Electromagnetic Compatibility

Electromedical equipment needs special precautions regarding EMI and needs to be installed and put into service according to the EMC information provided in this document. Corresponds to the electromagnetic compatibility in accordance with IEC 60601-1. Declaration by the manufacturer regarding electromagnetic compatibility.

Hose Junction
Hose with connector type ProStyle E Motor. Brushless type, 3 phases. Effective power according to the type of electronic power supply used. Synchronous motor with permanent magnets. Body of chromium and indelible plated brass. Stainless steel nose.

Electrical and Pressure Data
Voltage: 100 – 240 VAC Frequency: 47 – 63 Hz Nominal power: 90 W Maximum input power: 160 W Maximum air pressure: 43.5 psi (5 bar) Minimum air pressure: 40.6 psi (3 bar) Caution! If the input air pressure is below the minimum threshold (40.6 psi), the motor could not reach the set point speed. Cooling: Though compressed air from the unit. Place the flow meter on the connector and set to 10 normal/min (figure 2). Air consumption: 10 l/min Dimensions: ProStyle E Motor Control box: 125 x 145 x 75 mm Motor hose length: 1.66M Power supply: 130 x 75 x 45 mm Weight: ProStyle E Motor Control box: 600 (62.8 oz.) without the cable. Power Supply: 653 g Motor speed: Maximum 40,000 rpm Recommended Rotation speed: From 1000 rpm to a maximum 40,000 rpm Direction: Clockwise and anti-clockwise

Important
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 8-10 standard liters per minute on the nose of the micro motor (figure 2). Never mount an instrument on a rotating motor. Ensure that the ProStyle E Motor hose is not bent or pinched.

Installation
Before installing, please read carefully this product instruction. Place the ProStyle E Motor control on a flat surface capable of bearing its weight. It may be positioned on a table, dental unit or any other surface but under no circumstances on the floor. It is not designed to be placed on wet surfaces or to come in contact with liquids. Connect the power cord, (figure 3). Be sure the power switch is off. Connect the power supply cable (2) to the input connector (2) and turn right to lock (4). Connect the ProStyle E Motor to the end of the control tube; align the connector to the motor with the index pin. (figure 3). Connect the 4-way hose to the Prostyle E Motor Control, tighten clockwise, (figure 6). Turn on the dental unit, then turn on the Prostyle E Motor Control. (figure 7). The power on light on the front panel lights up and is ready for use.

Operation

Environmental Temperature: +10°C (50°F) and 25°C (77°F) Relative Humidity: 30% and 80% Atmospheric pressure: 70 kPa to 1060 Pa Altitude: 0 to 10,000 ft ProStyle E motor speed: Set the maximum motor speed by turning the speed knob clockwise to increase speed. The maximum motor speed can be set to any value between 1000 rpm and 40,000 rpm (1.3 bar); 3000 to 40,000 rpm (1.5 bar); 5000 to 20000 rpm. ProStyle E motor rotation direction: Change the direction by pressing the button on the front panel (next to the speed knob). Pressed = reverse direction (Counterclockwise) Unpressed = forward direction (clockwise; normal status). Caution! Always check the instrument rotation direction before using it.

Caution: Connect a handpiece. Set the maximum speed. Select the rotation direction to forward (clockwise) or reverse (counterclockwise). Press the dental unit foot pedal to start the Prostyle E Motor (the pedal actuation is progressive; motor speed varies up to the set maximum based on how far the pedal is depressed). Caution! If the foot pedal is pressed before switching on the Prostyle E Motor Control the motor will not start to run until the foot pedal is released and pressed again. Caution!! Verify that the handlepiece gear ratio corresponds to one of those displayed on the speed knob.

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).

Maintenance
Separately clean the device before the treatment of each patient. Important
● The instrument is delivered “non-sterile”.
● Before using for the first time and at least every 30 minutes after each treatment, clean and disinfect. Observing this procedure eliminates any blood, saliva or saline solution residues and prevents the transmission system from being blocked.
● Do not clean in a washer/disinfector unit.
● Do not immerse in an ultra-sonic bath.
● Use only Lares Research provided maintenance products and parts or those recommended by Lares Research. Using other products or parts may cause operational failure and/or void the warranty.

Precautions of Use

The universal precautions, in particular wearing of personal protective equipment (gloves, goggels 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. We recommend that the motor control is cleaned as directed below before the initial first use and subsequently after each treatment.

Important
In the event of prolonged disuse, the instrument must be stored in a dry environment.

Cleaning-disinfection
Disinfect the external surfaces of the Prostyle E Motor Control unit and hose by gently rubbing with a clean cloth soaked in a suitable product (isopropyl alcohol for about 15 seconds) or with a disinfesting/disposable wipe recommended for dental or surgical instruments. Caution! Products containing acetone, chlorhex 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 doused with talcum powder.
Do not immerse in disinfectant solution.
Do not immerse in ultrasonic bath.

Servicing
Never disassemble the device. For any modification or repair, we recommend that you contact your account manager directly. Lares Research asks that you have the device checked or inspected once per year.

Transport and storage conditions

Temperature between +25°C (+77°F) and 70°C (158°F), relative humidity between 10% and 100%, atmospheric pressure 50 kPa to 1060 kPa (7.3 to 15.3 psi).

Information
These 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.

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 repair center.
● 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 motor 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 in order 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 contaminated 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
Each Lares ProStyle E Motor Control is warranted against defects in materials and workmanship for a period of 3 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 motor must be operated and maintained in accordance with procedures outlined in these instructions.
3. The motor must not be subjected to abuse or misuse.
4. The motor 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 ProStyle E Motor 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.
Electromagnetic Compatibility

Precautions Regarding Electromagnetic Compatibility (EMC)

Electro-medical equipment need special precautions regarding EMC and need to be installed and put into service according to the EMC information provided in this document.

Caution! Dental professionals need to be aware of potential electromagnetic interference between electronic dental devices and active implantable medical devices, and should always inquire about any devices implanted in the patient.

Caution! The ProStyle E system complies with the EMC requirements according to IEC 60601-1-2. Radio transmitting equipment, cellular phones, etc. shall not be used in close proximity to the unit since they could influence the performance of the unit. Special precautions must be taken when using the strong emission sources such as High Frequency surgical equipment and similar equipment so that the RF cables are not routed on or near the unit. If in doubt, please contact a qualified technician or Lares Research.

The ProStyle E system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, ProStyle E system should be monitored to verify normal operation in the configuration in which it will be used.

Caution! The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Lares Research as replacement parts for internal components, may result in increased emissions or decreased immunity of the ProStyle E system.

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

The ProStyle E system is intended for use in the electromagnetic environment specified in tables 1 through 3. The customer or user of the ProStyle E system should ensure that it is used in such and environment.

Table 1.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group I</td>
<td>ProStyle E system uses RF energy only for its internal function. CISPR 11 therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class B</td>
<td>The ProStyle E system is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
</tbody>
</table>

Table 2.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electromagnetic emissions</td>
<td>±6 kV contact</td>
<td>±6 kV contact</td>
<td>Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient burst</td>
<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge</td>
<td>±3 kV line to line</td>
<td>±3 kV line to earth</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips and sags</td>
<td>&lt;5% U₀ (±5% dip in U₀) for 0.5 cycle</td>
<td>&lt;5% U₀ (±5% dip in U₀) for 5 seconds</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz)</td>
<td>±1 kV</td>
<td>±1 kV</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Magnetic field</td>
<td>3 A/m</td>
<td>≤3 A/m</td>
<td>Protective level for electromagnetic compatibility (EMC) environments.</td>
</tr>
</tbody>
</table>

Note: U₀ is the AC Mains voltage prior to application of the test level.

Recommended separation distances between portable and mobile RF communications equipment and the ProStyle E system

The ProStyle E system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the ProStyle E system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ProStyle E system as recommended in table 3, according to the maximum output power of the communication equipment.

Table 3.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.36</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed in table 3, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.