

Perceptive Dual LED Motor Control Instructions for Use

REF 13511

RX Only

Lares Research
295 Lockheed Ave
Chico, CA 95973

Device Specifications

⚠ Caution: This device is not designed for use in an explosive atmosphere (anesthetic gas).

Contents:

The Perceptive Dual LED Motor Control System consists of:

- Motor hose output
- A pneumatic 4-hole connection input
- An electrical power supply and plug cord
- Perceptive Dual LED motor control box
- Perceptve Dual LED motor
- Electronic display and mount

Identification:

Electronically controlled unit for dentistry allowing operation of the Dual LED Perceptive Motor with variable speed using the dental unit rheostat pedal in conjunction with the included electronic display.

Intended Use:

- Product intended for professional use only. Use in dentistry for general dentistry work. The system is designed to control a Dual LED Perceptive Motor which can drive a dental handpiece (gear ratio 1:1, 10:1, or 1:5) fitted with appropriate burs.
- Any use other than that for which this device is intended is prohibited and may prove dangerous.

Classification:

Class IIa in accordance with European Directive 93/42/EEC concerning medical devices. This medical device is in compliance with the legislation in force.

Electrical Safety:

According to IEC 60601-1 standard (General safety for medical Electrical Equipment), the device shall be classified as a class II type B device.

The following requirements as specified in IEC 60601-1 apply:

- Protection against electrical shock.
- Ingress of liquids.
- Protection against excessive temperatures and other safety hazards.

Electric insulation class:

Class 1 per IEC60601-1 (apparatus protected against electric shock).

Degree of protection:

IP40 (protection against insertion of objects larger than 1mm).

Electromagnetic Compatibility:

Electro-medical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document. This unit corresponds to the electromagnetic compatibility in accordance with IEC 60601-1-2 and IEC 80601-2-60 and declaration by the manufacturer regarding electromagnetic compatibility.

Motor Type:

Brushless type, 3 phase motor, synchronous with permanent magnets.

Electrical and Pressure Data:

Voltage: 100 – 240 VAC.
Frequency: 50-60 Hz.
Nominal power: 65 W.
Maximum input power: 150W.
Maximum air pressure: 72.5 psi (5 bar).
Minimum air pressure: 43.5 psi (3 bar).
Air consumption: Less than 40 nl/min

⚠ Caution

If the input air pressure is below the minimum threshold 17.5 psi (1.2 bar), the motor will not turn on. If operating in variable speed mode, a minimum of 43.5 psi (3 bar) is required to meet maximum motor speed.

Cooling:

Cooling is conducted through compressed air from the unit.

Spray Air and Water:

Set spray air and water pressure per contra-angle attachment instructions, but do not exceed 40 psi (2.8 bar).

Dimensions:

Perceptive Motor Control box; 103 x 84 x 28 mm.
Motor hose length; 1.6M.
Power supply; 178 x 64 x 41mm.
Electronic Display; 168 x 78 x 10mm.

Weight:

Perceptive Motor Control box; 235g (8.29 oz.) without the cable.
Power Supply; 870g (w/ cable).
Electronic Display; 202g.

Motor Rotation Speed:

From 1,000 rpm to a maximum 40,000 rpm

Motor Direction:

Clockwise and anti-clockwise

Fluoresce™ Technical Data:

The Fluoresce HD Dual LED motor has a blue light (405 nm wavelength) power of 30-40 mW/cm² and white light brightness of 25k-35k lux at the end of a handpiece.

Table 1: IEC 62471 Risk Group Classifications		
Actinic UV (200 nm - 400 nm)	Es	Exempt group
Near UV (315 nm - 400 nm)	Euva	Exempt group
Blue Light (300 nm - 700 nm)	Ln	Moderate, Risk group 2
Retinal Thermal (380 nm - 1400 nm)	Ln	Exempt group
IR radiation, eye (780 nm - 3000 nm)	En	Exempt group
Skin Thermal (380 nm - 3000 nm)	Ev	Exempt group

Filter Glasses: Amber color, 99.9% UVA and UVB blockage; (alternate specification: Optical Density (OD) > 5 for 190 - 410 nm wavelengths; > 50% visible light transmission (vlt)).

Fluoresce HD Introduction

This motor control box is equipped with a Fluoresce HD Dual Wavelength technology when combined with the Perceptive Dual LED motor. The dual LED consists of a white light and a 405 nm wavelength blue light. The white/blue toggle switch in the Perceptive app is used to switch between the two light types. The Fluoresce Dual Wavelength motor is a visualization accessory that enables the clinician to observe caries and demineralized areas under blue/violet light and observe restorative treatment under white light. The 405 nm light (henceforthreferred to as blue light), together with the Fluoresce HD filter glasses, form a tool which can be used as an aid to directly visualize bacterially infected dentin (referred to henceforth as caries). Fluoresce blue light is used to aid in the detection of caries and helps the practitioner to get a spatial map of opened tissue areas which are suspect.

As shown in figure 1, the tooth is illuminated with a blue-violet light. Carious tooth material and healthy dentin is excited to fluorescence. The operator views the cavity through a filter. Shorter wavelengths are thereby filtered out, in particular the violet excitation light. Light with higher wavelengths remain visible through the filter, so that the red-fluorescent sections of caries can be precisely indicated. The red-fluorescent carious tooth material can be easily indicated and compared to neighboring green-fluorescent, healthy tooth material. The blue light causes healthy enamel & dentin to fluoresce with a green color (see table 2 for examples). The contrasting colors of the viewable prepared surfaces can be used to aid the practitioner to perform caries diagnosis. As an aid in the detection of caries, any color other than shades of green visible on the prepared tooth surface through the filter glasses should direct the dental professional to examine that area using the Gold Standard techniques. Fluoresce HD Dual LED system can provide additional information to supplement the dentist's visual observations, patient history and information from other diagnostic techniques. Diagnosis subsequent to the use of Fluoresce HD Dual LED system is performed and provided by the dental practitioner.

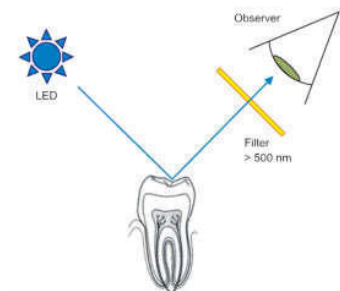


Figure 1.

Installation

Before installing, please read carefully.

Electronic Display Setup:

1. Turn on the electronic display by pressing and holding the power button until the display manufacturer logo appears. (Figure 8)
2. The app comes pre-loaded on the electronic display. After the display has been on for 10-20 seconds, the app will open automatically.

System Installation:

1. Chose a location to mount the Perceptive motor control box on a flat surface capable of bearing its weight. It may be positioned horizontally or vertically on, or under, a table, dental unit, or any other surface but under no circumstances on the floor. It should be located close to where the handpiece supply hoses exit on the delivery system. It is not designed to be placed on wet surfaces or to come in contact with liquids.
2. For under-mounting clean mounting surfaces with included alcohol wipes. Wipe away excess alcohol with the provided dry wipe.
3. Apply two adhesive backed Velcro pads to one side of the control box. (Figure 2) Attach the other Velcro pads to the first pads by velcro. Remove the adhesive covers and push firmly against surface to mount box. Note: if the control box will not be mounted with the Velcro pads the four rubber feet may be affixed to one side of the control box.
4. Connect the power cord to the power supply (Figure 3). Place the power supply on the floor or in the electrical outlet box and plug the power cord into an electrical outlet.

⚠ Caution

Do not connect control box to a power supply other than the included unit.

5. Connect the power supply cable to the motor control box (Figure 4).
6. Connect the Perceptive motor to the end of the control tubing; align the connector pins on the motor with the holes on the tubing, tighten clockwise (Figure 5).
7. Connect a 4 hole handpiece hose from your delivery system to the Perceptive motor control and tighten clockwise (Figure 6). Place the Perceptive motor in the vacated handpiece hose nest.
8. Plug the electronic display communication cable into the motor control box (Figure 7).
9. Make sure the electronic display is turned on. If not, turn on the display by holding the power button down until the device manufacturer logo appears (Figure 8).
10. Plug the communication cable into the electronic display (Figure 9). The Perceptive app will open automatically.

11. Chose a location to mount the electronic display on a flat surface capable of bearing the weight of the display (Figure 10). It may be mounted on a dental unit arm or any other available surface. It should be located where the user can easily view and reach it during operation.

The display mount uses a combination of adhesive and suction to adhere to its mounting surface. Before applying the adhesive surface, clean the mounting surface with an alcohol pad, then dry with the dry wipe.

Remove the adhesive cover and depress the mount's adhesive surface in the desired location. Then depress the lever on the base of the mount to activate the suction.

12. Attach the electronic display to the mount (figure 11). The display is retained on the mount by magnetism.

13. Secure any loose cords with the included adhesive "C"clamps. The Perceptive Motor Control System is now ready to use!

Device Operation

⚠ Caution

- The device must not be started without a bur inserted into the chuck.
- To ensure that your Contra-angle/micro motor unit functions with maximum efficiency, it must be cooled by an air supply of 5-10 NI/min on the nose of the micro-motor.
- Never mount an instrument on a rotating motor.
- Ensure that the Perceptive Motor hose is not bent or pinched.
- Only use the Fluoresce HD Dual LED motor as a visualization accessory to enable the clinician to view caries and demineralized areas. Restorative treatment must be conducted under white light.
- Do not use the Fluoresce HD Dual LED motor 405 nm light if you have red-green color vision deficiency or similar visual impairment.
- Do not use parts from other sources and/or make any type of modification. Both may result in damage or injury.
- Only use handpieces with clean undamaged optics (solid optic handpieces recommended).
- Do not look directly at the LED bulb while energized.
- Do not use the Fluoresce HD motor 405 nm light in conjunction with caries detection dyes. The use of staining materials can negatively influence the detection of dental caries using the Fluoresce HD motor.
- The Fluoresce HD Dual LED Motor cannot assess initial caries and this device has not been proven to detect incipient or just beginning caries.

Operating Environment:

Temperature: +10°C (50°F) to +25°C (77°F).
Relative Humidity: 20% and 90%.
Atmospheric pressure: 700 hPa to 1060 hPa. Altitude: 0 to 3048m (0 to 10,000 ft).
Selecting Attachment Gear Ratio:
Use the electronic display touch screen (figure 12) to select from the following available attachment gear ratios (3):
-Green, 10:1 handpiece: 100 to 4,000 rpm.
-Blue, 1:1 handpiece: 1000 to 40,000 rpm.
-Red, 1:5 handpiece: 5000 to 200,000 rpm.

⚠ Caution

Verify that the handpiece gear ratio corresponds to the ratio selected on the tablet. The buttons are color coded to match the handpiece color ring with the correct ratio.

Any of the attachment gear ratio buttons can be changed to a different ratio by long pressing on the button and selecting a new one.

Setting Maximum Motor Speed:

To set your maximum rpm for the current gear ratio. You have three options:

1. Select one of the preset rpm buttons.
2. Slide the maximum rpm slider bar to the desired maximum speed.
3. Tap on the RPM readout, then key in the RPM you want. Click the blue checkmark to accept the value. (Figure 12). The maximum rpm chosen will display above the slider bar (1).

The factory preset maximum rpm values for each gear ratio can be changed by setting the speed you want on the slider bar, long pressing one of the preset buttons, and clicking SAVE. Long press the preset button and hit RESET to go back to the factory default values.

Motor Rotation Direction:

Press the FWD/REV button (4) on the display to toggle direction (figure 12). FWD is clockwise and REV is anti-clockwise while viewing from the back of the handpiece. (Clockwise is normal status)

⚠ Caution

Always check the instrument rotation direct on before using the device

Motor LED Light ON/OFF:

Press the LED light ON/OFF button (5) on the Perceptive app to turn lighting on or off (Figure 12).

Wavelength Selection:

Press the White/Blue button (6) on the display to toggle between the normal white light or the blue 405 nm wavelength light (Figure 12).

Airflow Method:

Press the airflow button (7) on the Perceptive app (figure 12) to toggle between the two modes.

- Progressive mode (one small arrow) allows the user to vary the handpiece speed, up to the maximum set rpm, using the foot pedal.
- Instant mode (two small converging arrows) will instantly reach the maximum set rpm once the foot pedal is pressed.

Voice Commands:

Voice commands can be used to change speed presets, turn the handpiece LED lighting on/off, and change motor direction to forward/reverse (the motor must not be operating to use voice commands).

- Be sure the microphone (8) symbol on the Perceptive app (figure 12) does not show a knockout line indicating voice commands are disabled. Touch the symbol once to enable voice commands.
- The voice control wake up command is "Hey Motor". The electronic display will respond to "Hey Motor" with an audible beep indicating it is ready to respond to a command. A visual timer will also appear on the app screen indicating how much time the user has left to give the command before the display returns to sleep mode.
- To change a maximum rpm preset, simply say, "Hey Motor" followed by "One", "Two", or "Three" depending on the maximum rpm preset you want.
- To change the motor rotation direction, simply say, "Hey Motor" followed by either "Forward" or "Reverse".
- To turn the attachment LED light on or off, simply say, "Hey Motor" followed by "Light On" or "Light Off".

⚠ Caution

When using the voice activation, the end user must visually verify the desired selection is correct before utilizing system.

Steps For Normal Use:

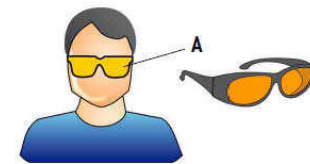
- Connect an attachment to the motor.
- Select the gear ratio for the attachment.
- Select a maximum rpm preset (manually or by voice command)
- Select the rotation direction of forward (clockwise) or reverse (counter-clockwise) (manually or by voice command).
- Select the air flow method of progressive or instant.
- Press the dental unit foot pedal to start the Perceptive motor.

⚠ Caution

Unplug power supply from mains to safely terminate operation of the Perceptive System.

To Use Fluoresce HD visual aid (405 nm light):

1. Open the previously diagnosed carious lesion in the tooth using a dental handpiece and white light. The white light (in conjunction with a handpiece) can be used for all typical restorative procedures.
2. Fit the filter glasses on eyes (or over prescription glasses).



3. View the opened area with the blue light to aid in visualizing the extent of remaining caries.
4. Remove decay with typical dental instruments. Prepare the tooth restoration using a handpiece and white light.

5. While viewing a deep caries, the fluorescent light may appear brown near the pulp. In this case in particular, a further detection tool (e.g. probe) should be used to decide on the course of treatment. The Fluoresce HD Dual LED motor helps to check the exeresis quality of damaged tissue during or at the end of the preparation in several clinical situations common in general practice. Diagnosis subsequent to the use of Fluoresce is performed and provided by the dental practitioner. The prepared surfaces viewed through the filter glasses display colors that can be interpreted in the following table.

TABLE 2	Normal signal	Alert signal	
Viewed color	Light green	Bright Red/Orange	Black/Brown/Dark green
Supposed state of tissue	Healthy dentin	infected dentin or affected interface	Unknown material, utilize standard methods for end of treatment diagnosis
Examine for	Healthy tooth	Infected dentin	Presumed end of treatment*

*Diagnosis subsequent to the use of the Fluoresce HD Dual LED system is performed and provided by the dental practitioner. Alert signal is only an indication, the dental practitioner is the only expert to judge and adapt the treatment options to the situation and also decide to stop treatment based on their clinical knowledge.

General Settings:

Additional motor control settings may be adjusted by first pressing the Settings (9) button (Figure 12). These consist of (Figure 13):

- Display sleep: adjusts time of non-use before the display goes into sleep mode.
- Pressure: select to display air pressure in PSI or BAR.
- Variable Pressure Mode: FULL uses the entire air pressure range of the foot control to change motor speed. LIMIT only uses a portion of the air pressure range. (Full is recommended.)
- Status LED: Adjusts the brightness of the motor control box LED status indicator. (See below for description of Status LED signals).
- Motor LED Brightness: Adjusts the brightness of the motor LED output and therefore the attachment light output brightness.
- Motor LED Fade-in: Adjusts how fast the light comes on after foot control depression.
- Motor LED Fade-out: Adjusts how fast the light goes out after foot control is released.
- Motor LED Time-out: Adjusts how long light remains on (delayed shut off) after motor operation ends.

To return to the main screen, touch the back arrow at the top left of the screen.

Motor Control Box Status LED Meaning:

The front panel of the motor control box is equipped with a status LED light with the following meanings:

Front panel LED:	Meaning:
GREEN (steady)	Normal operation
RED (blinking)	Overcurrent
RED (steady)	Drive Fault
WHITE (pulsating)	System Low Power Mode

Device Maintenance

⚠ Caution

- Wearing of personal protective equipment (gloves, goggles etc.), should be complied with by medical personnel using or performing maintenance of medical devices that are contaminated or potentially contaminated.
- Pointed and sharp instruments should be handled with great caution.
- In the event of prolonged disuse, the instrument must be stored in a dry environment.
- Products containing acetone, chlorine and bleaches are not recommended as disinfectants. To keep the surfaces of the hose in good condition, it is advisable to periodically wipe the complete length of it with a cloth dusted with talcum powder. Do not immerse in disinfectant solution. Do not immerse in ultrasonic bath.
- We recommend that the motor control is cleaned as directed below before the initial first use and subsequently after each treatment.

Cleaning-disinfection of External Surfaces: Clean and disinfect the external surfaces of the Perceptive motor control unit, electronic display, and hose by gently rubbing for about 15 seconds with a clean cloth soaked in isopropyl alcohol.

General Precautions

⚠ USA Caution: Federal law restricts this device to sale by or on the order of a Dentist.

Other Precautions for Use:

- The device must be used by a qualified person in accordance with the current legal provisions concerning industrial safety, health and accident prevention measures, and these working instructions. In accordance with these requirements, the operators:

-Must only use operating devices that are in perfect working order. In the event of irregular functioning, excessive vibration, abnormal heating or other signs indicating malfunction of the device, the work must be stopped immediately; in this case, contact Lares Research for repair.

- must use the Fluoresce blue light as a visualization accessory only, this enables the clinician to observe caries and demineralized areas under blue/violet light and observe restorative treatment under white light.

-Must ensure that the device is used only for the purpose for which it is intended, must protect themselves, their patients and third parties from any danger, and must avoid contamination through the use of the product.

-Rest the device on a suitable support to avoid risks of infection for yourself, the patient or third parties.

-Excess material from products used for maintenance (lubricants, cleaning products and disinfectants) originating from the attachments may penetrate into the electric motor and interfere with its functioning. It is essential to follow the maintenance instructions accompanying each product. Never lubricate the electric motor.

Recommendations:

- It is essential to use dry, purified compressed air to ensure the long working life of the device. Maintain the quality of the air and water by regular maintenance of the compressor and filtration systems. The use of unfiltered hard water will lead to early blockage of the tubes, connectors, and spray ports.
- The device must not be used in the presence of open lesions, injury to soft tissue or recent extractions. The exhaust air could propel infected material into the wounds and cause infections and risk embolism.
- The device is intended for medical treatment only; any use other than that for which this product is intended is unauthorized and may be dangerous. The medical device meets all the current legal requirements.

Warranty and Service

Warranty:

Each Perceptive motor control box, power supply and supply hose is warranted against defects in materials and workmanship for a period of 2 years from the date of purchase.

Additional Conditions of Warranty:

1. Warranty registration is automatic as of shipping date (Outside the US warranty registration may be required).
2. The product must be operated and maintained in accordance with procedures outlined in these instructions.
3. The product must not be subjected to abuse and/or neglect.
4. The product must not be repaired or disassembled by anyone other than Lares Research or your authorized Lares distributor.

Lares Research will repair or replace at its discretion without charge, any defective parts covered by this warranty provided the Perceptive motor control box, power supply and supply hose is returned to the factory, transportation prepaid. (Outside the US return to your authorized Lares distributor.) Lares Research makes no other warranties expressed or implied.

Servicing:

Never disassemble the device. For any modification or repair, we recommend that you contact your Lares account manager directly. Lares Research recommends that you have the device checked or inspected once every 3 years.

Transportation, Storage & Disposal

Transport and Storage Conditions:

Temperature between -25°C (-13°F) and 70°C (158°F), relative humidity between 20% and 80%, atmospheric pressure 500 hPa to 1060 hPa (7.25 to 15.37 psi). Do not store the motor with a contra angle attached for extended periods of time.

Serious Event Notification:

If a serious event occurs during the operation of this device it should be reported to Lares Research. In the European Union it should also be reported to the competent authority of the Member State in which the user and/or patient is established.

Disposal:

This device must be recycled. Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. The user must return the device to an approved body for treatment and recovery of this type of equipment (European Directive 2002/96/EC).

Troubleshooting

Motor Error:

When an error is detected on one of the motor phases, an error tone (three long beeps) will sound once on the electronic display, and the icon above will keep blinking as long as the drive is activated by air pressure. To reset the error, release the pressure to deactivate the drive and ensure connectivity of the motor.

Temperature Warning:

A motor overheat protection system is in place. This will trigger:

- a) If the average current over a long period of time exceeds 600mA, motor torque will be slowly limited until the average current falls below 600mA.
- b) If peak current exceeds 2500mA, motor torque will be quickly limited until peak current drops below 2500mA.

This issue is commonly caused by a faulty attachment (contra-angle, etc). If the issue only exists with the attachment on the motor, it is likely time to have that attachment repaired. Contact Lares Research with any questions.

When any of the above conditions occur, the icon above will blink on the display, and a warning signal (three short beeps) will sound. The warning signal will keep repeating until the unit has exited the overheat condition.

Electronic Display Updates

- We recommend logging in to Wi-Fi and leaving it connected to automatically receive necessary app updates to your electronic display.
 - 1) Click the setting icon on the lower right side of the Perceptive app.
 - 2) Click the WiFi Settings button.
 - 3) Connect to your WiFi network.
- When an app update is available, a red banner will appear on the app home screen that reads "UPDATE AVAILABLE" (Figure 14).
- Click on the red banner and follow the on-screen prompts to update the app and firmware. When prompted, allow access to the microphone to enable voice control.

Information:

The technical specifications, illustration and dimensions contained in these instructions are given only as a guide. They may not be the subject of any claim. The manufacturer reserves the right to make technical improvements to its equipment, without amending these instructions. For all additional information, please contact Lares Research directly at 1-888-333-8440.

Accessories, Detachable Parts and

Materials:

- Item #
- 13513- Replacement Dual LED Motor Control
 - 13512- Replacement Dual LED Motor
 - 13194- Replacement Electronic Display
 - 13190- Replacement Display Mount
 - 13506- Replacement O-Rings, Motor Nose Cone (3)
 - 13191- Replacement Motor Sterilization Caps (Set of front and back)
 - 13192- Replacement Power Supply
 - 13507- Replacement Hose Nut O-Ring
 - 13510- Replacement Communication Cable

Perceptive App Menu Guide: (Figure 12)

NOTE: See Operation sections for detailed use descriptions.

- 1) Maximum rpm chosen
- 2) Preset rpm buttons
- 3) Gear ratios (green, blue, red)
- 4) FWD/REV button
- 5) LED light ON/OFF button
- 6) White/Blue light toggle
- 7) Airflow button (Progressive mode, Instant mode)
- 8) Voice command symbol
- 9) Settings button
- 10) The air pressure being supplied to the system.
- 11) The speed at which the motor is spinning (bur speed will vary from this based on attachment ratio).
- 12) The current supplied to the motor.
- 13) The voltage supplied to the motor.

Questions?

Call 1-888-333-8440, Ext. 1
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Symbol Description	
REF	Catalog Part Number
SN	Product Serial Number
EC	European Community Representative
REP	European Community Representative
Consult	Consult Accompanying Documents
CE	Conformity Marking
Manufacturer	Manufacturer
YYYY-MM	Manufacture Date
Parts	Parts Applied to Patient
Steam	Steam Autoclave

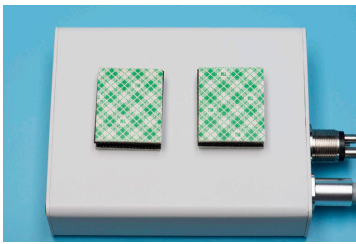


Figure 2

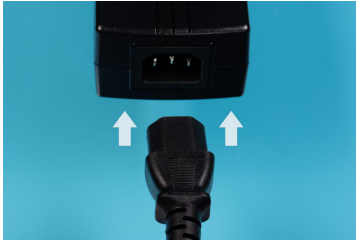


Figure 3



Figure 4

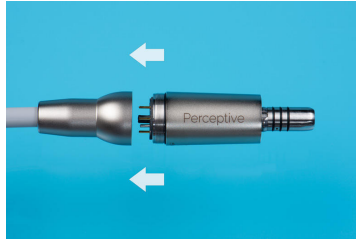


Figure 5

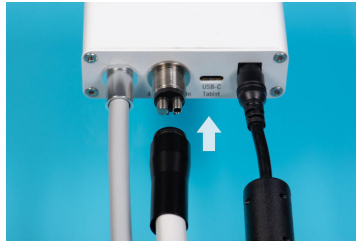


Figure 6



Figure 7

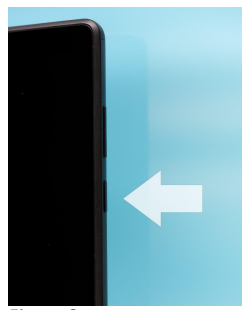


Figure 8



Figure 9

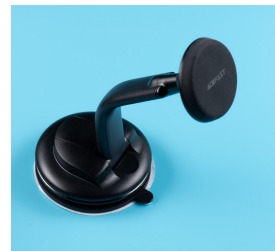


Figure 10



Figure 11

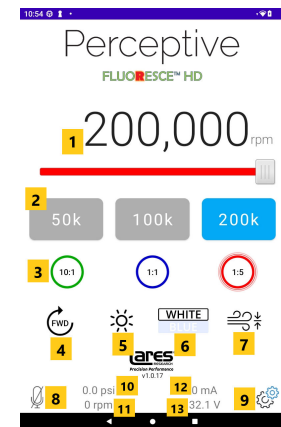


Figure 12

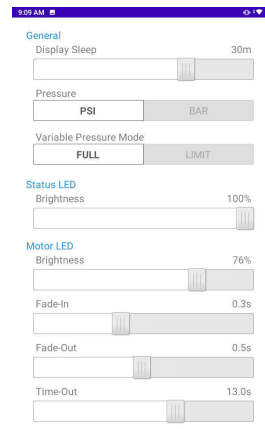


Figure 13

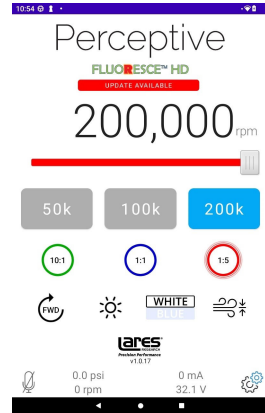


Figure 14