

E-STAT/IS

Motor

Operator's Manual

CAUTION: Federal law restricts this device to sale by or on the order of a dentist.

SciCan
A HIGHER STANDARD

www.scican.com

E-STAT/IS Operator's Manual
Copyright 2009 SciCan. All rights reserved.

Doc. No. 2.000.3441 - Rev. 07/27/09

E-STAT/S is a trademark of SciCan Ltd. All other trademarks referred to in this manual are the property of their respective owners.

For all service and repair inquiries:

In Canada: +1-800-870-7777
United States: +1-800-572-1211
International: +1-416-446-4500
E-Mail: techservice.ca@scican.com

Manufactured by:

SciCan GmbH
Kurzes Gelände 10
86156 Augsburg
GERMANY

Phone: +49-821-567456-0
Fax: +49-821-567456-99



REPRESENTATIVE:

SciCan LTD.

1440 Don Mills Road,
Toronto ON M3B 3P9, CANADA
Telefon: +1-416-445-1600
Fax: +1-416-445-2727
Toll free: +1-800-667-7733

SciCan Medtech AG

Alpenstrasse 16,
6300 Zug, SCHWEIZ
Phone: +41-41-727-70-27
Fax: +41-41-727-70-29

SciCan INC

701 Technology Drive,
Canonsburg, PA 15317, USA
Phone: +1-724-820-1600
Fax: +1-724-820-1479

Table of Contents

1	Introduction.....	5
2	Important Information	6
	Applied Symbols	6
	Safety Precautions	10
	Proper Use - Purpose	14
3	Accessories	16
	Description.....	16
4	Processing Methods.....	17
	Cleaning.....	18
	Disinfection	20
	Sterilization	22
5	Installation and Operation.....	25
6	Operation	27
7	Maintenance	30
8	Specifications	35

Table of Contents

9	Spare Parts	38
10	Conditions of Installation	39
11	Limited Warranty	40

1 Introduction






Dear user,

We hope that you will enjoy using your new quality product. In order to ensure that you can work in a trouble-free, economical and safe manner, please comply with the instructions below.

2 Important Information









Applied Symbols

Appearing in the manual / on the unit:

	Situations where failure to follow the instructions may lead to danger, damage to material or operating faults.
	Important information for operator and engineer
	Disposal information see important information "Disposal"
	Sterilizable up to 135 °C
	CE mark (Communauté Européenne)

2 Important Information

Appearing on the packaging:

	Fragile
	Keep dry
	Transport upright with the arrows pointing upwards.
	Stacking restrictions
	Temperature range
	Air pressure
	Humidity
	Quantity

2 Important Information

Modifications and improvements to the product as a result of new technical developments are possible.

This does not imply any right to retrofitting of existing units.

The manufacturer assumes no responsibility for damage arising through:

- External influences (poor quality of the media or faulty installation)
- Use of incorrect information
- Improper use
- Improperly performed repairs.

2 Important Information

Repair and maintenance work - apart from the activities described in this Operator's Manual - may be performed only by qualified technical staff.



- In the event of modifications by third parties, the licences become null and void.
- Only use original parts and spare parts.



Disposal of equipment and accessories at the end of their service lives: On the basis of EC Directive 2002/96/EC on Waste Electrical and Electronic Equipment, we would like to point out that this product is currently in compliance with the labelling requirements but is not yet subject to the disposal requirements of this Directive. However, the unit may be disposed of in Europe in special waste management centres. Additional information can be obtained from the manufacturer or your dental supplier.

2 Important Information

Safety Precautions



Risks caused by electromagnetic fields (pacemakers).

The functions of implanted systems (such as pacemakers) can be influenced by electromagnetic fields.

Ask patients before starting treatment and inform them about the risks.

Electricity



Electrical shock with incorrect connection of a third-party system to the dental motor.

When installing and operating the dental motor with treatment equipment and devices from other manufacturers, observe the provisions in "Protection against electrical shock," "Leakage current," and "Non-grounding the application part" in accordance with IEC 60601-1.

2 Important Information



WARNING: Electric micro motors generate significantly more power than traditional air turbines and air motors. Poorly maintained, worn, damaged or misused hand-pieces may generate frictional heat capable of causing serious burn injuries to the patient. Heat generation may occur quickly and without prior warning. Hand-pieces must be properly maintained according to the specified maintenance schedule and inspected for signs of wear prior to each use.



Risk caused by the lack of control equipment.

Hazards can arise if control equipment is not available for changing the speed and the direction of rotation.

- The connected dental treatment unit must have control equipment for changing the speed and direction of rotation.

2 Important Information

- In the accompanying documents must be a notice about the responsibilities arising from safety, reliability and performance by hazards.



Endangerment to the practitioner and patient.

You must stop using the device immediately in the event of damage, irregular running noises, excessive vibrations, unusual generation of heat or if the drill bit is not firmly gripped.

The instrument must be cleaned, serviced and stored dry if it is to be put into extended storage.



Risk due to incorrectly stored motor.

Damage to the dental motor from dropping

2 Important Information

After treatment, place the dental motor in the hand-piece holder of the delivery unit.



Damage to the dental motor.

Never put an attachment on a running dental motor!



Note:

Together with the dental treatment device, this dental motor meets the requirements of IEC 60601-1-2. Only trained personnel are authorized by the manufacturer to repair and maintain the dental motor.



Any claim under warranty shall be excluded if defects or the consequences thereof are due to manipulation or modifications to the product by the customer or by any third parties not authorized by SciCan.

2 Important Information

Proper Use - Purpose

This dental motor is:

- Only intended for dental treatment. Any other type of use or alteration to the product is impermissible and can be hazardous. The dental motor is intended for the following use: Removal of carious material, cavities and crown preparations, removal of fillings, processing of tooth and restoration surfaces and endodontic treatment.
- A dental motor according to relevant national statutory regulations.

This medical product:

- Includes a low-voltage electric dental motor in accordance with ISO 11498 type 2.
- Is not approved for use in areas with an increased risk of explosion.

2 Important Information

According to these provisions, the dental motor is only to be used by an experienced user for the described application in accordance with:

- The applicable health and safety regulations
- The applicable accident prevention regulations
- This Operator's Manual

According to these regulations, the user is required to:

- Only use equipment which is free of faults and works properly
- Only use the equipment for the proper purpose
- Protect himself, the patient and third parties from danger
- Avoid contamination from the product

3 Accessories

Description	Material no.
Motor O-rings black, attachment end	300002
Motor O-rings, large black	300003
Motor O-rings, large green	300004
Motor bulb	S15102
Motor O-rings black (small)	300005

4 Processing Methods

“THE DENTAL MOTOR MUST BE STERILIZED BEFORE FIRST USE AND AFTER EACH USE.”

Processing Methods - According to ISO 17664

Preparation at the site of use.



Hazard from nonsterile products.

An infection hazard exists from contaminated dental motors.

Observe suitable personal protective measures.

Remove residual cement, composite or blood at the site of use.

The dental motor must be dry when transporting it to be prepared.

Do not place it in a solution.

The dental motor should be prepared as close to the treatment time as possible.

4 Processing Methods

CLEANING

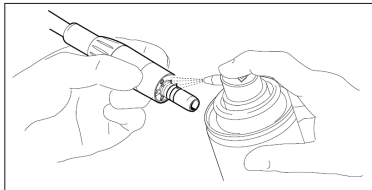
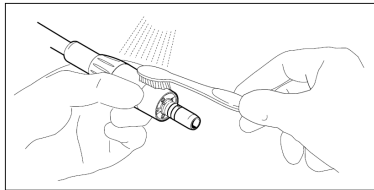
Malfunctions caused by cleaning in ultrasonic units.
Defect to the product.

Only clean manually!
Clean the surface.

Necessary accessories:

Tap water $30^{\circ}\text{C} \pm 5^{\circ}\text{C}$ or a 60 to 70% alcohol solution
Brush such as a medium-hard toothbrush

4 Processing Methods



Clean the interior.

No internal cleaning is stipulated for this dental motor.

4 Processing Methods

DISINFECTION

Malfunction may occur from using a disinfectant bath or a chlorine-containing disinfectant.

Only disinfect manually!

Disinfect the dental motor by wiping after each treatment.

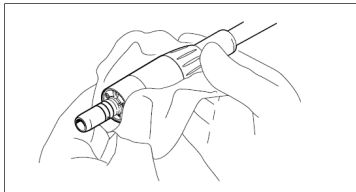
Disinfect the exterior.

When cleaning, protect the dental motor from water penetration.

Clean external surfaces with a cotton swab soaked in isopropyl alcohol.

Dry using syringe air.

4 Processing Methods



Required tools:

Use wiping cloth to wipe the dental motor. Spray the disinfectant on a wiping cloth then wipe the dental motor according to the instructions of the disinfectant manufacturer.



Note:

Observe the operating manual of the disinfectant solution manufacturer.

Disinfect the interior.

No internal disinfection is stipulated for this dental motor.

4 Processing Methods

STERILIZATION

**Sterilization in a sterilizer compliant with EN 13060
Contact corrosion from moisture can occur.**



Immediately remove the product from the steam sterilizer after the sterilization cycle is complete!



The dental motor has a max. temperature resistance of 138 °C.
The recommendation from the manufacturer is:
- Sterilization in a *STATIM* Autoclave by SciCan

4 Processing Methods



Note:

The motor is autoclavable with two different validated methods:

- Three pre-vacuum cycles for at least 4 minutes at $134^{\circ}\text{C} \pm 1$

or

- Autoclave using the gravitation method for at least 90 minutes at $121^{\circ}\text{C} \pm 1$

Follow the manufacturer's operating manual.

Packaging



Note:

The sterilization bag must be large enough for the instrument so that the bag is not stretched.

4 Processing Methods

The quality and use of the packaging of the items to be sterilized must satisfy the applicable standards and be appropriate for sterilizing.

Shrink-wrap the dental motor separately in a sterilizable package!

Storage

Prepared products should be stored protected germ-free from dust in a dry, dark and cool room.

! **Note:**
Observe the expiration date of the sterilized item.

5 Installation and Operation



Possible hazard caused by non-sterile products.

Danger of infection to the practitioner and patient.

The dental motor must be sterilized before first use and after each use.



Damage caused by contaminated and moist cooling air.

Contaminated and moist cooling air can cause malfunctions and premature bearing wear. In general, ensure that a dry, clean and uncontaminated supply of cooling air is provided in accordance with ISO 7494-2.

5 Installation and Operation



Burning hazard caused by hot dental motor.

When the instrument overheats, burning in the oral area can occur.

Never contact soft tissue with the dental motor!

The user should monitor the motor and the contra angle handpiece used with it for possible overheating.



Risk due to incorrectly stored dental motor.

Damage to the dental motor from dropping.

After treatment, place the dental motor in the rack.



Damage of the dental motor.

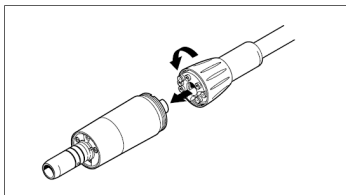
Never put an instrument on a running dental motor!

6 Operation

Connection with the motor tube: Mounting

Lightly coat the O-rings on the motor tube with a lubricant spray such as the SciCan STATCARE or STATMATIC spray.

Push the dental motor onto the supply hose until it clicks home and secure it with a nut connector.



6 Operation

Damage of the medical product.



A dental motor that is not connected correctly can become loose from the supply hose and become disconnected.

Before each treatment, check that the dental motor is safely connected to the supply hose by gentle pulling on the dental motor.

Connection with the supply hose: Disconnection

Separate the dental motor from the supply hose in axial direction by loosening the nut connector.

6 Operation

Loss of functionality.



Pressing the footswitch while connecting or disconnecting the medical unit can cause damage to the medical unit and to the supply hose.

Do not connect or disconnect the medical unit while the footswitch is operating.

Spray cooling



Risk due to insufficient quantities of water for spray cooling.

If the supply of cooling water is insufficient then this can cause the tooth to heat up.

A water supply of at least 50 cm³ / min is required for the spray cooling.

7 Maintenance

Check for malfunctions

The medical product heats up and gets excessively hot.

When running without a load:

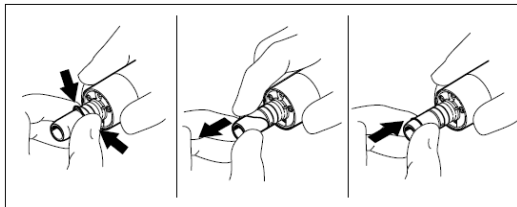
- Check the amount of cooling air.

O-ring missing on the supply hose:

- Replace the O-ring

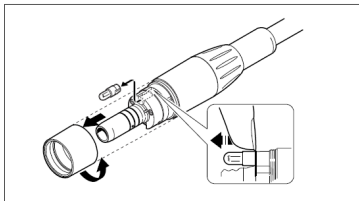
O-ring missing on the coupling:

- Replace the O-ring



7 Maintenance

The dental motor has no lighting:



High pressure bulb defective
- replace

Lighting control not activated
- check on the dental element

7 Maintenance

Missing or damaged O-rings.

If the O-rings are missing or damaged, malfunctions and premature failure can occur.

Check that all O-rings are present and undamaged on the coupling.

Exchange the bulb.

Danger due to hot bulb

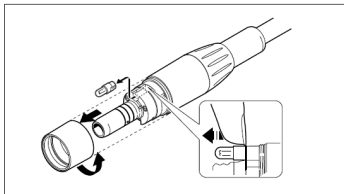
Burning hazard.

Do not touch the bulb after it has been used.

Let the bulb cool off.



7 Maintenance



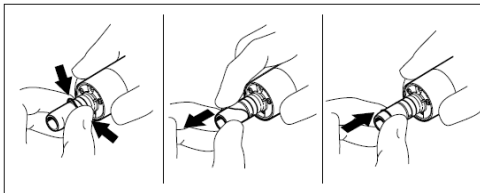
Exchange the O-rings on the instrument coupling.

! **Note:**

The O-rings on the instrument coupling must only be oiled with a cotton wool bud that has been coated with lubricant spray such as the SciCan STATCARE or STATMATIC spray.

7 Maintenance

Squeeze the O-ring between your fingers until its shape resembles a bow. Slide the O-ring to the front and remove it. Insert new O-rings into the grooves.



Risks caused by incorrect care of the O-rings.

Incorrect care of the O-rings on this product can cause malfunctions or complete failure of the device.

Do not use Vaseline or other types of grease or oil.

8 Specifications

Motor speed range:	100 to 40,000	rpm (min^{-1})
Motor power:	max. 47	W
Motor electronics:	2.000.2642	
Motor voltage:	max. 22	V AC
Output torque:	max. 3.0	Ncm
Operation mode:	Duty cycle: 0.5 on / 9 off	min
Operation voltage of the bulb:	3.2	V DC
Power of the bulb:	2.5	W
Air outlet of the coupling (cooling air):	7 to 10	NI/min
Spray air pressure:	1 to 2.5 bar (14.5 to 36.2 psi)	
Spray water pressure:	0.8 to 2.0 bar (11.6 to 29.0 psi)	
Weight:	99 g (0.218 pds)	

8 Specifications

Dimensions:	42 x 22 mm (1.65 x 0.87 inch)
Rotation:	clockwise / counter-clockwise
Sound level:	< 40 dBa
Connection of attachments:	ISO 3964

Ambient conditions

Location:	Permitted in interior rooms
Ambient temperature:	10 to 40 °C (50 to 104 °F)
Relative humidity:	30 to 75 %
Max. altitude:	2000 m

8 Specifications

Storage and transport conditions for control unit and power supply



Hazard from starting the dental motor after very cold storage.

The dental motor cannot function.

Products that are very cold must be warmed to 20°C to 25°C (68°F to 77°F) before use.

Ambient temperature: -30 to 70 °C (-22 to 158 °F)

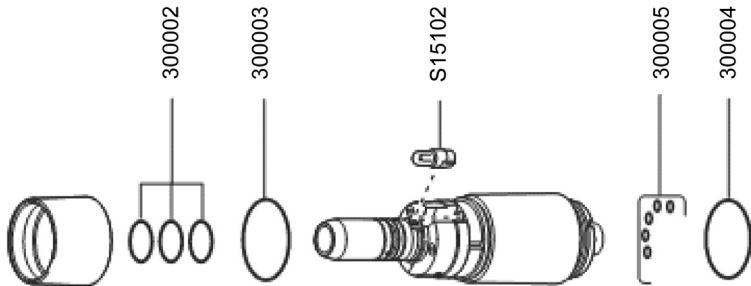
Relative humidity: 5 to 95 %

Air pressure: 700 to 1060 hPa

Keep dry!

We reserve the right to make technical modifications.

9 Spare Parts



10 Conditions of Installation

! Instructions for installation of the dental motor

- The dental motor is only intended for installation in dental treatment units.
- Follow all terms and specifications of the Operator's Manual.
- The dental motor is classified as an accessory to dental products.
- When installing and mounting to dental treatment units observe the provisions of national regulations and law.
- The safety inspection of the motor in accordance to EN 60601-1 and EN 60601-1-2 has been conducted in conjunction with the dental treatment units.
- Only use the dental motor with a control unit approved by SciCan.

11 Limited Warranty

For a period of three years, **SciCan** guarantees that the **E-STATIS Motor**, when manufactured by **SciCan** in new and unused condition, will not fail during normal service due to defects in material and workmanship that are not due to apparent abuse, misuse, or accident. The three years warranty will cover the performance of all components of the unit except consumables, provided that the product is being used and maintained according to the description in the Operator's Manual.

In the event of failure due to such defects during this period of time, the exclusive remedies shall be repair or replacement, at **SciCan's** option and without charge, of any defected part(s) (except gaskets, seals, O-rings and couplings), provided **SciCan** is notified in writing within thirty (30) days of the date of such a failure and further provided that the defective part(s) are returned to **SciCan** prepaid. This warranty shall be considered to be validated, if the product is accompanied by the original purchase invoice from the authorized **SciCan** dealer, and such invoice identifies the item by serial number and clearly states the date of purchase. No other validation is acceptable.

After three years, all **SciCan** warranties and other duties with respect to the quality of the product shall be conclusively presumed to have been satisfied. All liability, therefore, shall terminate and no action or breach of any such warranty or duty may thereafter be commenced against **SciCan**.

Any express warranty not provided hereon and any implied warranty or representation as to performance, and any remedy for breach of contract which, but for this provision, might arise by implication, operation of law, custom of trade or course of dealing, including any implied warranty of merchantability or of fitness for particular purpose with respect to all and any products manufactured by **SciCan** is excluded and disclaimed by **SciCan**. If you would like to learn more about **SciCan** products and features, visit our website at www.scican.com.

