CLEANING & DISINFECTING

Do not autoclave the Bio/Screen unit. **Doing so will damage the device and invalidate the warranty.**

Do not immerse the Bio/Screen unit in solution. **Doing so will damage the device and invalidate the warranty.**

The Bio/Screen may be disinfected following these guidelines:

a) The metal handle, housing and Delrin plastic eyepiece may be wiped down with a disinfectant comprising 55% - 72% alcohol and .33% -.5% quaternary ammonium following the manufacturer's directions.

Some popular disinfectant wipes in this category are:

1 - Monarch Surface Disinfectant Wipes (Air Techniques)
2 - Opticide 3 Wipes (Biotrol)
3 - Super Sani-Cloth Wipes (PDI)

Wipe, do not spray, solution onto housings. Prevent liquids from entering openings on unit.

b) The BioScreen viewing filter and clear plastic lens cover may be cleaned using a mild soap & water solution or a common household glass cleaner with a clean, soft cotton swab or microfiber cloth:

Do not spray solution directly onto viewing filter or plastic lens cover.

- Viewing Filter - Lightly dampen the end of a cotton swab and apply to the viewing filter in a light circular motion.
- Plastic Lens Cover - Lightly dampen a clean soft microfiber cloth and apply to the plastic lens cover in a light circular motion.
- Use the disposable protective lens covers (PN. 620063) to help keep the lens clean.

REPORTING OBLIGATION

Any event such as death or serious injury that has occurred to the patient, user or other persons in relation to use of this device should be reported to AdDent, Inc. and the competent authority of the Member State in which the user and/or patient is established.

ACCESSORIES AND REPLACEMENT PARTS

PN 110090	Bio/Screen Kit
PN 620063	Pack of 50 Disposable Protective Lens Covers
PN 650026	Patient Eyeglasses
PN 650022	Battery Charger
PN 620006	Cell Phone Adaptor

PRODUCT SPECIFICATIONS

Bio/Screen Dimensions	Length: 8.5" (215mm) Width: 2.6" (66mm) Height: 2.1" (54 mm) Weight: 11 oz (312 grams) with battery pack
AC Supply Connection	100-240 Volts AC ± 10%, 50/60 Hz
Charging Circuit Performance	Fully discharged battery pack charges to 100% in approximately 3 hours. Smart charging circuit provides correct voltage and current characteristics for charging battery pack: Constant current then constant voltage, 8.4 Volts, 1.0A, @ 20°C.
Smart Charger Power Output	12VA, Nominal
Battery Pack Specifications	Output: 7.4 Volts nominal @ 2000 mAh Type: Lithium Ion. Performance: Approximately 120 one-minute examinations starting with 100% charge Battery Pack life: 500 full recharge cycles, approximately 5 years worth of use. Safety: Batteries are protected from over charging, over discharging and short circuiting by means of a built-in safety circuit
Output Working Distance	Approximately 3" (76mm)
Output LEDs	5 violet high power LEDs (Light Emitting Diodes) arranged in a circular pattern
Output LED Wavelength	400-450 nm (violet)

MANUFACTURER

AdDent, Inc.
43 Miry Brook Road,
Danbury CT 06810, USA
Phone: 203-778-0200 | Fax: 203-792-2275
Email: info@addent.com |Website: www.addent.com

MD

EC REP EMERGO EUROPE Westervoortsedijk 60, 6827 AT Arnhem The Netherlands

CE

ISO 13485 COMPLIANT

P/N 660113 REV. F 2024/01

BIO/SCREEN®

ORAL EXAM LIGHT

INSTRUCTIONS FOR USE

Contents of package: *(1) Bio/Screen Oral Exam Light, (1) Plug-in Battery Charger, (25) Single use Disposable Lens Covers, (1) Pair of Patient Eyeglasses, Instructions for use, and various marketing materials.*

Warranty Registration at www.addent.com.

PRECAUTIONS

Not Sterile - Refer to cleaning & disinfecting section.

Risk Group 2, Caution - Possibly Hazardous optical radiation emitted from this product. The Bio/Screen produces high intensity light output. Do not look directly at the light emitted from this unit or point the light directly at the operator, assistant, or any person in the room.

Do not use this device without suitable eye protection for the patient. One pair of patient eyeglasses is included with this unit. Additional patient eyeglasses are available from AdDent. Refer to section "Accessories and Replacement Parts".

Do not attempt to use the Bio/Screen when the unit is charging. The output LEDs cannot be activated while the battery charger is connected to the unit.

Do not autoclave the Bio/Screen device. Doing so will damage the device and invalidate the warranty.

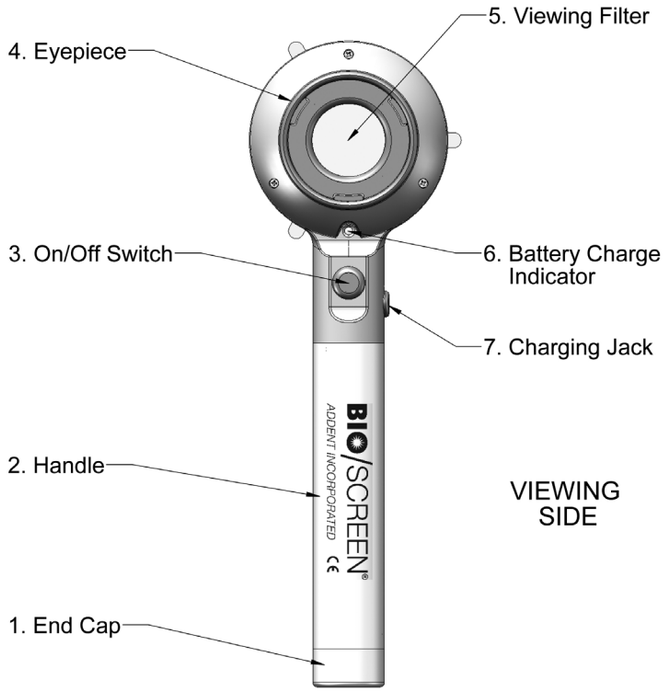
Battery Disposal: The battery pack contains rechargeable Lithium Ion batteries (Li-Ion). Recycle or dispose of battery pack according to national, state, and local regulations.

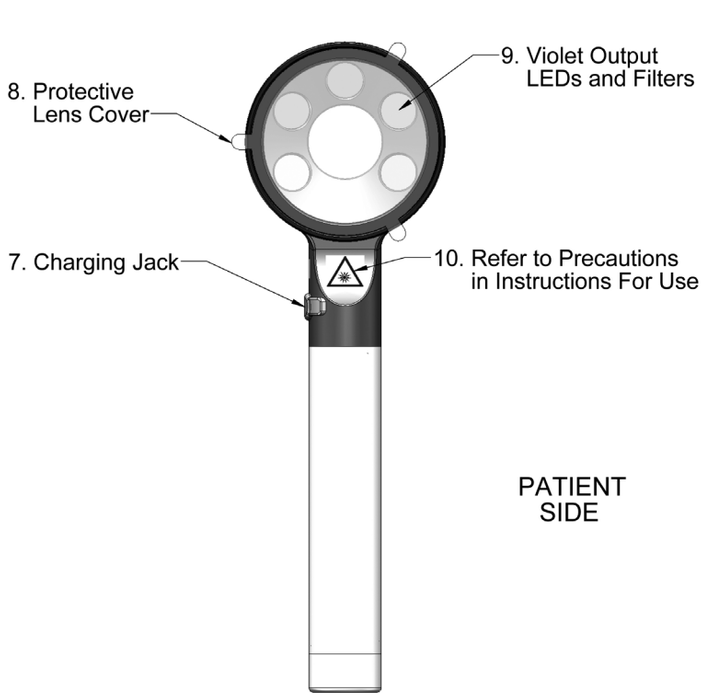
INTENDED USE

The Bio/Screen Oral Exam Light is a device intended for use as an adjunct to traditional oral examination to enhance the visualization of oral mucosal abnormalities.

BIO/SCREEN OPERATION AND FIRST TIME USE

The Bio/Screen unit should be fully charged prior to first time use. A wall plug-in battery charger is provided. A fully discharged battery pack charges





to 100% in approximately 3 hours. A solid green indicator light will illuminate on the charger when fully charged.

A disposable protective lens cover should be placed on the front of the unit prior to patient examination. Pressing the blue button once turns on power to the 5 violet LEDs. Pressing the button a second time will turn off the 5 violet LEDs and the unit will return to standby mode. Once activated and after five minutes of continuous operation, the LEDs will automatically turn off and the unit will return to standby mode to conserve battery power. The Bio/Screen will operate for approximately 120 one-minute examinations starting with 100% charge.

GENERAL DESCRIPTION

The Bio/Screen uses 5 short wave violet LEDs (9) that provide biofluorescence in the oral cavity. It is powered by an internal rechargeable lithium ion battery. An on/off push button (3) is located on the viewing side. An eyepiece (4) and an optical viewing filter (5) increases contrast between healthy and abnormal tissue and improves visualization. A battery charge indicator (6) is located on the viewing side of the handle. A separate wall plug-in charger is plugged into the charging jack (7). A full charge will take approximately 3 hours. Twenty five single use protective lens covers (8) are provided. A lens cover should be placed on the front of the unit prior to examination to help prevent cross contamination.

Lack of tissue fluorescence reveals damaged or abnormal cells before they may be noticed visually using a normal clinical exam light.

BIO/SCREEN FEATURES

The Bio/Screen has a special optical filter to improve contrast between healthy and abnormal tissue and to improve visualization.

Bio/Screen Battery – The custom lithium ion battery pack is rated for 500 full recharge cycles, approximately 5 years worth of use. The battery pack is protected from overcharging, over discharging and short circuiting by means of a built-in safety circuit.

Light Output Regulation – the Bio/Screen output LEDs maintain full power until battery is depleted.

Auto Shut Off – To conserve battery power, once activated and after five minutes of continuous on time, the violet output LEDs will automatically turn off and the unit will return to standby mode.

BATTERY CHARGE INDICATOR

Charging the Bio/Screen: The wall plug-in smart charger has a built-in LED charge indicator. During charging, the indicator is red. When the battery is fully charged, the indicator turns green. Do not attempt to use the Bio/Screen while it is connected to the charger.

Operating the Bio/Screen: A multicolor LED battery charge indicator is located on the handle of the Bio/Screen and operates as follows:

Green - Battery charged, normal operation.
Orange - Battery has approximately 10 minutes charge remaining.
Red - Battery discharged, output LEDs will turn off and battery requires recharging.

STEP BY STEP EXAMINATION GUIDE

⚠ Ensure the patient is wearing suitable protective eyewear during procedure.

1. Review patient's medical and dental history.
2. Thoroughly examine head and neck both visually and manually using the operatory overhead light.
3. Grasp tongue with gauze pad and gently pull it forward and to the sides to examine lateral surfaces and base.
4. Peel the thin protective film from both sides of a Bio/Screen Disposable Lens Cover using the tabs marked "Remove Film". Install the Lens Cover on the front of the Bio/Screen unit by placing the three tabs in the openings provided.
5. Press the blue on/off button and begin screening the oral cavity with the Bio/Screen. The unit should be held near the opening of the mouth but not touching the lips, at approximately 3" working distance. Abnormal tissues will appear as dark areas among the bright fluorescence of surrounding healthy tissues.
6. Note suspicious areas and re-examine the oral cavity first under white light and then again using the Bio/Screen unit.
7. Document suspicious lesions or take photographs.
8. Optional: Use an oral lesion marking system to validate the suspicious lesion.
9. Tactfully inform and instruct patient about your findings and take appropriate actions.

CLEANING & DISINFECTING

Refer to Cleaning and Disinfecting section on the reverse side of these instructions.