

PRODUCT SPECIFICATIONS

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|------------------------------|---|
| 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 1.5 hours. Smart charging circuit provides correct voltage and current characteristics for charging battery pack: Constant current then constant voltage, 8.4 Volts, 1.2A, @ 20°C. |
| Smart Charger Power Output | 12VA, Nominal |
| Battery Pack Specifications | Output: 7.4 Volts nominal @ 2000 mAh Type: Lithium Ion. Performance: Approximately 100 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) |

ORABLU ORAL LESION MARKING SYSTEM

OraBlu by AdDent is used to enhance the visualization of oral mucosal abnormalities and as an aid in defining lesion borders for further evaluation. OraBlu Oral Lesion Marking System should be used as an adjunct to traditional oral examinations, and in conjunction with the Bio/Screen examination, as required.

WARRANTY

AdDent, Inc. hereby warranties that for a period of one year from date of purchase, this instrument (excluding battery) shall be free from defects in materials and workmanship and will perform satisfactorily under normal use.

REFERENCE

See our website – www.addent.com

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 112001 OraBlu Oral Lesion Marking System
- PN 620005 SLR Camera Adaptor
- PN 620006 Cell Phone Adaptor

MANUFACTURER

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ISO 13485 COMPLIANT



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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.

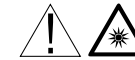
PRECAUTIONS



Not Sterile - Refer to cleaning & disinfecting section.



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 "Reorder Information" for additional suitable eye protection.



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.



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

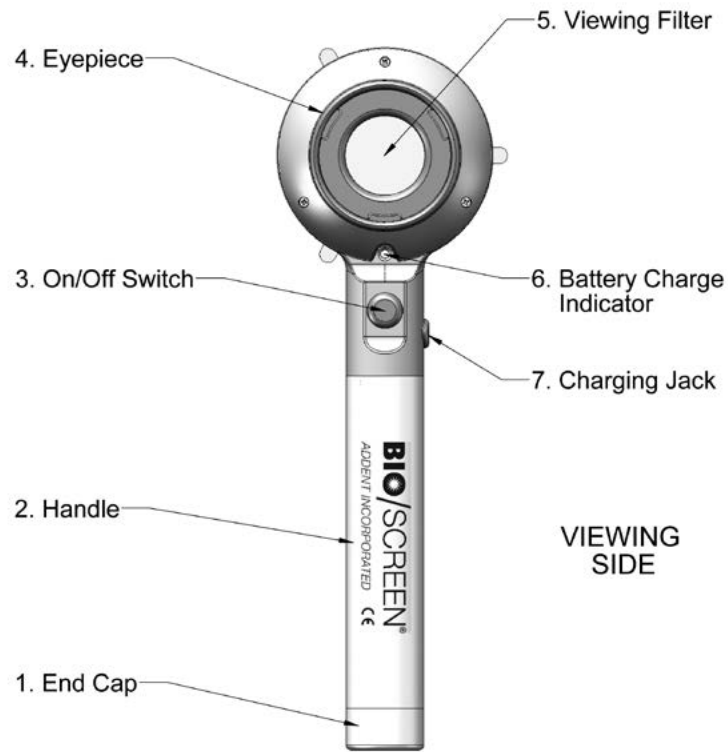
The Bio/Screen Oral Exam Light is a device intended for use as an adjunct to traditional oral examination to enhance the visualization of oral mucosal abnormalities.

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 1.5 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

P/N 660113 REV. D 1/2020



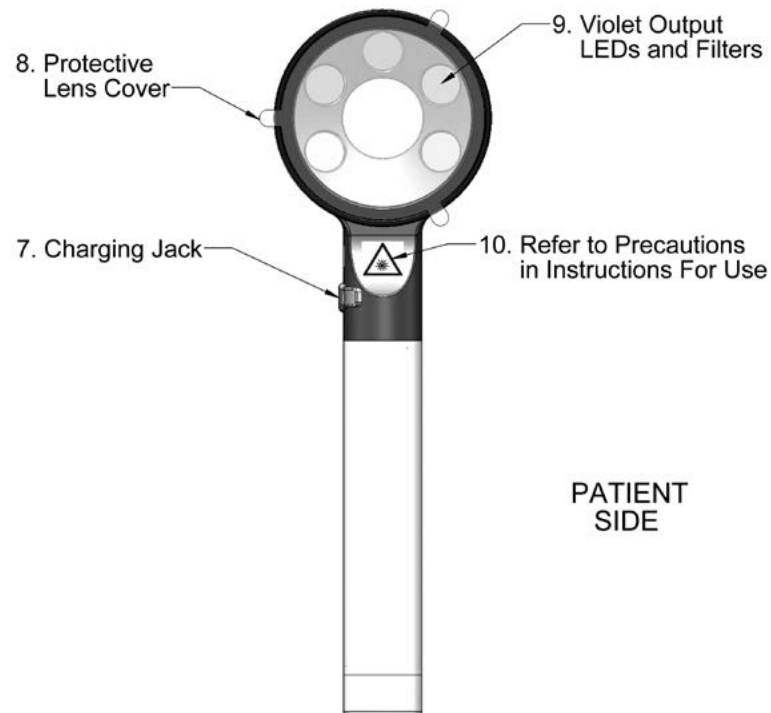
VIEWING SIDE

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 60 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 1.5 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 prevent cross contamination.

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



PATIENT SIDE

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

1. Review patient's medical and dental history.
2. Thoroughly examine head and neck both visually and manually using the operatory overhead light. Grasp tongue with gauze pad and gently pull it forward and to the sides to examine lateral surfaces and base.
3. Ensure the patient is wearing suitable protective eyewear during procedure.
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. Screen the oral cavity with the Bio/Screen. Unit should be held at opening of mouth but not touching the lips, at approximately 3" working distance. Abnormal tissues appear as dark areas among the bright fluorescence of surrounding healthy tissues.
6. Note suspicious areas and re-examine under white light and again while using Bio/Screen.
7. Document suspicious lesions or take photographs.
8. Optional: Use OraBlu Oral Lesion Marking System to validate the suspicious lesion. See instructions for use of OraBlu on our website, and product description in this manual.
9. Tactfully inform and instruct patient about findings and take appropriate actions.

CLEANING & DISINFECTING

The Bio/Screen metal housing may be wiped down with Cavicide or similar disinfection product:

- Wipe, do not spray, solution onto metal housings. Prevent liquids from entering openings on unit. Do not immerse unit in solution.



Do not autoclave unit. **Doing so will damage the unit and invalidate the warranty.**

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:

- 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.
- Do not spray solution directly onto viewing filter or plastic lens cover.
- Use of the disposable protective lens covers (PN. 620053) will help keep the lens clean.