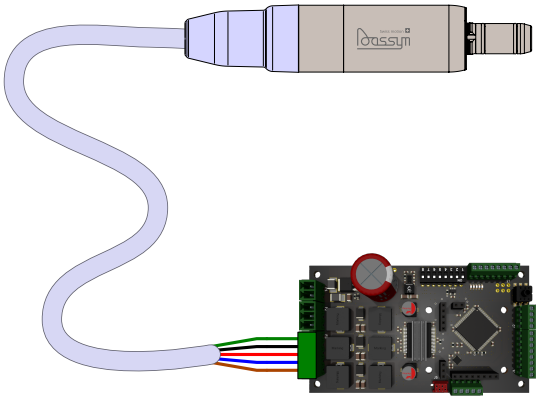
Swiss motion

Instruction For Use

S-60-I Medical Device



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Revisions

2025–10–10	1.1	Initial release
2025–03–06	1.0	Initial version

ENGLISH — Other languages and further instruction available on www.dassym.com/ifu

1 Introduction

Thank you for purchasing a high quality **Dassym** dental equipment.

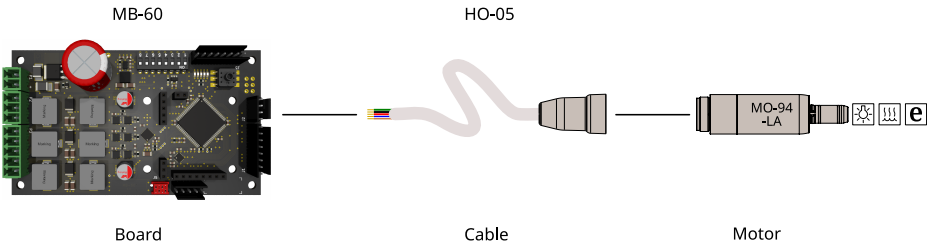
Before you begin

- Carefully read the instruction for use prior to use of the medical device.
- Use the medical device only for applications described in the instruction for use.
- Follow the relevant hygiene standards, safety regulations and accident prevention measures.

1.1 Identification

The **S-60-I** medical device, composed of a micromotor (prefix **MO**), an electronic board (prefix **MB**) and a cable connection (prefix **HO**), is intended to drive a straight or contra-angle handpiece as part of a dental treatment unit. Possible compositions are:

UDI-DI	Trade name	Trade mark	Product reference	Composition	Part reference
EDAS1506004010	S-60-I	Dassym	150.60.941	MO-94-LA MB-60 HO-05	102.08.200 251.60.000 121.05.001



1.2 Intended use

The **S-60-I** medical device is intended for use in dental treatment.

1.3 Intended user

This product is intended for professional use only. Intended users are dentists, hygienists and professionals with a university degree in dentistry.

1.4 Intended patients

This device can be used on any patient, regardless of age or gender, who needs a dental treatment as defined in intended use. The intended user is responsible to select the adequate device for the patient according to the specific clinical application.

1.5 Use environment

The use environment is a professional healthcare facility.

1.6 Medical indications

The **S-60-I** medical device is mainly intended for the following medical indications:

- Implantology: drilling holes into bone tissue.
- Prophylaxis: hygienist, polishing, etc.

The clinical benefit shall be achieved while the medical device drives an accessory such as a straight or contra-angle handpiece during dental treatment.

1.7 Contraindications

There are no known contraindications or side effects for this device if it is used as intended and in accordance with the technical specification declared by **Dassym**.

1.8 Service life

Dassym ensures full traceability of its products for **10 years**, which corresponds to their stated service life. Maintenance and servicing shall be performed according to this instruction for use.

No warranty claim can be inferred here, as wear may occur earlier or later than indicated above depending on use, frequency of sterilization and frequency of maintenance and servicing.

1.9 Warnings, formats & symbols

The formats used in the instruction for use have the following meaning:

✓ Prerequisite	⇒ Actions result
1. First action step	→ Individual action step
2. Second action step	↪ Alternative action
• List item	[→ 2] Reference to another section

The symbols used in instruction for use and product marking & labeling are:

Symbol	Description	Symbol	Description
CE 0051	CE marking with number of the notified body	EC REP	Authorized EC representative in the European Community
	Manufacturer		Date of manufacture
MD	Medical device	REF	Reference number
UDI	Unique device identification	SN	Serial number
	Consult instruction for use	#	Model number
	Type B applied part		Temperature limit
	Keep away from rain		Humidity limitation
	Ultraviolet radiation		Atmospheric pressure limitation
135°C	Sterilizable in a steam sterilizer (autoclave) at the specified temperature		Recyclable electrical and electronic material

To prevent injuries and material damage, please observe all the following indications:

DANGER	Indicates a danger leading to death or serious injury if not avoided.
WARNING	Indicates a danger that may lead to death or serious injury if not avoided.
CAUTION	Indicates a danger that may lead to injury if not avoided.
NOTICE	Indicates measures for the prevention of material damage and expenses.

2 Safety information

2.1 Obligations of the user

When working with this product, the practioner shall follow these guidelines:

- Use only fault-free materials that do not deviate from the specified data.
- Protect yourself, patients, and others against any foreseeable dangers.
- Comply with the intended use of equipment.
- Always keep this instruction for use within reach for further reference.

2.2 Potential explosion hazard

⚠ **DANGER** Do not use this product in areas subject to explosion hazards.

2.3 Preventing the spread of infections and cross contamination

Prevent the spread of infection and cross contamination between patients, users and third parties. Clean and disinfect equipment after each patient. Dassym recommends a daily sterilization. Take the appropriate hygiene measures, for example wear protective gloves.

2.4 Malfunction or damage

Immediately abort use of in case of malfunction, damage, unusual or different sounds. Damaged devices may cause injury. Notify the dental depot or the manufacturer.

ⓘ **NOTICE** Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user is established.

2.5 Electrical safety and electromagnetic compatibility

When installed and used in accordance with Dassym instructions, this equipment is IEC 60601-1 compliant. The complete IEC 60601-1-2 electromagnetic compatibility statement and instruction are available in the MB-60 Instruction for Integration.

⚠ **WARNING** Electrical safety can only be claimed when this medical device is installed and used in accordance with Dassym instructions. Always refer to your dental unit instruction for use to confirm electrical safety compliance.

⚠ **WARNING** Electromagnetic compatibility can only be claimed when this medical device is installed and used in accordance with Dassym instructions. Always refer to your dental unit instruction for use to confirm electromagnetic compatibility compliance.

2.6 Preventing radiation hazards

Operating lamp is not intended to be stared at.

⚠ **CAUTION** Device generates **UV radiation risk 1** according to IEC 62471.

2.7 Repairs and spare parts

⚠ **WARNING** Do not repair the device yourself.

This equipment shall be repaired only by **Dassym** qualified and approved personal. Safe operation cannot be guaranteed for repairs and parts that have not been approved by **Dassym**. If you have any questions, please contact your your service technician or the manufacturer.

2.8 Residual risks

The residual risks have been deemed to be low enough and/or rare enough to be acceptable.

3 Description

3.1 The motor

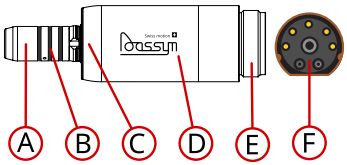
Purpose

The motor converts electrical energy to rotation and transfers rotation to the instrument's tool.

Construction

The motor is especially designed to drive an accessory such as a straight handpiece or contra-angle to which a rotating or oscillating tool is attached. The motor is equipped with LED lighting.

Accessories must comply with IEC-80601-2-60, ISO 14457 & ISO 3964 standards and shall be CE certified in accordance with European Regulation (EU) 2017/745 or Council Directive 93/42/EEC.



A Handpiece holder
B O-Ring Ø8.4 × ø0.7
C Marking under the sleeve
D Removable sleeve
E Coupling connector
F Flat gasket

The motor does not contain organic materials of animal or human origin. The materials are latex free and phthalate free. The external parts of the motor are made of stainless steel (X10CrNiS18).

Technical data

Dimensions	**MO-94-LA**	**Unit**
Length excluding coupling	61	mm
Maximum diameter	21.8	mm
Performances	**MO-94-LA**	**Unit**
Maximum speed	40 000	rpm
Maximum torque	5	Ncm
Maximum power	80	W
Features	**MO-94-LA**	
Standstill and extra low speed torque	✓	
White lighting	✓	
Blue lighting		
Optional air cooling	✓	
Spray function		
ISO 3964 & INTRAmatic Lux® coupling	✓	

INTRAmatic Lux® is a Kaltenbach & Voigt trade mark.

Characteristics	MO-94-LA	Unit
Optional cooling air pressure	300	kPa
Cooling air flow consumption	< 40	Nl/min
Cooling air flow at the nozzle	—	

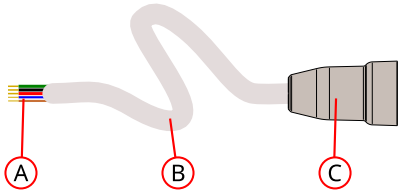
3.2 The cable

Purpose

The cable conveys electrical energy from the dental unit to the motor. It allows disconnection of the motor side. The unit manufacturer may also provide detachable connection on the unit side.

Construction

The connection cable comprises a Dassym proprietary motor connector with its nut and encloses a length of cabling for dental unit connection.



A Wires
B Silicone enclosure
C Motor connector

The external parts of the connection cable are made of silicone and stainless steel (X10CrNiS18).

Technical data

Dimensions	HO-05	Unit
Cable length	1.6	m
Cable mean diameter	5.3	mm

Features	HO-05
Stranded wires for motor phases and lighting	✓

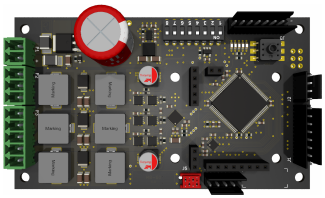
3.3 The board

Purpose

The motor driver board receives commands from the dental unit and sends controlled electrical energy to the motor. The board is buried in the dental unit and shall not be accessible to the user.

Construction and technical data

Board construction and technical data are available in the MB-60 Instruction for Integration.



3.4 Software requirements

The MB-60 board embarks a STM32 a microcontroller with 128 KiB ROM, 64 KiB RAM and no mass storage nor network access. It runs an embedded proprietary firmware which is protected against unauthorized access and not intended to be updated in the field. No measures from the user are necessary for the embedded software to work as expected.

3.5 Operating conditions

Ambient temperature		10 – 40 °C
Relative humidity		30 - 85 %
Air pressure		70 - 106 kPa
Operating times	No limitation for the user. Operating times may be electronically curbed by the motor board, as a function of applied power.	

3.6 Classification

Class IIa in accordance with European Medical Regulation (EU) 2017/745.
Class II type B device in accordance with IEC 60601-1 standard.

4 Installation

Your dental unit shall be delivered with this **Dassym** equipment already integrated. Please consult with your dental unit manufacturer for further information about your installation.

⚠ **WARNING** Installation of the **S-60-I** medical device in a dental unit shall be performed by qualified technicians only and is outside the scope of this instruction for use. Instructions for the integration of this equipment are available in the MB-60 Instruction for Integration.

5 Operation

⚠ **CAUTION** Do not detach the motor from the cable during operation. This may cause injury.

⚠ **CAUTION** If the motor overheats under high load, let it cool off by running at half speed or less before continuing treatment.

ⓘ **NOTICE** The **MO-94-LA** motor is intended to operate without cooling air. Depending on the duty, it may be cooled by air. Please consult with the manufacturer for further information.

5.1 Initial commissioning

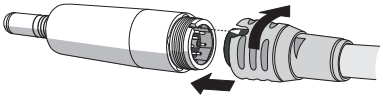
- Sterilize the motor and accessories prior to first use. [→ 6]

5.2 After longer times of non use

- Maintain the motor after longer times of non use. [→ 7]

5.3 Initial motor connection setup

1. Slide back the cap nut at the cable coupling.
2. Attach the motor onto the cable coupling up to the stop, observing the contact pins.
3. Place the cap nut onto the thread, then turn it counterclockwise until a faint click is heard.
4. Screw the cap nut tightly onto the motor by turning it clockwise.



5.4 Replacing the instrument

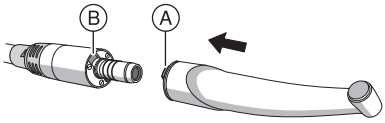
Hand pieces and contra-angles must comply with the ISO 3964 standard specifications.

⚠ **CAUTION** The instrument should only be fitted or removed when the motor is standstill.

Attach the instrument to the motor

✓ The motor is at standstill.

1. Align the nib (A) of the instrument, if there is any, with the groove of the motor (B).
2. Insert the instrument until it snaps into place.



Remove the instrument from the motor

✓ The motor is at standstill.

1. Detach the instrument.

ⓘ **NOTICE** Do not pull on the cable when removing the instrument from the motor.

5.5 After each treatment session

ⓘ **NOTICE** Condition the motor and cable within 30 minutes after treatment.

1. Condition the motor and cable in accordance with national and local regulations. [→ 6]

5.6 By the end of the day

ⓘ **NOTICE** Do not leave any instruments attached to the motor overnight, in order to prevent oil from leaking into the electrical parts. Never lubricate the interior of the motor.

5.7 Once a week

✓ The motor has been conditioned. Lubricate the lock washer. [→ 7]

6 Conditioning

The motor and cable external surfaces must be cleaned to remove impurities. The motor supports sterilizing. The cable may be sterilized according to dental unit manufacturer instructions.

6.1 Cleaning

✓ Wear appropriate protective clothing.

✓ Only use detergents with no protein-fixing properties.

✓ Do not clean motors and cables in an automatic system.

ⓘ **NOTICE** Motors and cable connections shouldn't be completely submerged.

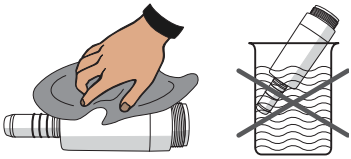
Cleaning the motor

1. Hold the motor by its nose under tap water for 1 minute at 15 – 35 °C provided that the local tap water has a pH within the range of 6.5 – 8.5 and a chloride content below 100 mg/l. If the tap water does not meet these requirements, use demineralized (deionized) water instead.
2. With the aid of a smooth flexible brush, clean the external surface of the motor using ICEPUR disinfecting cleanser with a 2 % dilution (for preparing 1 liter ready to use 2 % dilution add 20 ml ICEPUR concentrate in 1 liter drinking quality water).
3. Clean the surface of the motor thoroughly and after the cleaning process rinse the surface with tap water for at least 30 seconds.

⇒ For further conditioning, the motor shall be dry and free of residue.

Cleaning the cable

1. Clean with a cloth soaked in an appropriate product for dissolving protein and blood residues.
2. Remove the solvent or disinfectant residues with a cloth moistened in clean water.



6.2 Sterilizing

✓ The motor is cleaned.

✓ The motor sleeve is unscrewed and removed.

✓ The motor and motor sleeve can be packed in packaging suitable for sterilization and storage, for example paper/plastic composite packaging or container in accordance with ISO 11607.

↪ Sterilize the motor and its sleeve in the steam sterilizer with saturated vapor.

134°C 3min	Temperature of 134 °C $^{+3}_{-0}$ during 3 minutes for unpackaged instruments, over-pressure 2.04 bar. A drying time of 30 minutes must be respected at the end of the cycle.
135°C 18min	In jurisdictions where the Prion sterilization is mandatory, sterilize at 135 °C $^{+3}_{-0}$ during 18 minutes. A drying time of 30 minutes must be observed at the end of the cycle.

Suitable are steam sterilizers that fulfill the requirements of EN 13060, either class B or class S. Please observe the sterilizer instruction for use.

⚠ **WARNING** The motor and motor sleeve are hot. Risk of burns!

ⓘ **NOTICE** Do not attempt to accelerate the cooling process by immersing the motor in cold water. This will damage your motor.

1. Remove the motor and motor sleeve from the steam sterilizer immediately.
2. Store all motors so that they are protected from contamination.
3. If the motor is not stored in a sterilization pouch or if the pouch is no longer sterile, clean, dry and sterilize the motor before using it.

ⓘ **NOTICE** After approximately **1000 sterilization cycles** or **3 years**, it is recommended to service the motor in a facility authorized by **Dassym**.

⚠ **CAUTION** Except the sleeve, never disassemble any part of the motor! For any service or repair, please contact a facility authorized by **Dassym**.

7 Maintenance

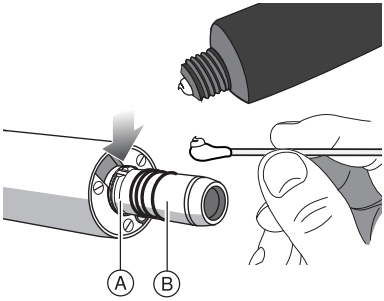
Only the motor part of the **Dassym S-60-I** medical device requires regular maintenance from the user. If the cable presents some wear, it must be replaced. The board doesn't need maintenance.

7.1 Replacing the cable

NOTICE The replacement of the cable shall be performed in accordance with the dental unit manufacturer instructions.

7.2 Lubricating the motor lock washer

The lock washer should be lubricated on a weekly schedule.



1. With a Q-tip place a fine layer of food grease on the hand-piece holder (B) and on the retainer ring (A). T1 spray may be used also.
2. Swab some grease inside the slot at the opening of the retainer ring.
3. Manually turn the retainer ring to distribute the grease.

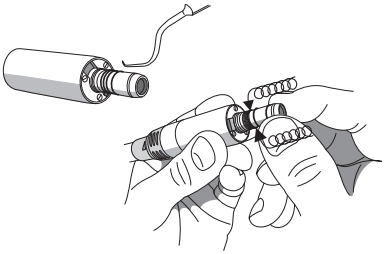
7.3 Replacing the motor O-rings

If the hand piece coupling leaks, the O-rings must be replaced.

NOTICE Do not use any sharp tools and do not stretch the new O-rings.

NOTICE Do not use Vaseline or silicone grease on the O-rings.

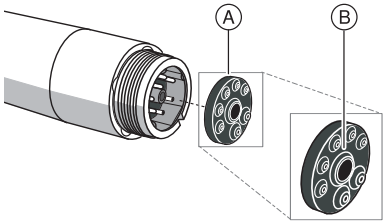
Removing/inserting O-rings



1. Remove the defective O-rings.
2. Insert the O-rings one after another. Start with the first groove.

7.4 Replacing the motor flat gasket

In case of wear or unwanted leaks, the flat gasket should be replaced.



1. Disconnect the motor from the cable.
2. Use a probe or the like to remove the defective flat gasket (B) from the rear of the motor.
3. Place a new flat gasket (A) observing the position of the contact pins and press it to the stop.

NOTICE The protruded side of the gasket must be directed towards the hose.

NOTICE **Dassym** recommends regular full service every **3 years**.

7.5 Replacing the motor lighting

NOTICE The motor lighting cannot be replaced by unqualified nor unapproved personal. Please contact your service technician or the manufacturer in case of lighting malfunction.

7.6 Servicing kit

Rubbers such as O-rings or flat washer must be replaced depending on their degree of wear.

Use only original **Dassym** parts or parts approved by **Dassym**.

Servicing kit for	Reference	Contents
MO-94-LA	151.94.010	2 × Flat gasket 4 × O-Ring Ø 8 × ø 1 2 × O-Ring Ø 17 × ø 1

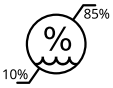
8 Storage and transport conditions

The shelf life for the **S-60-I** medical device is essentially unlimited, but after **3 years** the motor should be serviced to ensure proper function.

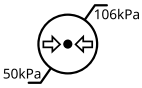
Protect from moisture

Sensitive contents

Temperature range −40 to +70 °C



Relative humidity 10 % to 85 %



Air pressure 50 to 106 kPa

9 Recycling and disposal

Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. The user must return the device to its dealer or establish direct contact with an approved body for treatment and recovery of this type of equipment (European Directive 2012/19/EU).

This equipment may also be returned directly to **Dassym** for reconditioning, recycling or disposal.

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