PRODUCT SPECIFICATIONS

Compex Measurements:	Unit Length: 5.75 inches (145 mm) Unit Height: 5.2 inches (130 mm) Unit Width: 1.2 inches (27 mm) Unit Weight: 5.3 ounces (150 grams)
AC Supply Connection:	100-240 Volts AC ± 10%, 50/60 Hz.
USB Power Supply:	5 VDC, 2A
Battery Specification:	Li-Ion single cell battery pack with safety circuit Output: 3.6V, 3350mAh Type: Lithium Ion. Performance: Approximately 100 applications 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.
Charging Circuit Performance:	Fully discharged battery pack charges to 100% in approximately 4.5 hours. Smart charging circuit provides correct voltage and current characteristics for charging battery pack: Constant current then constant voltage, 3.6 Volts,1.2A, @ 20°C.
Safety:	This device complies with ANSI/AAMI/IEC 60601-1, “Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (2006/A2:2021).”
EMC:	This device complies with ANSI/AAMI/IEC 60601-1-2, “Medical Electrical Equipment, Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests, 4th Ed. (2015/A1:2021).”

WARRANTY

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

ACCESSORIES AND REPLACEMENT PARTS

P/N 131033 Disposable Barrier Bags – box of 150
P/N 132001 Autoclavable Silicone Sleeves – box of 10
P/N 130002 Medical grade power supply

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.

PATENTS

This product is covered by one or more of the following patents with other patents pending: 6,312,254 • 6,616,448 • 7,097,452 • 10,172,690 • 10,548,688 • EP1190681

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

QAS INTERNATIONAL ISO 9001:2015 REGISTERED COMPANY

ISO 13485 COMPLIANT

P/N 660202 REV. C 2024/05

Compex HD™

HEATED DISPENSER

COMPEX HD INSTRUCTIONS FOR USE

MADE IN THE USA

Contents of package: (1) Compex HD unit, (1) wall plug-in USB power supply, (1) USB charging cord, (25) sample disposable barrier bags, (10) silicone sleeves, and (1) Instructions for Use.

PRECAUTIONS

Not Sterile – The silicone sleeves are patient contact parts and are provided in a non-sterile condition. They must be sterilized prior to initial patient contact and between patient applications. Refer to instructions for a) Cleaning and b) Sterilizing the silicone sleeve.

The Compex unit can be disinfected to prevent cross contamination. The plastic housing should only be wiped with a cloth and disinfectant. Do not spray the plastic housing. Refer to instructions for c) Disinfecting the Compex HD housing.

DO NOT AUTOCLAVE THE COMPEX UNIT. Do not soak the Compex unit in disinfectant solution. The Compex contains sensitive electronic components.

Before heating and expressing composite, ensure that the compule (PLT) is fully seated in the compule holder by inserting compule with even firm pressure.

Attempting to express composite that has not been warmed to operating temperature may result in damage 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 Compex HD unit is intended to be used by a dentist or health care provider to warm and dispense dental composite materials contained in a compule or PLT (Pre-Loaded Tip) to 155°F (68°C).

CHARGING THE UNIT

Note: The Compex HD unit should be fully charged prior to first time use.

A wall plug-in USB power supply is provided to charge the unit. The power supply operates from wall Voltages from 100 to 240 Volts, AC. Connect the USB cord to the power supply and plug the power supply into a suitable wall outlet. Plug the opposite end of the USB cord into the connector located on the bottom of the Compex HD handle.

Do not attempt to use the Compex HD when the unit is charging. The unit cannot be activated while the power supply is connected to the unit.

BATTERY CHARGE INDICATOR

Charging the Compex HD: While charging the unit, the right side LED battery charge indicator blinks red. When the unit is fully charged, the LED turns solid green.

Operating the Compex HD: While using the unit, the right side LED battery charge indicator operates as follows:

GREEN - Battery is charged, normal operation.
AMBER - Battery charge at approximately 20%, unit has 10 minutes of useful charge remaining.
RED - Battery is at the end of useful charge and requires recharging.

TEMPERATURE STATUS INDICATOR

The LED on the left side indicates the temperature status. For the initial part of the heating cycle the temperature status LED blinks AMBER. At approximately 40 seconds the LED turns solid GREEN. The LED stays solid GREEN for the remainder of the heating cycle.

INSTALLING THE COMPULE (PLT)

1. Place the compule into the opening in the barrel ensuring that the compule flange is positioned as far back as possible.
2. Press the compule into the compule holder with firm even pressure. The compule will snap into place.
3. Ensure that the compule body is fully seated against the compule holder with the compule flange as far back as possible.

OPERATION – HEATING AND DISPENSING COMPULES

- **The heating cycle warms the composite to 155°F (68°C):** Pressing the on/off button once activates the heating cycle. For the initial part of the heating cycle the temperature status LED blinks AMBER. At approximately 40 seconds the LED turns solid GREEN. The LED stays solid GREEN for the remainder of the heating cycle.

Note - We suggest you try shorter and longer heating cycles to determine the optimum heating time for the composite you are using prior to clinical application.

Heating one compule:
1. Install a compule and press the on/off button once.
2. Allow the compule to heat for 40 seconds. At approximately 40 seconds the temperature status LED will turn solid GREEN and the composite is warm and ready to express.

Heating additional compules:
3. Do not turn the unit off.
4. Remove the first compule.
5. **Install a new compule and immediately press the on/off button once.**
6. Allow the compule to heat for **32 seconds**. At 32 seconds the temperature status LED will turn from blinking AMBER to solid GREEN and the composite is warm and ready to express.
7. Additional compules can be heated by repeating steps 3 through 6.

- Once a heating cycle has been activated, pressing the on/off button for 1.5 seconds will shut off the unit and switch it back into sleep mode.
- The auto shut off feature takes place after 10 minutes of ON time to conserve battery power.
- Tip: Avoid touching the patient with the compule ejector while dispensing material to avoid accidently ejecting the compule.
- Tip: To conserve battery power, turn off dispenser after procedure is complete.

Caution: To avoid damage to the unit, always remove compule after procedure is complete. Do not store the Compex HD unit with compule installed in the compule holder.

COMPULE HEAT UP TIME

- The Compex will heat the composite from 72°F (22°C), room temperature, to 155°F (68°C) in approximately 40 seconds.

REMOVING THE COMPULE

Caution. Some compules can forcefully eject during the removal process. Be sure to hold your hand below the compule to catch it when it comes out.

- To remove the compule, press on the raised portion of the compule ejector. This feature allows the rear of most compules to tilt up for easy removal.

CLEANING/DISINFECTING/STERILIZING

A. Cleaning the silicone sleeve:
- Immerse/thoroughly drench parts in a surface decontaminate cleaner (soap and water cleaning solution).
- After 10 minutes, scrub with an instrument cleaning brush until visibly free from debris.
- Rinse all parts with warm water.

B. Sterilizing the silicone sleeve:
- Sterilize in a steam autoclave using distilled water at a temperature of 270°F (132°C) for 20 minutes.
- Do not add chemical solutions to the autoclave.
- Do not use a chemical autoclave.

C. Disinfecting: The Compex HD housing can be disinfected following these guidelines:
- Wipe all surfaces with a disinfectant comprising 72% - 55% alcohol and .33% -.5% quaternary ammonium and follow 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 the Compex HD housing. Prevent liquids from entering openings on unit.

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

In order to protect this device and help prevent cross contamination we have developed a disposable barrier bag and an autoclavable silicone sleeve.

TROUBLESHOOTING GUIDE

Problem	Cause	Solution
1. Battery not charging	a. USB Charging cable connection	a. Ensure USB charging cable is securely connected to USB power supply and to the Compex HD unit.
	b. No power to the USB Power Supply.	b. Ensure there is power at the USB power supply.
	c. Battery at end of life	c. Replace the battery
2. Trigger sticking after expressing composite material.	Composite accumulated on plunger tip	Squeeze trigger to expose plunger tip and use soft cloth or Q-tip to remove accumulated composite material.
3. Compule not heating	a. Composite material accumulated on heating element.	a. Use soft cloth or Q-tip to remove accumulated composite material.
	b. Battery discharged (battery indicator red or unit will not turn on)	b. Charge battery
	c. Unit has turned off	c. Restart heating cycle
4. Compule not heating - left side LED heat indicator turns RED for five seconds then turns off.	Faulty temperature sensor	Return unit for repair.

COMPULES THAT FIT THE COMPEX DISPENSER

The Compex was designed to fit most compules on the market with a diameter of 6.32 mm to 6.68 mm. Please see our website for a comprehensive list, www.addent.com

After continuous use of larger diameter compules, check to ensure that smaller diameter compules have a secure fit in the compule holder prior to use.