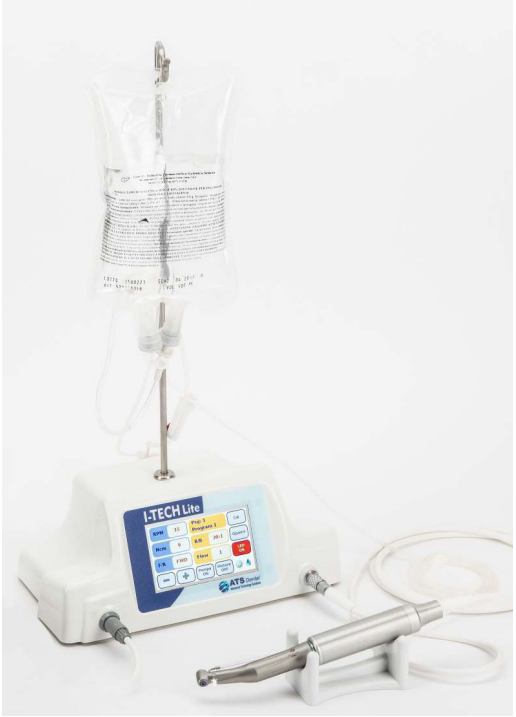
I-TECH Lite

Mechanical drive unit with coolant supply for driving instruments with compatible connection according to ISO 3964 (DIN 13940), suitable for use in dental surgery, implantology and stomatological surgery.



OPERATION AND MAINTENANCE INSTRUCTION MANUAL

REF	Model
ITL500	I TECH LITE

Refer to the "REF" on the bottom to identify the model.

1. SYMBOLS

CE 0425	2017/745 UE		Risk of electric shock
	Follow Instructions for use		Disposal Information
	Type B appliance	V	Supply Voltage
	Manufacturer	REF	Reference
		#	Model Name
SN	Serial Number		Web user manual
	Class I Equipment		Mode: continuous operation with intermittent load
	Production year	MD	MEDICAL DEVICE

Read this instruction booklet carefully before installing and using the machine. In this way, you will obtain the best possible results and maximum operating safety. This booklet must be kept with the apparatus in case of sale or transfer to another user.

2. NOTICE/WARNING

DM Classification Reg 2017/745UEC (AnnexVIII) CLASSIIa rule 9.

Classification CEI EN 60601

- Class I Equipment
- Type BF Applied Part
- Ordinary Equipment - degree of protection against ingress of water

Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

2.1 Purpose – Proper use:

I TECH LITE is intended only for use in the field of dentistry, for surgery to expose and dissect oral tissue structures (such as the periodontal gap, gingival, bone, the jaw, extractions, and implantations). The product may not be used for a purpose for which it was not intended.
"Proper use" includes following all the instructions for use and ensuring that all inspections and service tasks are performed.
The overarching guidelines and/or national laws, national regulations, and the rules of technology applicable to medical devices for start-up and use of the ATS DENTAL product for the intended purpose are to be applied and complied with.
The user must ensure that that the unit works properly and is in a satisfactory condition before each use.
During use, national legal regulations must be observed, in particular:

* the applicable health and safety regulations
* the applicable accident prevention regulations

Users have a duty to:

* Only use equipment that is operating correctly.
* To protect himself, the patient and third parties from danger
* To avoid contamination from the product

Device users:

- Use of the I TECH LITE is restricted solely to qualified, trained and competent dental health practitioners in the normal context of their work.
- If you have received this device by error, please contact the supplier so that it can be removed.

User population:

This medical device can only be used by skilled and capable qualified dental health professionals, as a part of their normal activities. The user must have a perfect practical knowledge of the accepted dental rules and practices in compliance with established data of the science, and of the principles of medical hygiene such as the cleaning, disinfection, and sterilisation of medical devices, and must observe those rules, practices and principles.
This medical device can be used irrespectively of specific (adult) user details, such as weight, age, height, gender, and nationality. The user must wear gloves. The user is not the patient.
Users must not have any of the following ailments:

- Eye problems unless the latter are appropriately corrected.
- Disability of the upper limbs (correct holding of a rotary handpiece) or of the lower limbs (operation of a control pedal).
- Ear problems (use of audible signals, depending on the equipment).
- Memory or concentration problems (settings, sequences, or medical procedures, etc.).

Specific training for users:
No specific training other than the original professional training is required to use this medical equipment.
Patient population:
This medical device is intended for use on the following patient population: children, teenagers, adults, and elderly people.
This medical device can be used irrespectively of specific patient details such as weight (except for children), age, height, gender, and nationality. The use of this medical device is prohibited on the following patient population: infants, pregnant or breastfeeding women, patients with medical complications, allergic patients, patients with a clinical zone that is not suitable for the treatment. The patient must be calm, relaxed, still, and ideally lying on a dental chair.
Body areas or types of tissue treated:
The medical care can only be carried out in the patient's oral environment.
Principle of operation of the medical device:
An electrical signal output by the medical device is supplied to the micromotor (dental or oral surgery). The micromotor is connected to medical device by a lead.
The micromotor is equipped with a rotary instrument holder onto which a tool (drill, burs, etc.) is attached. The rotation of the micromotor activates the tool.
Part(s) applied:
Rotary instrument holder. Tool (drill, bur, etc.).
Utilization:
The medical device must not be used above an altitude of 2,000 metres (6,500 feet).
The medical device is not restricted by a limited number of utilisations.
Electrical connection:

- Your device must be connected to the electric power supply by a certified dental installation technician. The electric supply to which the device is connected must comply with the standards in force in your country.

Using the device:

- Do not use the device if it appears to be damaged or faulty.
- Turn the device off before unplugging the power cord.
- To unplug the power cord, grip the external transformer and hold the wall socket.
- Never use any other irrigation solution containers than those intended for suspension from the supplied brackets.
- The device must only be used with bottles or bags of physiological saline.
- The capacity of the irrigation solution containers used must not exceed one liter.
- When the device is not to be used for a long period of time, unplug the device from the electric supply.
- Do not move the device during use.
- Do not insert anything inside the motor.
- The “micromotor” is supplied non-Sterile!
- Use only power cord provided.
- Use for intended purposes only. Failure to observe the operating instructions may result in the patient or user suffering serious injury. Before using this product, make sure that you have studied and understood the operating instructions.
- Do not install where there is a risk of an explosion. The Systems are not intended for operation in the presence of flammable anesthetics or gases.
- Do not disassemble or alter the System motor, console, or footswitch.
- Connect mains power cable to a properly outlet only.
- Never touch drills, burs, or other handpiece tips when they are still rotating.
- Handpiece should only be attached when the motor has stopped running.

Environment:

- Do not cover the device or obstruct the ventilation vents.
- Do not immerse the device in liquid, and do not use it outdoors.
- Do not tilt the device at an angle greater than 5°.
- Do not place the device near a heat source.
- Make sure that the cords are not in a traffic path.
- The device should be stored in its original packaging in a safe place.
- Do not expose the device to water vapor, or splashes.
- The device is not designed to work near ionizing radiation.

- Do not insert metal objects into the device (risk of electric shock, short-circuit or emission of hazardous substances).

Maintenance:

- Before and after each use, your device must be disinfected with products recommended by the manufacturer.
- Before each procedure, it is essential to make sure that the accessories to be used have been cleaned, disinfected. Do not use agents containing phenol, per acetic acid, peroxide and other agents that break up the oxygen.
- **DO NOT (for any reason), lubricate the micromotor. After lubricating the handpiece, ensure that the lubricant does not penetrate into the micromotor.**

Accessories:

- The device can only accept accessories distributed by ATS DENTAL for the particular use for which they are intended.
- Use of accessories from other manufacturers is a potential hazard for you or your patients.

Repair:

- Do not repair or modify the device without prior authorization from the manufacturer.
- In the case of a fault, contact the supplier of your device. Do not use unauthorized repairers, who might make your device dangerous for you and your patients.

If you have any doubt, contact an approved dealer or our customer support department:
Information concerning the accuracy and precision of this product may be obtained upon request by contacting:
ATS Dental srl Via Vecchia Provinciale Lucchese,49/F Serravalle Pistoiese – Italy
Tel: +39 0573 518137 info@atsdental.it

2.2 Electromagnetic Interferences

- To avoid possible risks of electromagnetic interferences do not use other electro-medical instruments of similar nature near I TECH LITE. The unit complies with the current normative electromagnetic radiation law**.**
- This device has been tested and found to comply with the emissions requirements of IEC 60601-1-2. These requirements provide reasonable protection against harmful electromagnetic interference in a typical medical installation. However, high levels of radiofrequency (RF) emissions from electrical devices, such as cellular phones, may disrupt the performance of this device. To mitigate disruptive electromagnetic interference, position this device away from RF transmitters and other sources of electromagnetic energy.
- The device complies with applicable electromagnetic compatibility standards. The user should nevertheless ensure that any potential electromagnetic interference does not cause an additional risk (presence of radiofrequency emitters, electronic devices, etc.). Interference may occur when used on patients with cardiac pacemakers. This system emits electromagnetic fields, which means there are some potential risks. The malfunctioning of implantable devices such as cardiac pacemakers and ICDs (implantable cardioverter defibrillator) is possible. Ask patients and users if they have an implanted device before using this product. Explain the circumstances to them. Weight the risks and benefits and contact your patient's cardiologist or appropriate qualified healthcare professional prior to performing the treatment Keep this product away from implanted devices Make appropriate emergency provisions and take immediate action if patients become ill. Symptom including a raised heartbeat, irregular pulse, and dizziness may signal problems with a cardiac pacemaker or ICD.

2.3 Responsibility of the manufacturer

The ATS Dental can only accept responsibility for the safety, reliability, and performance of the I TECH LITE when there is compliance with the following directions:

- The I TECH LITE must be used in accordance with these Instructions for Use.
- The I TECH LITE has no components which can be repaired by the user.
  Assembly, modifications, or repairs must only be undertaken by an authorized service organization.
- Unauthorized opening of the equipment invalidates all claims under warranty and any other claims.
- Use on electrical circuit complying with the terms of regulation CEI 64-8 section 710.
- Use of components which are not original or different from those specified in the paragraph PACKAGE CONTENTS.

2.4 Disposal of the equipment

Please observe the regulations applicable in your country.
Within the European Economic Community, Council Directive 2002/96/EU (WEEE) requires environmentally sound recycling/disposal of electrical and electronic devices. Your product is marked with the adjacent symbol. Disposal of your product with domestic refuse is not compatible with the objectives of environmentally sound recycling/disposal. The black bar underneath the "garbage can" symbol means that it was put into circulation after Aug. 13, 2005. (See EN 50419:2005) Please note that this product is subject to Council Directive 2002/96/EU(WEEE) and the applicable national law of your country and must be recycled or disposed of in an environmentally sound manner. Please contact your dealer if final disposal of your product is required.

NOTICE:
It is necessary for the user to report to the manufacturer and the competent authority of his state any serious accident that occurs in relation to the device.

3. PACKAGE CONTENTS

REF	*Model*
ITL500	**"I TECH LITE Autoclavable Motor + DeLuxe Pedal + L.E.D. Light"** • Electronic Control Console • Micromotor Assembly Autoclavable • Pedal "DeLuxe" • Irrigation Bag Hanger Rod • Peristaltic Pump Irrigation Line (*see page 15*) • C- Power Supply • L.E.D. Light • 1 Contrangle LED – 20:1 (*see page 15*)

Refer to the "REF" on the bottom to identify the model.

4. SET UP

4.1 Environmental and transport conditions:

- Internal use. Altitude lower than 3000 m (10,000 ft).
- Temperature: 18°C / 40°C (64°F / 104°F).
- Relative Humidity: < 80% (non-condensing).

4.2 Safety precautions:

a) Do not insert anything inside the motor.
b) The "Motor" is supplied non-Sterile.
c) Use only power cord as described in the section Package Contents
d) Use for intended purposes only. Failure to observe the operating instructions may result in the patient or user suffering serious injury. Before using this product, make sure that you have studied and understood the operating instructions.
e) Do not install where there is a risk of an explosion. The Systems are not intended for operation in the presence of flammable anesthetics or gases.
f) Do not disassemble or alter the System motor, console, or foot switch.
g) Connect mains power cable to a properly grounded outlet only.
h) Never touch drills, burs, or other handpiece tips when they are still rotating.
i) Handpiece should only be attached when the motor has stopped running.

4.3 Setting up the unit:

1. Cut the adhesive tape and open the suitcase. Remove the unit and its accessories from their original packaging and place on a flat surface. Not install near heat sources, direct or indirect.
2. Verify the contents of the box according to the section **"PACKAGE CONTENTS"**
3. Do not kink the motor hose since it may damage it.
4. All accessories are supplied non-sterile except for tubing.
5. The serial number on the Unit's rear panel must be the same as the one on transport documents.
6. Allow at least 150 mm free space around the unit for cooling ventilation.

Damage in Transit

If the packaging is visibly damaged on delivery, please proceed as follows:

a. The recipient of the package must record the loss or damage on the delivery receipt. The recipient and the representative of the shipping company must sign this delivery receipt. Without this evidence, the recipient will not be able to assert a claim for damages against the shipping company.
b. Leave the product and packaging in the condition in which you received it and do not use the product.

If the product is damaged but there was no discernable damage to the packaging upon delivery, proceed as follows:

a. Report the damage immediately or at least 7 days after the delivery to the delivery company.
b. Leave the product and packaging in the condition in which you received it and do not use a damaged product.

4.4Assembling the unit

Micro Motor connection

- Connect the micro motor into the receptacle on the front of the central unit.
- Connect the Contrangle to the Micro Motor.
- Only for "REF" ABNE300 press the button on the rear side to switch on LED Light
- Place the Micro Motor on the motor holder.

Foot Pedal connection

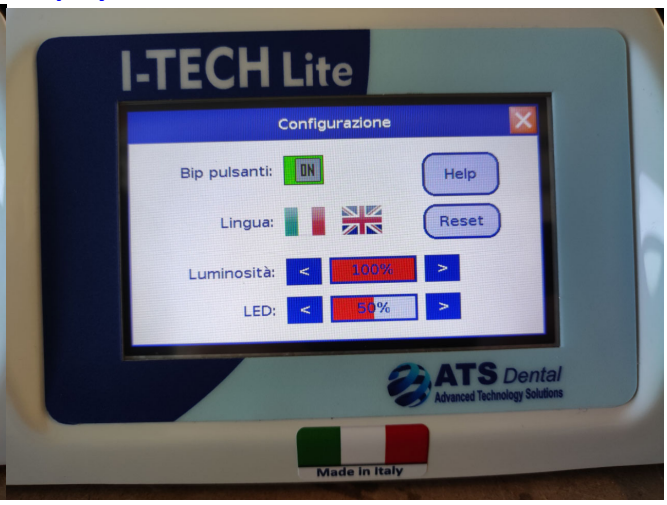
- Connect the foot pedal into the receptacle on the front of the central unit.
- Place the foot pedal on the ground.

While inserting the plug, align the guide on the connector in an upright position to fit into the corresponding female guide on the I TECH LITE. Connectors have a spring retention system to help avoid accidentally disconnecting the unit's cords and cables.

5. CONTROL PANEL FUNCTIONS

Display screen n° 1

Display screen n° 2



Display Screen N°1

FIRST ROW: * "RPM" = Set Speed +/- * "Prg: 1" = Set 5 Programs * "Cal" = Calibration *
SECOND ROW: * "Ncm" = Set Torque +/- * "R/R" = Ratio of the contrangle * "Opzioni" = Switch to display n° 2 *
THIRD ROW: * "F/R" = Set Forward Reverse * "Flow "= Pump Flow * "LED" = Set ON/OFF *
FOURTH ROW: * "-" = Decrease values * "+" = Increase values * "Pompa" = Set OFF/ON * "Motore" = Set OFF/ON *

Display Screen N°2

"Bip Pulsanti": Set Bip ON/OFF
"Help": Coming soon
"Lingua": Set ITA/ENG
"RESET" : To perform SYSTEM RESET (*Restore default parameters*)
"Luminosità" : Brightness Increase/Decrease
"LED" Increase/Decrease Intensity of LED (*Default 50%*)

6. CONSOLE BACK

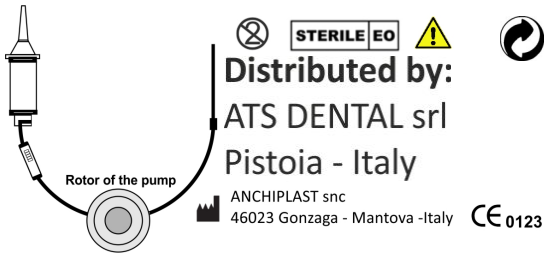
REF: BNE300

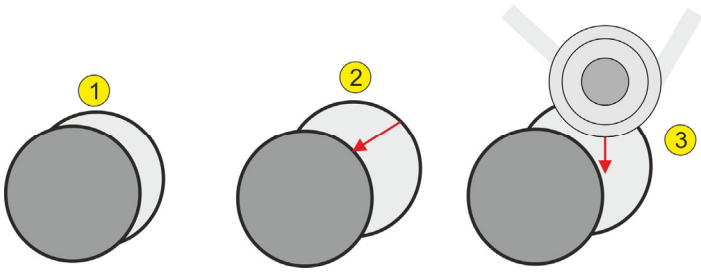
1. PUMP
2. MAIN I POWER On/Off
3.. Power Cord In

7. PEDAL (FOOT CONTROL OPERATION)

"REF": BNE300 **"DELUXE"**		✓ The **left-hand button** allows user to change the value of the coolant pump as well as the key "flow" on the keyboard. ✓ The **central up button** allows user to change the programs as well as the key "P - programs" on the keyboard. ✓ The **right-hand button** allows user to switch between forward and reverse motor rotation (when in reverse, console will emit a beeping tone), as well as the key "Fwd/Rev" on the keyboard. ✓ The **central down button** allows user to control up to the pre-selected maximum speed and switch on the pump if enabled.

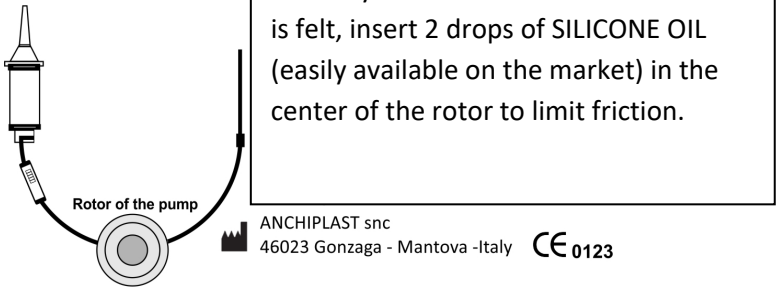
8. IRRIGATION LINE SETUP





1. **Open the pump Insert the rotor of the pump inside the pump. Close the pump.**
2. **Hang the bottle or bag of physiological saline from the bracket.**
3. **Insert the irrigation line perforating into the bottle or bag of physiological saline.**
4. **Connect the end of irrigation line to the contrangle.**

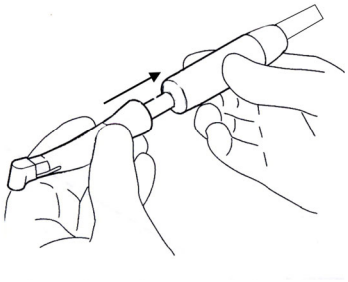
NB: Use only ATS DENTAL Tube. Do not run the pump without tube.
Do not use coolant reservoirs that can hold more than 1 liter. Ensure that the device is standing securely. Use transparent coolant reservoirs.



9.Use

After the unit has been set up and the user has become familiar with the System's control panel functions:

1. Attach the appropriate "E-Type" handpiece to the motor. It can be used with most surgical contra-angles without internal light or spray on the market. Use only handpiece that conform to ISO 3964. Change the handpiece and angle piece only when the motor not running.



1. Insert bag hanger rod into socket on the top of the console.
2. Attach the motor to the connector on the right side (facing the unit) on the front panel.
3. Attach the foot control to the connector (gray color) on the front panel.
4. Install irrigation tubing into pump on the rear panel. Use only tubing as described in "Irrigation Tube Set Up".
5. Switch on (on the rear panel.

In every program Programs [1 to 5] are set the same parameters by the manufacturer.
Perform torque calibration, press "**Cal"** key on front panel while holding the motor. This function checks the handpiece mechanical inertia, to off-set this value.
This operation will take a few seconds, the drill will run at different speed.
The drill must not be engaged in any operation when this function is performed.
Calibration should be done before each surgical session or anytime the handpiece is changed or lubricated.

I TECH LITE will store the operative parameters for each "program" as soon as the user sets them. They will be maintained in the memory even if the central unit is switched off. For each "program" it is possible to set speed, torque, ratio, direction of rotation and flow. To reset the parameters of the manufacturer (SystemReset), press "RESET" key on Display screen N° 2. Wait until the end of the operation.

9.1Programming the unit

R/R: Sets handpiece reduction ratio. See the available reduction ratio in the following table:

1:1	16:1	20:1	24:1	32:1	64:1	80:1

RPM +/-: Sets motor rotation speed (value in rpm). Speed values depend on contra-angle reduction rate.
Max speed is 2000 rpm with 20:1 contrangle. Min speed is 20 rpm with 20:1 contrangle.
Ncm +/-: increases or decreases the torque values. Torque values are in Ncm and depend on contra-angle reduction rate.
Max torque is 80 Ncm with 20:1 contrangle.
Pay special attention to use the same ratio of the handpiece. Torque accuracy is guarantee only with 20:1 Contrangle correctly maintained. The torque values are only for handpieces that operate properly. Micro motor stops when set torque is reached. The torque value in counterclockwise rotation is always = Max Ncm
LED = LED ON/OFF
FLOW: Selects variable irrigation pump flow rate. See the following table:

0 = no irrigation	1	2	3	4

F/R: Switch between forward and reverse motor rotation (when in reverse, console will emit a beeping tone).

MOTOR ON/OFF: Switches motor ON and OFF (if enabled). **PUMP ON/OFF:** Switches pump ON and OFF (if enabled).

10. Cleaning and Sterilization

Unplug the main unit from power source before cleaning or disinfecting. Do not use directly on liquids and sprays. Never immerse the unit or its parts in liquid.
External surface of the console may be cleaned with a damp cloth or disinfectant wipe. The housing is not waterproof. Do not use ultrasonic or steam sterilizers. External surface of the micro motor may be cleaned with a damp cloth or disinfectant wipe. Do not place micro motor in ultrasonic sterilizers. Motor Holder and Irrigation Bag Hanger Rod may be cleaned with a damp cloth or disinfectant wipe. The exterior of the foot controls may be cleaned by wiping with a soft cloth moistened with mild detergent or disinfecting solution.

WHAT CAN BE STERILIZED:	**STERILIZATION METHOD:**
"REF" ITL500 • Micromotor Assembly (Motor-Cable-Connector) • Motor Holder • Irrigation Bag Hanger Rod	➢ Sterilization with steam or chemical vapor ➢ Sterilization time :18 minutes at 134°C/2 bar. ➢ Do not exceed 138° C or 275° F ➢ Cooling down time: 2 hours ➢ Working temperature: 40°C ➢ Max sterilization cycles: 500. Do not submerge in any solutions. Do not use ultrasonic cleaners. Do not sterilize with Ethylene Oxide

When treating patients who may have an acute, critical infectious disease, be sure to observe the hygienic measures cited in applicable publications and reports. If possible, use suitable disposable products to avoid the transmission of critical pathogens. These protect the user, the patient, and all participants in the surgery. A microbiologically appropriate coolant liquid must be used. Only use prescribed isotonic saline solution NaCl 0.9 (identified as an infusion solution; follow the instructions on the package insert) for cooling and spraying wounds. Not all autoclaves can reach 134° C. Not all autoclaves draw a pre-vacuum. Please refer to your autoclave manufacturer for specific sterilization instructions.

11.Maintenance

The micro motor cable has limited durability and is considered a consumable product. The durability of the cable is largely dependent upon use and treatment, i.e., handling, reprocessing and frequency of use.
Caution must be exercised when connecting or disconnecting the micro motor and foot control cable from the device to avoid damage to the cable.
Periodically inspect the micromotor cord for damage prior to use. If there is damage noted, contact the Manufacturer.

LUBRICATING:

- **Do not oil or lubricate the micromotor.**

RUBBER O-RING:

- If necessary, substitute. Contact the Manufacturer

1.Do not attempt to disassemble the motor or motor connector.
2.Do not oil or lubricate the motor.
3. Do not attach a handpiece to the motor while the motor is running.
4.Do not bend motor cord sharply.

- The Micromotor is sensitive to shock. Do not drop or impact micromotor against hard surface.

Failure to comply with any of the above instructions may void your warranty.

12.TECHNICAL DATA

Manufacturer	**ATS Dental – Pistoia – Italy**	**Nominal Power**	**100 VA**
Model	**I TECH LITE**	**Frequency**	**50/60 Hz**
Dimensions	**185x160x100**	**Protection**	**Class 1**
Materials	**ABS**	**Type**	**BF**
Micromotor	**Brushless 40000/30000**	**Class MD**	**IIa rule 9 in Annex IX 93/42/EEC**
Noise	**< 65 dBA**	**Console**	**IP21**
Supply Voltage	**24-30 VDC**	**Micromotor and Pedals**	**IP21**
Not suitable for use in presence of flammable anesthetics or oxygen.			
Conditions of use: Temp +18°C/+40°C (+64°F/+140°F) RH < 80%			
Shipping and Storage conditions: Temp +5°C/+65°C (+41°F/+149°F) RH < 20-95% non-condensing. **Life of the device: When used as prescribed = 5 years. No warranty claim may be made if the failure happens sooner or later than indicated, because of the frequency of use, sterilization and maintenance.**			

14." TROUBLESHOOTING"

Problem: The central unit does not switch on.	
Possible cause	**Solution**
•Power cord not connected properly	Make sure the power cord is properly plugged into the electrical outlet and the connector on the back of the unit.
•Unit has not been switched on.	Check the back of the unit to see that the on button has been pressed.
•Broken connections inside. • Transformer damaged. • PCB faulty. • Filter supply defective. • Power interrupted.	Immediately discontinue use of the device and contact your distributor, service center, or the manufacturer directly.
Problem: The display is not working properly	
Possible cause	**Solution**
•Possible interference.	Check to see if the central unit has been positioned too close to another electrical device which can cause interference. In this case, move the interfering electrical device further away from the central unit.
•Broken connections inside. •Display damaged. •PCB damaged.	If you cannot find the cause of the malfunction, immediately discontinue use of the device and contact dealer, the authorized service center, or the manufacturer directly.
Problem: The keyboard is not working properly	
Possible cause	**Solution**
•Keyboard damaged. •Broken connections inside.	Attempt to change parameters by using the foot pedal. Contact your distributor, service center, or the manufacturer directly.
Problem: The motor doesn't work	
Possible cause	**Solution**
• Micro motor cable not connected properly	Check to see that the micro motor cable is plugged into the connector on the front right of the central unit, disconnect and reconnect
•Contrangle defective or not properly calibrated.	Check the integrity of the Contrangle. Remove the Contrangle and perform calibration.
•Foot pedal damaged.	Attempt to start the Micro Motor by using the **[Motor ON/OFF button]** on the central unit keyboard. If unit does not turn on, contact dealer, the authorized service center, or the manufacturer directly.
•PCB damaged. •Motor damaged. •Connector pins and/or cable damaged.	Immediately discontinue use of the device and contact dealer, the authorized service center, or the manufacturer directly.
Problem: The motor stops suddenly	
Possible cause	**Solution**
•Keyboard and/or foot pedal damaged	Try to turn off the motor by pressing the **[Motor ON/OFF] button** on the keyboard or by using the foot pedal. If the motor will not turn off, immediately discontinue use of the device and contact dealer, the authorized service center, or the manufacturer directly.
•Broken connections inside. •PCB damaged	Immediately discontinue use of the device and contact dealer, the authorized service center, or the manufacturer directly.
Problem: The pump is not working property	
Possible cause	**Solution**
•Tube not correctly inserted •Tube damaged.	To verify the proper tube connection, follow the instructions on this DFU. Check for damage along the tube, kinks, partial occlusions, etc. Arrange for immediate replacement of the tube.
Problem: The pump stops suddenly	
Possible cause	**Solution**
•Pump damaged/blocked. •PCB damaged.	Immediately discontinue use of the device and contact dealer, the authorized service center, or the manufacturer directly.

15. ACCOMPANYING DOCUMENTS

Electromagnetic emissions:

I TECH LITE is intended for use in the electromagnetic environment specified below. The **I TECH LITE** should only be used in such an environment.

RF emissions CISPR 11	Group 1	I TECH LITE uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	I TECH LITE is suitable for use in all establishment including domestic establishments and those directly connected to the public low-voltage power supply.
Harmonic emissions IEC 61000-3-2	Class A Conforms	
Voltage fluctuation/ flicker emissions IEC 61000-3-3	Conforms	

Electromagnetic Immunity:

I TECH LITE is intended for use in the electromagnetic environment specified below. The **I TECH LITE** should only be used in such an environment.

Immunity test	**Test level EN 60601-1-2**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) EN61000-4-2	±6kV contact ±8kV air	±6kV ±8kV	Floor should be wood, concrete, or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30%
Burst/Fast transient EN 61000-4-4	±2kV for power supply lines	±2kV for power supply lines	Quality of the Main power source should be that of a typical commercial or hospital environment
Surge EN 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Quality of the Main power source should be that of a typical commercial or hospital environment
Immunity test	**Test level ICE 60601**	**Compliance level**	**Electromagnetic environment - guidance**
Voltage dips, short interruptions and voltage variation on power supply input lines. EN 61100-4-11	<5%Ut (>95% dip in U_t) for 0,5 cycle 40% Ut (60% dip in U_v) for 5 cycle 70% U_t (30% dip in U_t) per 25 cycle <5% U_t (>95% dip in U_t) for 5 sec	<5%Ut (>95% dip in U_t) for 0,5 cycle 40% Ut (60% dip in U_v) for 5 cycle 70% U_t (30% dip in U_t) per 25 cycle <5% U_t (>95% dip in U_t) for 5 sec	Quality of the Main power source should be that of a typical commercial or hospital environment If the user of the I TECH LITE requires continued operation during power main interruptions, it is recommended than the I TECH LITE be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field EN 61100-4-8	3A/m	3A/m	Power frequency magnetic fields should be at a typical commercial or hospital establishment level.

I TECH LITE is intended for use in the electromagnetic environment specified below. The **I TECH LITE** should only be used in such an environment.

Immunity Test	Test level IEC 60601-1-2	Compliance level	Electromagnetic Environment - Guidance
Conducted RF EN 61000-4-6 Radiated RF IEC 61000-4-3	3 Veff from 150KHz to 80MHz 3 Veff from 80MHz to 2.5GHz	3 Veff from 150KHz to 80MHz 3 Veff from 80MHz to 2.5GHz	Portable and mobile RF communication equipment should be used no closer to any part of the I TECH LITE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ from 150KHz to 80MHz $d = 1,2\sqrt{P}$ from 80MHz to 800MHz $d = 2,3\sqrt{P}$ from 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer and recommended separation distance in metres (m).
Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range [b]. Interference may occur in the proxim ipment marked with the following symbol:			

Recommended separation distance between portable and mobile RF communications equipment and the I TECH LITE			
The I TECH LITE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the I TECH LITE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the I TECH LITE as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according in frequency of transmitter (m)		
	From 150kHz to 80MHz $d = 1,2\sqrt{P}$	From 80MHz to 800MHz $d = 1.2\sqrt{P}$	From 800MHz to 2,5GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, 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.

Included in Ref: ITL500 – Model: I TECH LITE

1 X Contra-Angle Handpiece - Ref: "201-ATSL"

TECHNICAL DATA

Gear Ratio	20:1
Max motor speed	40000 RPM
Max operating speed	2000 RPM
Torque	≥55 Ncm
Clamping system	CA
Shank diameter of the burs	2.334-2.350 mm

Symbols

REF	Catalogue number		Manufacturer		Thermo washer disinfectable
MD	Medical Device	CE	Reg. 2017/745 UE		
SN	Serial number		Date of manufacture	135°C	Sterilizable up to the stated temperature

SEE "DFU" IN THE PACKAGING

2 X IRRIGATION LINE

Manufacturer	ATS DENTAL ADVANCED TECHNOLOGY SOLUTIONS For more information, contact: ATS DENTAL srl Via Vecchia Prov.le Lucchese, 49 51034 Serravalle Pistoiese Italy +39 0573 518137 www.atsdental.it - info@atsdental.it Note: the instructions above have been validated by the manufacturer of the device as suitable for preparing the device for reuse. The proper implementation of the preparation process, as well as achieving the desired result, are full responsibility of the person performing the operation.

ATS DENTAL SRL reserves the right to modify the present DFU without prior notice.

ATS DENTAL ADVANCED TECHNOLOGY SOLUTIONS

Via Vecchia Provinciale Lucchese, 49/F - Loc. Masotti
51034 SERRAVALLE PISTOIESE (PT) - Italy
Tel.: +39 0573 518137 – Fax: +39 0573 1711140
info@atsdental.it internet: www.atsdental.it

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