope.

IMPORTANT

This instrument is intended for use by persons thoroughly trained in the techniques of nasopharyngoscopy. The Optim Nasopharyngoscope is specifically designed for these procedures and should not be used for any other purpose.

This manual describes the proper procedures for preparing and using the endoscope. The manual also contains pertinent information on the proper care and handling of the endoscope during use, reprocessing, and storage.

Please read this entire manual carefully before using the endoscope. If you have any questions concerning the material contained in this manual or concerning the operation or safety of the equipment, please contact our customer service department.

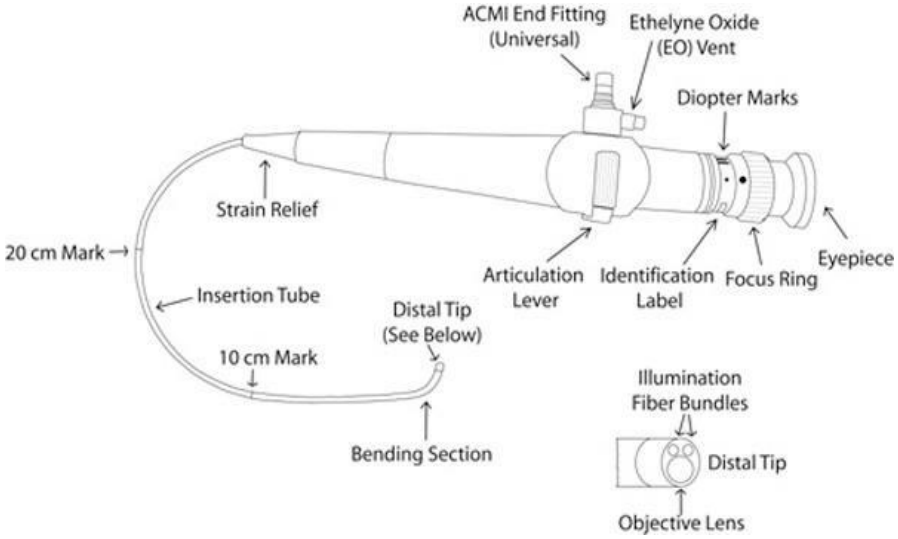
Precautions

- Damage may occur to the endoscope if used improperly. Read this Owner's Manual thoroughly before attempting to use the fiberscope.
- Check all items upon receipt to assure damage has not occurred during shipment.
- Verify compatibility of all components and accessories used with the endoscope by contacting Optim LLC at 1 (800) 225-7486 or 1 (508) 347-5100.
- Avoid excessive bending or twisting of the endoscope Insertion Tube and Light Guide Cable. While designed to bend, too much force can damage the fiber bundles and internal components.
- Do not use excessive force when wiping down the endoscope Insertion Tube. Hold the fiberscope by the Control Body and gently wipe back and forth along the Insertion Tube with a soft material (4x4 gauze).

Precautions (Cont.)

- Avoid storing or using the endoscope in areas of heavy traffic where the endoscope may sustain physical damage.
- The endoscope should not be stored in the Carrying Case, but in a well-ventilated environment. Avoid extreme temperatures, direct sunlight, and high humidity.
- Avoid immersing the endoscope for periods of time greater than recommended by the disinfectant manufacturer. Prolonged immersion may damage the outer coverings of the endoscope and could result in fluid invasion of the endoscope.
- Do not attempt to disassemble the endoscope in any way. There are no user-serviceable parts and disassembly will void all warranties.

Fiberscope Description



Control Body:

Eyepiece: The eyepiece allows the user to visualize the image directly or to connect a standard video camera, still photography system, or teaching attachment to the endoscope. The eyepiece is compatible with most C-mount adapters and video camera systems. Call Optim LLC at +1 (508) 347-5100 or (800) 225-7486 for information on video adapters, cameras, processors and monitors.

Focus Ring: The focus ring adjusts the image to the user's eyesight. Adjust the focus by rotating the Focus Ring (also known as the Diopter Adjustment Ring) clockwise or counterclockwise until the fiber pattern is in clear focus.

Diopter Markings: If using a video camera, still photography system, or teaching attachment, the white dot on the Control Body must be aligned with the white dot on the Focus Ring (Diopter Adjustment Ring). The colored lines provide reference markers for various users of the same endoscope.

Identification Label: Located below the focus ring. Label includes identity of the fiberscope by serial number.

Articulation Lever: The articulation lever controls the angular deflection of the Distal Tip.

Insertion Tube:

Depth Markers: Depth marks are located at 10cm and 20cm from the Distal Tip of the Insertion Tube.

Bending Section: The bending section deflects up and down when the Articulation Lever is rotated.

Distal Tip: The termination of the image fiber bundle (at the Objective Lens) and the Illumination fiber bundles (Light Guides).

ACMI End Fitting Post (Male, with Universal Threads)

Ethylene Oxide (EO) Vent: Equalizes the air pressure inside the endoscope during EO sterilization and shipping when the EO Cap is installed. It is also the connection to the Leak Tester (used to check that the fiberscope is fully sealed and can be used for procedures and/or immersed in liquid).

Accessories

EO Vent Cap:
Cap on: The EO Cap must be **PLACED ON** for aeration, shipping and EO sterilization. It holds the EO Vent open and prevents damage caused by changes in pressure and temperature.

Cap Off: The EO Cap must be **REMOVED** for patient use, leak-testing, and cold-soak. Removing the cap allows the EO Vent to close, preventing fluid invasion.

Scope Adaptor: Thread an Adaptor (P/N's F005512M, F005511M) onto the ACMI Post to adapt to different light guide cables.

Light Guide Cable: Attach Light Guide Cable to fiberscope (with proper Scope Adaptor attached) and insert cable into the Light Source (with proper Light Source Adaptor attached).

Specifications

Outer Diameter	Working Length	Field of View	Depth of Field	Articulation
3.6 mm	30 cm	70°	5-50 mm	135° Up/Down

Scope & Accessories Listing	**Part number**
OPTIM ENT-3.6FP30 Nasopharyngoscope	F005494
Storz Adaptor (Scope Adaptor)	F005512M
Wolf Adaptor (Scope Adpator)	F005511M
Universal Light Guide Cable	F433075P
Leak Tester	F004918
Olympus/ACMI Light Source Adaptor	R012809M
Storz Light Source Adaptor	F012811M
Wolf Light Source Adaptor	F012812M
Carrying Case	Vinyl Case
Owners' Manual	N005548D
EO Vent Cap	F006284

Endoscope Function

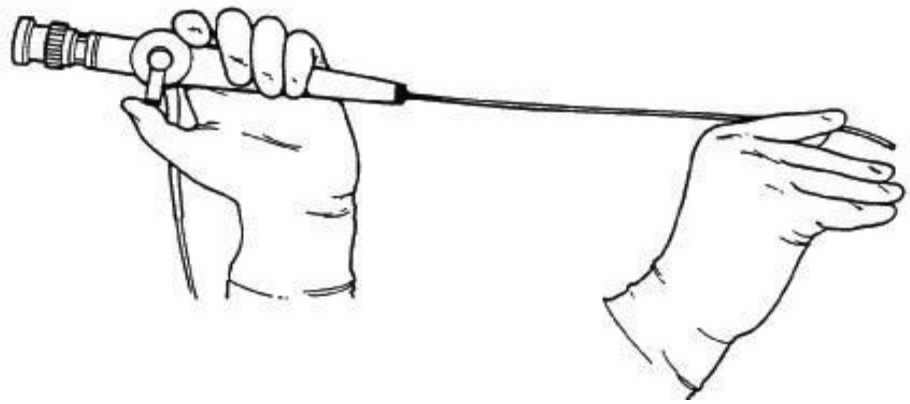
Preparation

- Before use, the endoscope should be reprocessed. ***Please refer to the Care & Maintenance Section of this manual for proper reprocessing protocol.***
- Check the Insertion Tube for holes, cuts or abrasions before each procedure by visually inspecting and by running your fingertips down the length of the Insertion Tube to verify its smoothness. ***Do not squeeze tightly against the outer coverings.***
- Check the Distal Tip deflection by rotating the Articulation Lever clockwise and counterclockwise. ***Do not apply excessive force rotating the Articulation Lever. Scope articulates 135° Up/Down.***
- Clean the Eyepiece and lens on the Distal Tip with an alcohol prep pad. ***Do not use abrasive cleaners on lens surfaces.***

Endoscope Operation

- Hold the endoscope so that the control body fits comfortably in one hand, allowing easy manipulation of the articulation lever with the thumb. Use the other hand to guide the Insertion Tube of the endoscope.

CAUTION: AVOID EXCESSIVE BENDING OR TWISTING OF THE ENDOSCOPE INSERTION TUBE. WHILE DESIGNED TO BEND, EXCESSIVE PRESSURE CAN DAMAGE THE FIBER BUNDLES AND INTERNAL COMPONENTS. DO NOT MANUALLY BEND THE DISTAL TIP; ALWAYS USE THE ARTICULATION LEVER TO ARTICULATE DISTAL TIP UP/DOWN.



- Thread the appropriate Scope Adaptor (if necessary) onto the ACMI End Fitting Post and attach Light Guide Cable to scope.
- Thread the appropriate Light Source Adaptor onto Light Guide Cable Connector, and then insert the Light Guide Connector into the light source until it snaps in securely.
- While viewing through the Eyepiece, rotate the Focus Ring clockwise or counterclockwise until the fiber pattern is in clear focus.
- Turn on the light source. Adjust the brightness to the desired level using the brightness adjustment control on the Light Source.
- Introduce the endoscope into the patient and operate the Articulation Lever as necessary to guide the Distal Tip & Insertion Tube for advancement and observation.
- At the completion of the exam, gently remove the endoscope under direct visualization and with the Articulation Lever in the neutral position.
- When using a video camera, still photography system, or teaching attachment with the endoscope, be sure the white dot on the Control Body is aligned with the white dot on the Focus Ring.

Use of the Endoscope with Video

The endoscope may be used with video camera or still photography systems. The endoscope's eyepiece will accommodate most video adapters for connection to a camera system and video chain.

When using a video camera, be sure to align the white dot on the Control Body of the scope with the white dot on the Focus Ring. This setting will optimize the focusing capabilities of your camera system. Call Optim LLC at +1 (508) 347-5100 to order video adapters, cameras, monitors and accessories for Optim's ENT 3.6FP Nasopharyngoscope.

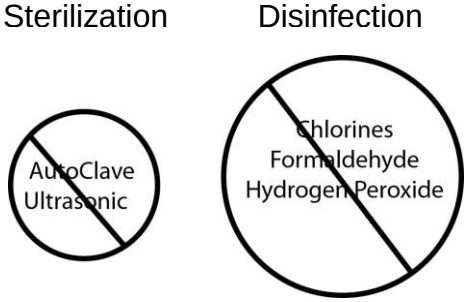
Care & Maintenance

I - <u>Methods of Endoscope Reprocessing</u>

Thorough cleaning and rinsing are the first and most important steps in the reprocessing of your endoscope. Without thorough cleaning and rinsing, it might not be possible to achieve high-level disinfection or sterilization. Cleaning is the removal of all adherent visible soil (i.e. blood, protein substances and other debris) from the surface, crevices and joints of the endoscope.

Use caution when cleaning, disinfecting and sterilizing your endoscope; some methods may be harmful to the endoscope and could result in extensive damage. Manual cleaning is the recommended method for cleaning your precision endoscope. To be effective, cleaning agents must assist in the removal of residual organic soil without damaging the device. No single cleaning agent removes all types of soil or is safe to use with every type of reusable device. Certain cleaning agents may damage the device materials. Cleaning agents should be used in the correct dilution/concentration and at the correct temperature in accordance with the cleaning agent manufacturer's directions. Please contact Optim LLC's Service Center at 1 (800) 225-7486 or 1 (508) 347-5100 to verify compatibility of a cleaning method not listed in this manual.

CAUTION! THE FOLLOWING METHODS OF STERILIZATION AND DISINFECTION WILL RESULT IN DAMAGE TO THE ENDOSCOPE AND SHOULD NOT BE USED:



Care & Maintenance (Cont.)

The Optim Nasopharyngoscope is a "semi-critical" device, as defined by the Centers for Disease Control, and requires high-level disinfection or sterilization.[1]

Attach the EO Vent Cap for EO Gas Sterilization.

Remove the EO Vent Cap for immersion in a cleaning or disinfecting solution.

FAILURE TO COMPLY WITH THE ABOVE MAY RESULT IN DAMAGE TO THE ENDOSCOPE AND WILL VOID THE PRODUCT WARRANTY.

II- Endoscope Reprocessing Protocol:

1. Pre-Cleaning
2. Leak-Testing
3. Enzymatic Cleaning and Rinsing
4. High-Level Disinfection or EO Sterilization
    a. 2% Glutaraldehyde Solution Disinfection
    b. EO Sterilization

1) Pre-Cleaning:

Optim recommends the endoscope be pre-cleaned immediately after every patient procedure. This will prevent patient material from adhering to the endoscope. Dried material is difficult to remove and can render the disinfection or sterilization process ineffective. Gently wipe all debris from the Insertion Tube and Distal Tip using a soft, lint-free cloth and water to which you have added a low sudsing detergent, diluted in accordance with the detergent manufacturer's instructions.

2) Leak Testing:

After every procedure, in preparation for high-level disinfection or sterilization, the endoscope should first be tested to ensure that it is watertight. This is accomplished using the Leak Tester. Gloves should be worn when performing the Leak Test procedure, as the endoscope has not yet been reprocessed.

- Remove EO Vent Cap. Connect the Leak Tester to the EO Vent by aligning the pin in the Leak Tester connector with the groove on the EO Vent, pushing down, and rotating the Leak Tester connector clockwise 1/4 turn.
- Pump the hand bulb of the Leak Tester until the needle is within 140-180mmHg or the green gauge area. Do not exceed 180mmHg. Observe the needle for 10 seconds. If the needle drops, the Leak Tester connection to the endoscope may be loose. Repeat procedure to verify.
- If the needle drops again, the endoscope may have a damaged seal and should not be immersed in any liquid. DO NOT CONTINUE TO USE THE ENDOSCOPE. Please contact Optim LLC's Service Center at 1 (800) 225-7486 or 1 (508) 347-5100 to arrange for evaluation and/or repair.
- If the needle stays in place, immerse the entire endoscope in water. Observe the endoscope for 30 seconds. Articulate the Distal Bending Section up and down during this period; holes in the soft covering of the Distal Bending Section may not be evident in a relaxed position.
- A STEADY STREAM OF AIR BUBBLES INDICATES A LEAK IN THE ENDOSCOPE. Remove the scope immediately from the water, while the scope is still pressurized. Air escaping the fiberscope at the leak site will have prevented fluid invasion.
- If a leak is detected, the endoscope should not be immersed in solution or used for patient procedures after the leak test. DO NOT CONTINUE USE OF THE ENDOSCOPE. Reprocess the endoscope by washing all its external surfaces with an enzymatic cleaning solution. Do not immerse the endoscope in the enzymatic cleaning solution. Do not conduct high-level disinfection or EO sterilization of the endoscope. Please contact Optim LLC's Service Center at 1 (800) 225-7486 or 1 (508) 347-5100 to arrange for evaluation and/or repair.

[1] CDC Guidelines for the Prevention and Control of Nonsocomial Infections - Guidelines for Hand washing and Hospital Environmental Control, 1985. Section 2: Cleaning, disinfecting, and sterilizing patient-care equipment.

Do not mistake the release of trapped air from the crevices on the endoscope's outer surface with a leak. Trapped air can be released by tapping the endoscope gently after immersing the endoscope in water.

- Absence of a steady stream of air bubbles confirms that the endoscope is watertight. Remove the endoscope from the water and disconnect the Leak Tester from the endoscope. It is now safe to immerse the endoscope in solution.

3) Enzymatic Cleaning and Rinsing

- Gently wash all external surfaces with an enzymatic cleaning solution and soak the endoscope in the enzymatic cleaning solution for the time recommended by the manufacturer.
- Remove endoscope from the solution and rinse thoroughly with clean, lukewarm water.
- Dry all external surfaces of the endoscope.

4) High-Level Disinfection or EO Sterilization

a) 2% Glutaraldehyde Solution:

1. Verify that the EO Vent Cap is removed.
2. Immerse the fiberscope in 2% glutaraldehyde solution.
3. Allow the fiberscope to remain in the disinfectant solution for the period of time recommended by the disinfectant manufacturer. DO NOT EXCEED TIME RECOMMENDED BY DISINFECTANT MANUFACTURER.
4. Following disinfection, remove the fiberscope from the solution.
5. Thoroughly rinse the outside of the fiberscope with clean, lukewarm water and place on a clean, dry surface.
6. Wipe all outside surfaces of the fiberscope gently with soft material (4x4 gauze) until completely dry.
7. Ensure the Eyepiece and lenses on the Distal Tip are free of solution residue.

b) *Ethylene Oxide Gas (EO) Sterilization*

1. To open the EO Vent, connect the EO Vent Cap to the EO Vent by aligning the pin in the EO Cap with the groove on the EO Vent, pushing down, and rotating the EO Cap clockwise 1/4 turn.
   If the EO Vent is not open during the EO cycle, the changes in heat and pressure from the process will cause internal damage.
2. Place the fiberscope in a sterilizer pouch or on a tray before EO reprocessing.
3. Reprocess the fiberscope:

   EO Conditions:
   Maximum EO Concentration: 12%
   Temperature: 125°F ± 5°F (52°C ± 3°C)
   Humidity: 70% RH Minimum
   Exposure Time: 60–90 minutes
   Mechanical Aeration: 12 hours at 130°F (54°C), or 72 hours at 75°F (24°C)
4. Aeration is required after EO exposure. Optim LLC recommends following the instructions supplied by the manufacturer of the EO Gas reprocessor and that a biological indicator be used to confirm effective reprocessing.

III - Endoscope Storage

- The endoscope should be stored in a dry and well-ventilated environment. Avoid extreme temperatures, direct sunlight, and high humidity.
- Avoid storing the endoscope in areas of heavy traffic where the endoscope may sustain physical damage.
- Do not store the endoscope in the carrying case. The carrying case is not sufficiently ventilated for storage of the endoscope. The carrying case is intended only for transport of the endoscope.
- The endoscope should be completely clean and dry before storing.
- When storing the endoscope, be sure to keep the Insertion Tube straight.

Troubleshooting

PROBLEM	POSSIBLE CAUSE	ACTION
Articulation feels “stiff”	Damaged distal bending section causing impairment of angulation	Contact Optim for evaluation
Articulation alignment is no longer up/down	Insertion tube rotated from excessive twisting	Contact Optim for evaluation
Loss of articulation up and/or down	Control wires are stretched or broken from use	Contact Optim for evaluation
Cloudy or Foggy Image	Focus ring not adjusted properly	Rotate focus ring until fiber pattern is in clear focus
	Eyepiece lens or objective lens is obscured by material or is stained	Clean lens with alcohol prepped pad to remove material or stain. If material or stain remains, contact Optim.
	Fluid invasion of the image bundle	Contact Optim for evaluation
	Damaged lens at the distal tip	Contact Optim for evaluation
	If using a video system, still photography or teaching attachment: White dot on control body not aligned with white dot on focus ring	Align dots of body and ring
Loss of Illumination	Light guides obscured by material or are stained	Clean objective end and ACMI post’s end-face with 70% isopropyl alcohol, 30% water to remove material or stains. It is important to avoid touching the end tip of the fiberscope and the ACMI post’s end-face, as oils from one’s fingers can cause staining. If staining remains, contact Optim.
	Damaged light guide fiber bundles	Contact Optim for evaluation
	Light source lamp output deteriorating	Replace lamp per light source instructions
Insertion tube has developed folds and/or wrinkles	Long-term effects of disinfecting the fiberscope in a chemical solution. Wiping the fiberscope with excessive pressure may cause the material to stretch and buckle	Contact Optim for evaluation
Insertion tube has dent(s)	Dents can be caused by physical damage to the fiberscope (i.e. closing the case on the insertion tube)	Contact Optim for evaluation
Rainbow glare seen in the image field	Fluid invasion of the fiberscope	Contact Optim for evaluation
Loss of pressure during leak tester	Leak Tester not connected to EO vent properly	Reconnect Leak Tester and perform leak test again.
	Hole or crack in the fiberscope has broken the watertight seal of the fiberscope	Contact Optim for evaluation.

Repair Service

Customer Service

- The Optim Nasopharyngoscope is serviced at Optim LLC's manufacturing facilities in Sturbridge, MA, USA. Use the following procedure to expedite returned goods for evaluation, repair or replacement.

1. Telephone Optim LLC at 1 (800) 225-7486 or 1 (508) 347-5100 or complete the online RMA Request form on our website www.optim-llc.com/rma-request.
2. Provide a detailed description of the problem.
3. If the scope needs to be sent to Optim, a Returned Material Authorization number will be issued.
4. The endoscope should then be returned to the address below for repair or replacement.
5. Include a copy of the RMA inside package.
6. Have RMA visible on package.

Returning Goods to Optim LLC

- Ship the endoscope with the EO Cap attached to the EO Vent, in the carrying case and within a corrugated box to prevent damage during shipment.

Ship to: Optim LLC
64 Technology Park Road
Sturbridge, MA 01566-1253
Attention: Customer Service / RMA#_____

IMPORTANT:

- **If the endoscope has been used in a clinical setting, the endoscope must be reprocessed according to procedures outlined in the Care & Maintenance section of this manual before shipment to Optim LLC.**
- **Upon evaluation, the customer will be contacted and advised of the findings and estimated repair cost. Repairs will not begin until authorization or a purchase order is issued indicating the approval of charges.**

Endoscope Warranty

The Nasopharyngoscope is warranted to be free from defects in materials and workmanship for a period of one (1) year from the date of purchase.

It is recommended that a Leak Tester be used prior to cleaning procedures, as a preventive measure that can extend the product's life and help minimize the need for repairs that could result from entry of fluid into the endoscope.

All non-warranty repairs will be warranted to be free from defects in materials and workmanship for a period of ninety (90) days from the date of the invoice.

Accidental damage and damage resulting from misuse, abuse, excessive sterilization, as well as normal wear and tear, will be subject to prevailing repair charges. Disassembly, alteration, or repair performed by any person not authorized by Optim LLC will result in immediate loss of warranty. THE ABOVE WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES EITHER EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Suitability for use of the medical device for any surgical procedure shall be determined by the user. Optim LLC shall not be liable for incidental or consequential damages of any kind.

Regardless of warranty status, all shipping charges to and from the OPTIM facility are the responsibility of the customer.

For service call Optim LLC's Service Center at 1 (800) 225-7486 or 1 (508) 347-5100.

Attention: See Instructions for Use

SN

Serial Number

Do Not Use if Package Is Damaged

REF

Reference

CE

The CE mark on this product indicates that it has been tested to and conforms with the provisions noted within the Medical Device Directive 93/42/EEC + 2007/47/EC (21.09.2007).

Authorized Representative:

Scanlan Group B.V.
Postbus 75664
1118 ZS Schiphol Triport
The Netherlands
Telephone +31(0)20 653 0553

In Compliance with:
ISO 9001:2008
ISO 13485:2003
ISO14971:2007
FDA CGMP 820
CDN MDR CMDCAS
MDD 93/42/EEC Annex II (2007)

Manufactured by: Optim LLC

64 Technology Park Road
Sturbridge, MA 01566-1253 USA
USA Tel: 1.800.225.7486
Tel: +1.508.347.5100
Fax: +1.508.347.2380
www.optim-llc.com
sales@optim-llc.com

Part Number N005548D Rev F
DCN: 05604A, 01005B, 02410C, 10010D, 04911E, 04213F
June, 2013