steriwave®

INSTRUCTIONS FOR USE

Steriwave Nasal Photodisinfection System

REF SW4000	# 00-1	Light Source
REF SW3200	# 00-1	Nasal Illuminator
REF SW3100	# 00-1	Formulation Applicator

REF SW9000 | P4126-001 Rev. C

CONTENTS

Ondine Biomedical, Inc. requires operators to read these entire Instructions For Use to ensure correct performance of the procedure.

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INTENDED USE

The Steriwave® Nasal Photodisinfection System (NPS) is a laser-based antimicrobial device and formulation intended for the decolonization of potentially pathogenic microorganisms from the anterior nasal passages.

SUMMARY AND EXPLANATION

The Steriwave NPS employs a photosensitizer formulation and low-intensity red laser light to achieve rapid microbial decolonization. The process works by selectively targeting microbial cells, leaving human tissue unharmed. When the photosensitizer is topically applied to the nasal mucosa, it selectively binds to components of microbial cell walls.

Upon exposure to red laser light emitted by the Steriwave device, the photosensitizer molecules undergo an electronic state transition, absorbing the light and transferring energy to nearby molecular oxygen. This reaction produces reactive oxygen species (ROS), which disrupt microbial cell walls, resulting in the destruction of pathogens. The production of ROS is localized and short-lived, ceasing immediately when the red light is deactivated.

The low-intensity red light used in the Steriwave system is specifically designed to be non-damaging to human tissue, minimizing the risk of adverse tissue reactions while effectively eliminating harmful microorganisms. The photodisinfection process is rapid, enhancing patient comfort, with the entire treatment typically lasting only a few minutes.

The Steriwave system is intended to be used in conjunction with standard infection control practices to reduce the burden of healthcare-associated pathogens and improve patient safety.

PROCEDURE SUMMARY

1. **Preparation:** The procedure begins by swabbing the patient's nasal passages with a photosensitizer formulation using a pre-saturated Formulation Applicator.
2. **Device Setup:** The healthcare provider connects the Nasal Illuminator to the Light Source and inserts the Nasal Illuminator tips into the patient's nostrils.
3. **Illumination:** The Light Source is activated for a 2-minute cycle, during which red light activates the photosensitizer, producing reactive oxygen species (ROS) that eliminate pathogens.
4. **Completion:** After the cycle, the process is repeated with new Formulation Applicators to ensure thorough decolonization. The procedure automatically stops after each cycle.

ADVERSE EVENT AND DEVICE MALFUNCTION REPORTING

Healthcare professionals may report any **device malfunctions** and **adverse events** during the use of the Steriwave NPS to the manufacturer and, where applicable, the relevant regulatory authorities.

To report an device malfunction and adverse event please contact:

Ondine Biomedical Inc.
Phone: +1 604 669 0555
Email: support@ondinebio.com
Website: ondinebio.com

Reports of adverse events can also be submitted to the appropriate national regulatory authorities in your country.

WARNINGS, PRECAUTIONS, AND CONTRAINDICATIONS

WARNINGS

- The NPS must be operated by healthcare professionals in compliance with applicable occupational safety regulations and accident prevention measures, in addition to these operating instructions.
- Operation of the NPS should be avoided where electromagnetic disturbances are high (e.g., MRI room or near high frequency surgical equipment).
- No modification of this equipment is allowed.
- Not specified for use in oxygen-rich environments.
- Only for use in patients ≥ 18 years of age.
- The single-use Nasal Illuminator and Formulation Applicators must be disposed of per standard hospital protocol.

CONTRAINDICATIONS

The potential for an adverse reaction may be observed in patients with any of the following conditions:

- Patients with allergies / hypersensitivity to methylene blue.
- Patients with allergies / hypersensitivity to chlorhexidine.
- Patients with undiagnosed nasal bleeding.
- Patients with a nasal anatomical defect that is sufficient to inhibit formulation application or laser illumination.

PRECAUTIONS

- The Light Source should be positioned close enough to the patient to allow the Nasal Illuminator to reach the patient's nose without tension on the Fiber Optic Cable.
- Do not use Formulation Applicator beyond the expiration date.
- To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth (ground).
- The Fiber Optic Cable must not be folded, kinked, or cut.
- Only approved Ondine Biomedical Inc. accessories should be used with the Light Source.
- Non-compliance with the instructions in this manual may damage equipment, void the warranty, and result in injury to the patient or operator.

POTENTIAL SIDE-EFFECTS

Potential side-effects associated with use of the NPS include:

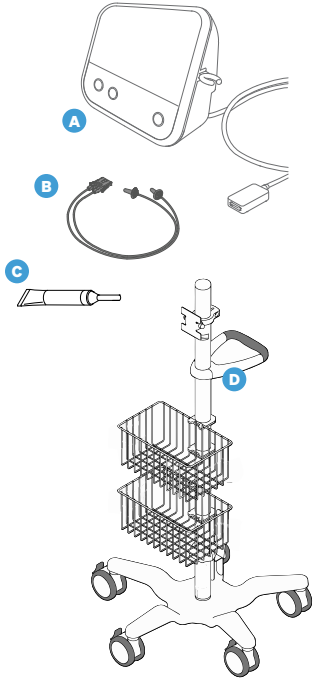
- Temporary staining of tissue around the nostrils.
- Sense of warmth during the illumination step of the treatment.
- Permanent staining of clothing.
- Temporary nose/throat irritation caused by post-nasal drip of formulation.
- Temporary runny nose, sneezing.

SYSTEM DESCRIPTION

TREATMENT COMPONENTS

The components described in the table below are provided with the NPS and are intended to be used together.

Device		Description
Light Source	A	Light emitting device. Shipped with Instructions For Use, region-specific power cord, and patient eyewear.
Nasal Illuminator (single-use)	B	Connects to Light Source and diffuses light into the anterior nares. Type B Applied Part.
Formulation Applicator (single-use)	C	Sealed applicator swab pre-saturated with the photosensitzer formulation.



OTHER PREPARATION MATERIALS

Ondine Biomedical recommends that the other preparation materials described in the table below be used during the procedure. These materials are not provided with the NPS.

Materials	Purpose
Stain prevention bib	Used to prevent incidental staining of clothing from the formulation.
Tissue	For patient to blow nose prior to procedure and to wipe away any formulation drips.
Alcohol wipe	To remove any visible formulation residue from patient's skin after procedure.
Gloves	Personal protective equipment (PPE).
Disinfectant wipes	To clean Light Source between patients.

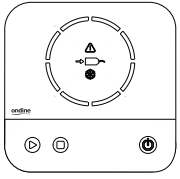
TOOLS & ACCESSORIES

Item		Description
Roll Stand (optional)	D	Mobile stand to support and transport Light Source and supplies.
Power Meter		Used to check the Light Source optical power output from the Fiber Optic Cable.

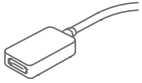
COMPONENT FUNCTIONS

LIGHT SOURCE

Generates the red light used to activate the formulation. The Light Source controls function as follows:



Light Source
User Interface



Fiber Optic Cable

Buttons

Buttons	Function	Action
	Standby	Press to turn on the Light Source. Press to reset the Light Source.
	Start	Will flash when Light Source is in READY mode. Press to begin illumination.
	Stop	During illumination, the Stop button may be pressed at any time to stop light emission.

LED-Display

Indicator	Indication	Action required
	Connector Symbol Flashing	Connect Nasal Illuminator to the Light Source. Indicator will disappear when the Nasal Illuminator is properly connected.
	Blue Snowflake Illuminated	Light Source is too cold. Allow Light Source to come to room temperature.
	Yellow Attention Illuminated	Error – Light Source operation is outside nominal ranges. Press Standby to reset the Light Source. If error persists, contact manufacturer for assistance.

Fiber Optic Cable: Connects the Light Source to the Nasal Illuminator.

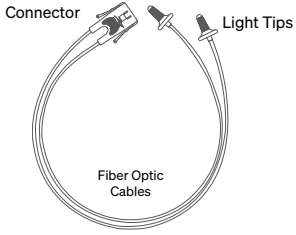
Mains Power Cord (hospital grade): Connects the Light Source to electrical power.

NASAL ILLUMINATOR

(SINGLE-USE)

Delivers red light to the patient's nose.

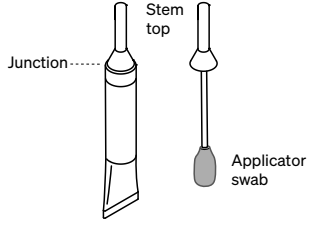
- **Light Tips:** Distribute light to the tissue surface.
- **Fiber Optic Cables:** Deliver the red illumination.
- **Connector:** Provides the connection to the Light Source Fiber Optic Cable.



FORMULATION APPLICATOR

(SINGLE-USE)

Single-use tube containing formulation applicator swab to apply formulation intranasally.



PROCEDURE

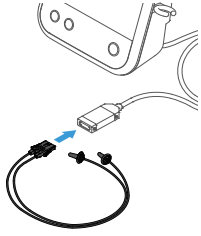
Use the following instructions to perform the nasal photodisinfection procedure.

PREPARE THE PATIENT & EQUIPMENT

Have the patient don Patient Eyewear. If desired, the patient may be provided with a bib to protect any clothing from staining.

1. Have the patient blow their nose thoroughly. It is important for treatment efficacy that the patient refrain from blowing their nose during or following the Steriwave treatment.
2. Position the patient in a seated, Semi-Fowler's, reverse Trendelenburg, or supine position. Avoid Trendelenburg, if possible.
3. Position the Light Source to ensure the Nasal Illuminator can reach the patient's nose without tension and connect the Light Source power cord to mains power outlet. Ensure the cord is not a tripping hazard and that the Light Source air vents are not obstructed.
4. Press ⏻. The indicators will flash on the LED display. Any startup errors will display on the LED display and an audible tone will sound. If there are no errors, ⇨▭ will flash, indicating system is ready to attach the Nasal Illuminator.

   NOTE: In case of an emergency, disconnect the power cord from the Light Source.



5. Open the Nasal Illuminator packaging and connect the Nasal Illuminator to the Light Source by plugging into the Fiber Optic Cable until it clicks. ⇨▭ will stop flashing on the LED display and ▷ will flash, indicating the Light Source is in READY mode.

   NOTE: The Nasal Illuminator must be properly connected for the Light Source to be activated.

   ***DO NOT** allow the Nasal Illuminator Light Tips to contact ANY surface before inserting into the patient's nose.*

   The accessory hook on the side of the Light Source may be used to hold the attached Nasal Illuminator until ready to use.

PROVIDE TREATMENT

-- First Round --

6. Open a single-use Formulation Applicator and insert Applicator Swab comfortably into a nostril. Firmly swab the nasal passage in a circular motion against the nasal wall at least 5 times, starting at the nostril entrance and rising as high as is comfortable for the patient (A). Finish with a firm twist in the most anterior nasal pocket (the tip of the nose) (B). Drips out of nose may be lightly wiped with a tissue. Repeat with a second Applicator Swab in the other nostril.

   Dispose of the used swabs per standard facility protocol.

7. **Posterior Illumination:** Gently insert Nasal Illuminator Light Tips into the nasal passages as far as comfortably possible and parallel to the bridge of the nose to maximize the light entering the nostrils (C). The Light Tips MUST be kept inserted during the entire illumination cycle.

8. Press ▷ to initiate light illumination. The circular indicator on the LED display turns off when the 2–minute illumination cycle is complete. An audible tone will sound, and illumination will automatically stop.

   NOTE: If illumination is interrupted for any reason, repeat full 2-minute cycle.

9. Remove the Light Tips from the patient's nose. Take care to prevent the Light Tips from contacting other surfaces (e.g., hang the Fiber Optic Cable on the accessory hook on the side of the Light Source).

-- Second Round --

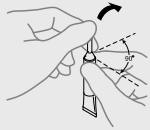
10. Repeat **step 6**, then proceed with **Anterior Illumination:** Gently insert Nasal Illuminator Light Tips into each nostril and orient the tips anteriorly and medially toward the tip of the nose (D). Repeat **steps 8-9** to complete the treatment. Temporary staining of the skin beneath the nose may be removed with an alcohol wipe or soap and water.

    IMPORTANT: patient should refrain from blowing nose or wiping inside nose after treatment.

DISCARD DISPOSABLES & CLEAN HARDWARE

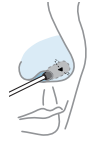
12. Squeeze Nasal Illuminator sides, then gently pull to disconnect it from the Fiber Optic Cable (E). Dispose per standard facility protocol. Return Fiber Optic Cable to the accessory hook on the side of the Light Source.

13. Press ⏻ to place the Light Source into SLEEP mode, then clean the system before next patient use according to the instructions on **Page 8**.



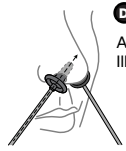
To Open Formulation Applicator
Squeeze on the hard junction (where the cone-shaped top meets the tube) to cause a small pop. Rotate 90° and squeeze the junction again for another pop. Twist stem to open.

(A) 5 firm circles per nostril up to the turbinate as indicated by blue shading.

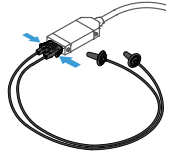


(B) Firm twist in tip of the nose.

(C) Posterior Illumination



(D) Anterior Illumination



(E) Squeeze sides, then pull.

CLEANING, INSPECTION, MAINTENANCE, AND DISPOSAL

WARNING: This device has a protective housing and optical diffusers which prevent human access to laser radiation in excess of the limit for Class 1 laser products. Any attempt to remove the protective housing, modify an accessory, or service or repair this device may result in exposure to laser radiation and the risk of permanent eye damage. All servicing should be performed by manufacturer-certified or authorized technicians only.

CLEANING

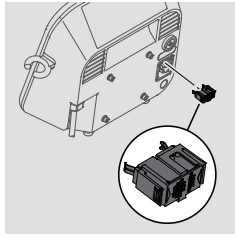
- Never allow liquids or moisture to enter any part of the Light Source or the end of the Fiber Optic Cable.
- Between patient procedures, clean any visible debris from the Light Source, then disinfect the device surfaces including the buttons, handle, and Fiber Optic Cable with a disinfecting wipe. This device has been tested for low-level disinfection with the following:
    - Quaternary Ammonium (e.g., CaviCide™ wipes or PDI Super Sani-Cloth®)
    - Sodium Hypochlorite Bleach (e.g., PDI Sani-Cloth Bleach®)
    - Accelerated Hydrogen Peroxide (e.g., Diversey Oxivir® Tb)
- Follow standard hospital procedures for disinfection of Patient Eyewear.

INSPECTION

Inspection of the Light Source should be performed quarterly using the following guidelines:

- Ensure that the power cord and plug are not frayed, kinked or damaged.
- Ensure that the Fiber Optic Cable is flexible, and not frayed, kinked or damaged.
- Check the optical power output from each channel of the Fiber Optic Cable with SW5000 Power Meter. Acceptable output range: 0.72 - 0.96W

MAINTENANCE



The only Light Source user-serviceable parts are the mains power cord fuses.

To replace the fuses, ensure the Light Source is disconnected from mains power before proceeding:

1. Use a flat-head screwdriver to gently pry the fuse drawer from the back of the power entry module.
2. Replace the fuses in the fuse drawer, with specified fuses only.
3. Insert the fuse drawer back into the power entry module until it clicks into place.

All other servicing and calibration, including maintenance of the Fiber Optic Cable must be performed by the manufacturer or manufacturer-certified technicians. Attempts to self-service or calibrate the Light Source may damage the device and will void the warranty.

DISPOSAL

Component	Disposal Details
Formulation Applicator	Dispose per standard hospital protocol and according to local, provincial, or state laws and regulations.
Nasal Illuminator	
Light Source	When at the end-of-life, do not dispose item as unsorted municipal waste. It may be returned to the manufacturer or sent to a designated collection point for electrical equipment recycling. *Note: in Europe, prepare the Light Source for reuse or separate collection as specified by Directive 2012/19/EU of the European Parliament and the Council of the European Union on Waste Electronics and Electrical Equipment (WEEE).*
Power Meter	
Roll Stand	May be disposed as non-hazardous waste.

LIGHT SOURCE TECHNICAL SPECIFICATIONS

This device meets the requirements of IEC 60601-1 Edition 3.2, IEC 60601-1-2 Edition 4.1, and IEC 60825-1 Edition 3.0.

Category	Item	Specification
Weight	Light Source	2.2 kg
	Roll Stand	21.3 kg (safe working load)
	Roll Stand Baskets	Maximum load 2.3 kg
Electrical	Input Voltage	100–240 V AC, 50/60 Hz, 250 VA
	Fuses	5 x 20 mm, T2AH, 250V
Medical Electrical Equipment Classification	Light Source	Class I CISPR 11 , Group 1, Class A
	Nasal Illuminator	Type B Applied Part
Ingress Protection	Light Source	IP20
Mode of Operation	Light Source	Non-Continuous Max Duty Cycle: 120s On, 60s Off
Sterility	Device	Non-sterile
Environment	Light Source	Not specified for use in an oxygen-rich environment
Laser Class	Light Source with Nasal Illuminator	Class 1
Embedded lasers	Power	2 × 1.5 W max
	Wavelength	664 nm continuous wave
Emitted radiation from Light Tips	Power	2 channels, 0.7W per channel
	Wavelength	664 nm continuous wave

Category	Item	Specification
Operating environment	Temperature	15 to 30 °C (59 to 86 °F) Light Tips may reach a maximum temperature of 43 °C (109 °F) when the Light Source is operated at 30 °C (86 °F) ambient.
	Humidity	30-75 % RH, non-condensing
Manufacturer		Ondine Biomedical, Inc. 888 - 1100 Melville Street Vancouver, BC V6E 4A6 Canada Tel.: 604 669 0555
SW4000 Model	00-1	
Equipotentiality		Provides an accessible earth reference point for maintenance of equipotential and testing purposes
		May be connected to Hospital Equipotential point.
		May be used to test ground bond when protective earth is intentionally interrupted.
		This terminal is not to be used for a Protective Earth Connection.

ELECTROMAGNETIC COMPATIBILITY

The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigating measures, such as relocating or re-orienting the equipment.

MRI COMPATIBILITY

The **Steriwave® NPS** has not been evaluated for use in **MRI environments**. This device is **not intended for use** within or near MRI systems, and users should avoid bringing the device into MRI rooms or environments where strong magnetic fields are present.

The materials and components of the Steriwave system have not been tested for magnetic interference or heating effects in MRI settings. The device is to be used exclusively in clinical environments outside MRI suites.

ESSENTIAL PERFORMANCE

Essential performance is delivery of laser light illumination to the patient's nares sufficient to achieve nasal decolonization when used as indicated with the photosensitizer formulation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in.) to any part of the SW4000 Light Source, including the cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: 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 that both are operating normally.

The Steriwave® NPS has been tested for the Electromagnetic environment specified below:

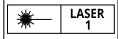
Electromagnetic Emissions Tests	**Test/ Compliance Level**
Radiated RF emissions	CISPR 11 Group 1, Class A
Conducted RF emissions	CISPR 11 Group 1, Class A
Harmonic Distortion	IEC 61000-3-2 Class A
Voltage fluctuations/flicker emissions	IEC 61000-3-3 Complies
Electromagnetic Immunity Tests	**Test/ Compliance Level**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV, 100 kHz repetition frequency for power supply lines ± 1 kV, 100 kHz repetition frequency for input/output lines
Surge IEC 61000-4-5	± 0.5 kV, ±1 kV line(s) to line(s) ± 0.5 kV, ±1 kV, ±2 kV line(s) to earth
Voltage dips on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle, @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles, @ 0°
Voltage interruptions IEC 61000-4-11	0 % UT; 250/300 cycle
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V, 0.15–80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz
NOTE: UT is the A.C. mains voltage prior to application of the test level.	

Proximity fields from RF wireless communications equipment IEC 61000-4-3		
Test Frequency (MHz)	**Modulation**	**Immunity Test Level (V/m)**
385	Pulse modulation 18 Hz	27
450	FM ± 5 kHz deviation 1 kHz sine	28
710	Pulse modulation 217 Hz	9
745	Pulse modulation 217 Hz	9
780	Pulse modulation 217 Hz	9
810	Pulse modulation 18 Hz	28
870	Pulse modulation 18 Hz	28
930	Pulse modulation 18 Hz	28
1720	Pulse modulation 217 Hz	28
1845	Pulse modulation 217 Hz	28
1970	Pulse modulation 217 Hz	28
2450	Pulse modulation 217 Hz	28
5240	Pulse modulation 217 Hz	28
5500	Pulse modulation 217 Hz	28
5785	Pulse modulation 217 Hz	9

KEY TO SYMBOLS

The following symbols have been used in this document or in the associated labeling.

Symbol	Definition
	Read the Instructions For Use
	Consult the Instructions For Use
	Caution, consult accompanying documents
MD	Medical Device
REF	Catalog or part number
#	Model number
LOT	Lot number
SN	Serial number
	Quantity of contents
	Manufacturer
	Date of Manufacture
	Use by date
	Non-sterile

Symbol	Definition
	Class 1 Laser System
	Mass
	Type B Applied Part
	Single Use Only, Do Not Reuse
	Operating humidity range
	REF SW4000 = Operating temperature range REF SW3100 = Storage temperature range
	Equipotentiality: Provides an accessible earth reference point for maintenance of equipotential and testing purposes. May be connected to Hospital Equipotential point. May be used to test ground bond when protective earth is intentionally interrupted. This terminal is not to be used for a Protective Earth Connection. Reference IEC 60601-1 clause 8.6.7
CE	This device complies with Medical Device Directive
	Demonstrates compliance to both USA and Canada medical device certification requirements
UKRP	United Kingdom Responsible Person
XX REP	Authorized Representative in the identified country or jurisdiction
	WEEE (Waste Electrical and Electronic Equipment)

TECHNICAL SUPPORT

For technical support, contact:

Ondine Biomedical Inc.

604.669.0555