

# SycoTec Dental Motors

## Installation Instruction

EN

Dental motor variants:

Type SycoDrill

Type SycoSLM

Type SycoSLX



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## 1 User information

Please read the Installation Instruction carefully before installation and keep it for later use!

It is the duty of the installer/technician to comply with all applicable national and regional directives, standards and laws (for example IEC 60601-1 etc.).

The technical specifications and illustrations in this manual are not binding and cannot give rise to any complaints. The manufacturer reserves the right to make technical changes to its product at any time without adapting this manual. For further information please contact SycoTec.



All information in the Instructions for Use of the SycoTec dental motors must be observed.

### 1.1 Target group of the document

This document is intended for:

- Installers and technicians

## 2 Safety

The manufacturer does not accept any liability for damage or harm caused to the product, users, patients or third parties as a result of:

- Failure to observe the operating, repair, installation and/or assembly instructions
- The use of incorrect information
- Misuse or improper use
- Repairs by unauthorized persons
- Changes or manipulations to the product

### 2.1 Applied symbols

|  |                       |
|--|-----------------------|
|  | Manufacturer          |
|  | Important information |

### 2.2 Warning signs

Structure of warning sign

**HAZARD SYMBOL** Nature or source of hazard

Description of the nature or source of hazard and its possible consequences.

- ▶ Measures to avoid the hazard

Risk levels

**WARNING** Warning

Indicates a hazardous situation that could lead to serious or fatal injuries.

**CAUTION** Caution

Indicates a hazardous situation that could lead to minor or moderate injuries.

**ATTENTION** Attention

Indicates a hazardous situation that could lead to property damage.

## 2.3 Warnings for the installation

### **⚠ WARNING** Non-fused system

Connecting the dental motor to a third-party system which does not comply with the provisions of IEC 60601-1 and IEC 60601-1-2 may endanger persons due to e.g. electric shock, electric fields, etc.

- ▶ Connect the dental motor only to treatment units approved by the manufacturer.
- ▶ Connect the dental motor only to systems which comply with the provisions of IEC 60601-1 and IEC 60601-1-2

### **⚠ WARNING** Insufficient cooling

If the tooth is inadequately cooled with spray water and spray air during treatment, it may be damaged by heating.

- ▶ Ensure a sufficient supply of spray water and spray air according to ISO 14457 or according to the chapter Technical data of the respective dental motor.

### **ATTENTION** Contaminated compressed air

The use of contaminated compressed air for operating the dental motor (spray air and cooling air) can lead to damage or a functional failure of the dental motor, accessories and other components.

- ▶ Use clean, dry, oil-free and non-contaminated cooling air in accordance with EN ISO 7494-2

### **ATTENTION** Contaminated water

The use of contaminated water for operating the dental motor (spray water) can lead to damage or functional failure of the dental motor, accessories and other components.

- ▶ Use water that corresponds to a water quality according to ISO 7494-2 and has a pH value of 7.2 - 7.8

## 3 Intended purpose and intended use

The product is a Class IIa medical device according to the requirements of the European Medical Devices Regulation (MDR 2017/745 / MDD 93/42/EEC),

It is a sterilizable dental motor according to ISO 14457.

The product is an electric extra-low voltage motor that is controlled via a treatment unit and has a handpiece coupling according to ISO 3964.

The product is intended for dental treatment in the field of dentistry only.

The product is intended for use in the area of the oral cavity for:

- Prophylaxis (SycoDrill, SycoSLM, SycoSLX)
- Restorative (SycoDrill, SycoSLM, SycoSLX)
- Endodontic work (SycoSLM, SycoSLX)

The application for endodontic work may be limited depending on the motor control used.

The dental motor is intended for the following:

- The operation of dental handpieces with a coupling according to ISO 3964.
- The supply of light, cooling air and spray water and spray air to the handpiece.
- The connection to an approved motor hose with media and power.
- Operation on a treatment unit with an approved motor control.

For more information, see the Instructions for Use of the respective dental motor.

## 4 Installation

### Important notes and regulations on installation

- ▶ The dental motor is intended only for installation in dental treatment units.
- ▶ The conditions and specifications of the Instructions for Use must be followed.
- ▶ Observe all notes on safety and performance requirements in the Instructions for Use of all other components used with these dental motors.
- ▶ When installing or attaching to dental treatment units, observe the national regulations and laws.
- ▶ The dental motor may only be operated on a motor control with current limitation approved by the manufacturer.
- ▶ The dental motor may only be operated on a motor hose approved by the manufacturer.
- ▶ The dental motor may only be operated via a power supply in accordance with IEC 60601-1 and IEC 80601-2-60, which has 2 MOPPs in accordance with IEC 60601-1 and IEC 80601-2-60.
- ▶ The dental motor may only be operated via a motor control whose signal inputs and outputs are fused with 2 MOPPs.
- ▶ The connected dental treatment unit must have a control device for changing the speed and direction of rotation (ISO 14457).
- ▶ The device safety test according to IEC 60601-1, IEC 80601-2-60 and IEC 60601-1-2 must be performed in connection with the dental treatment units.

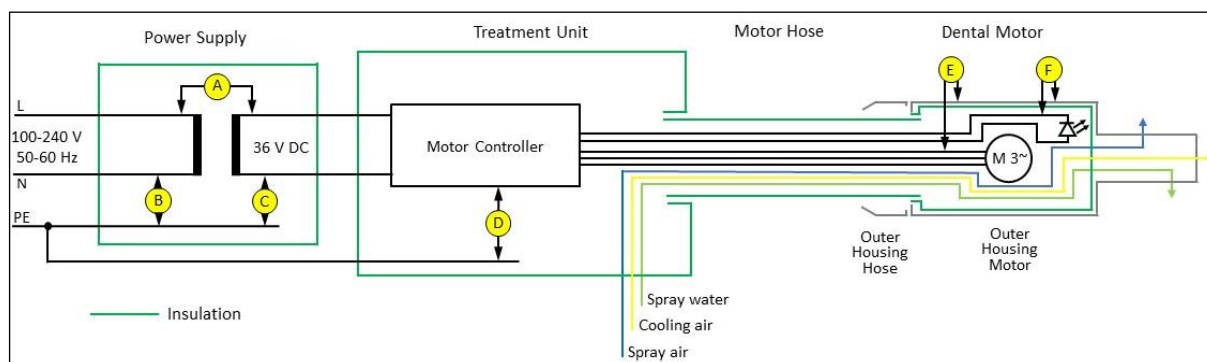
### 4.1 Isolation of the dental motor system

The dental motors including accessories and other components must be fused as shown below.

- ▶ Use only a double-insulated (2 MOPP) power supply approved for medical purposes (IEC 60601-1) without an earth connection on the secondary side!

Permissible power supplies can be obtained from the manufacturer.

#### Insulation diagram



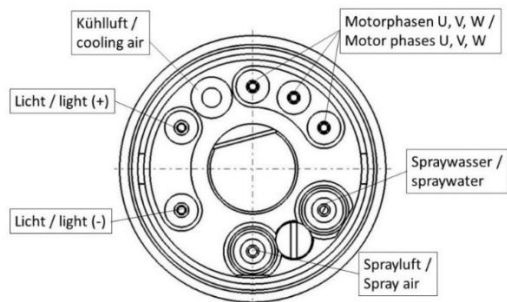
| Insulations |                               |              |   |
|-------------|-------------------------------|--------------|---|
|             | Type SycoDrill / Type SycoSLM | Type SycoSLX |   |
| A           | DI                            | DI           | Primary – secondary                     |
| B           | BI                            | BI           | Primary – protective earth              |
| C           | DI                            | DI           | Secondary – protective earth            |
| D           | DI                            | DI           | Secondary – protective earth            |
| E           | FI                            | BI           | Motor housing – phases electrical motor |
| F           | FI                            | BI           | Motor housing – LED electrical motor    |

BI = basic insulation / DI = double insulation / FI = functional insulation (tested with 500 V AC)

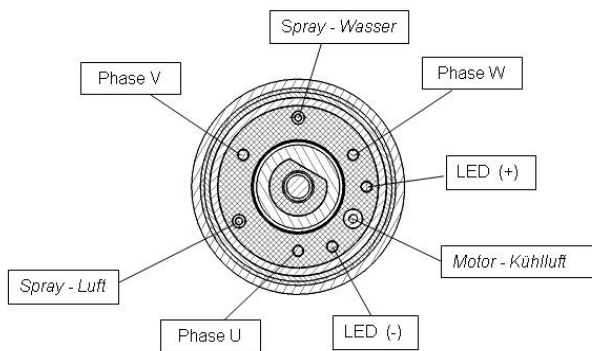
## 4.2 Dental motor connection

Each dental motor has a specific connection that corresponds to its respective motor hose.

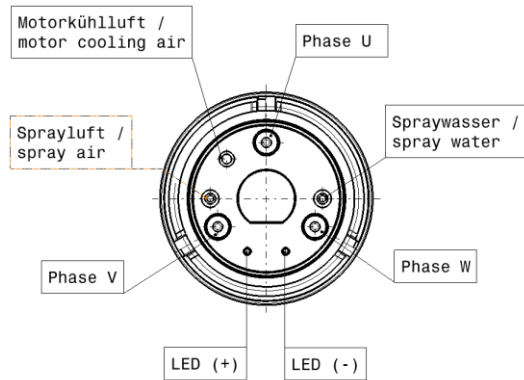
### Dental motor type SycoDrill



### Dental motor type SycoSLM



### Dental motor type SycoSLX



### 4.3 Connection Motor hose

#### Connection to approved motor controls

The dental motors or the motor hoses may only be connected to a motor control approved for the dental motor.

Below, the motor controls approved for the respective dental motor.

| Type SycoDrill  | Type SycoSLM   | Type SycoSLX  |
|---|--|---|
| <ul style="list-style-type: none"> <li>• Motor control SycoEI SD/SLM</li> </ul> | <ul style="list-style-type: none"> <li>• Motor control SycoEI SD/SLM</li> <li>• Motor control SycoMot</li> <li>• Motor control SycoInterface</li> <li>• Motor control SycoMCI</li> </ul> | <ul style="list-style-type: none"> <li>• Motor control SycoMCI</li> </ul> |

Further information on motor controls can be requested from SycoTec.

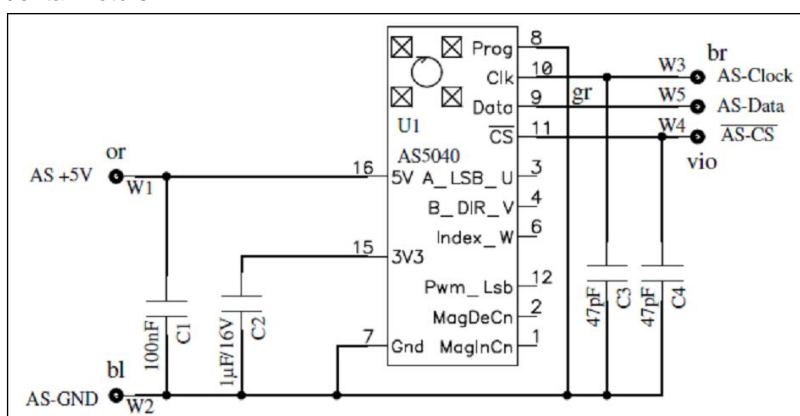
#### Motor hose connection diagram

The following are the connection diagrams for connecting the motor hoses to the motor control (stranded wires) and the water and compressed air supply (media lines).

| Assignment motor hose          |                               |                              |
|--------------------------------|-------------------------------|------------------------------|
| Stranded wires and media lines | Type SycoDrill / Type SycoSLM | Type SycoSLX                 |
| Phase U                        | ● Yellow 0,5 mm <sup>2</sup>  | ● Black 0,5 mm <sup>2</sup>  |
| Phase V                        | ● Red 0,5 mm <sup>2</sup>     | ● Red 0,5 mm <sup>2</sup>    |
| Phase W                        | ● Black 0,5 mm <sup>2</sup>   | ● Yellow 0,5 mm <sup>2</sup> |
| LED +                          | ○ White 0,25mm <sup>2</sup>   | ○ White 0,25mm <sup>2</sup>  |
| LED -                          | ● Black 0,25 mm <sup>2</sup>  | ● Black 0,25 mm <sup>2</sup> |
| Motor cooling air              | ○ Yellow                      | ○ Yellow                     |
| Spray water                    | ○ Green                       | ○ Green                      |
| Spray air                      | ○ Blue                        | ○ Blue                       |

#### Motor hose with position sensor connection diagram.

The position sensor connection diagram only applies to corresponding motor hoses of type SycoSLM and type SycoDrill dental motors.



Sensor AS5040 wire assignment

|          |        |
|----------|--------|
| AS +5V   | orange |
| AS GND   | blue   |
| AS Clock | brown  |
| AS Data  | grey   |
| AS CS    | violet |

## 5 Commissioning

The settings for the media (handpiece cooling air, spray air and spray water) must be made by an installer/technician when the dental motor is installed in the treatment unit. The settings therefore also apply to the operation of the dental motor.

The permissible values according to the Instructions for Use of the respective dental motor must be observed.

In addition, the minimum and maximum values for the media according to ISO 14457 must be observed:

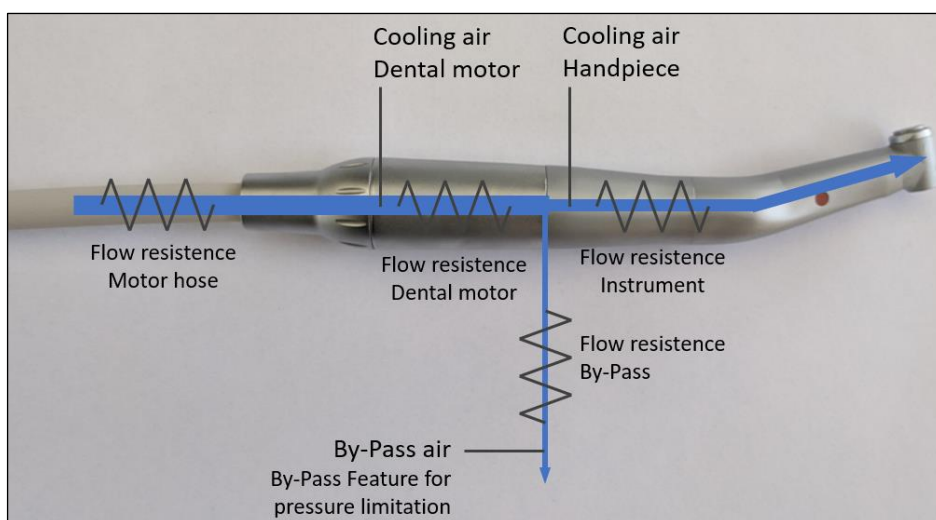
- Cooling air volume for handpiece: > 5 NI/min and < 40 NI/min
- Spray air volume: > 1.5 NI/min
- Spray water volume: > 50 ml/min

### 5.1 Setting the handpiece cooling air

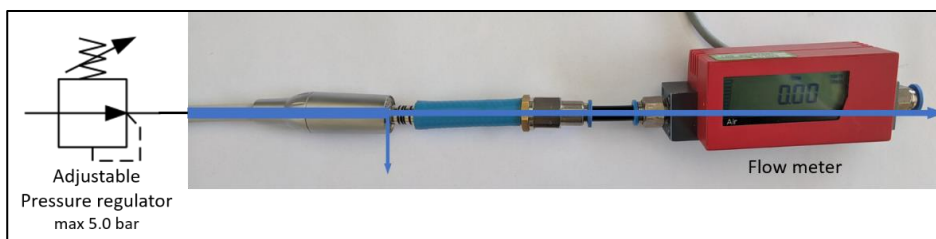
The permissible flow rates for the handpiece cooling air for the respective dental motor type can be taken from the Instructions for Use.

We recommend setting the handpiece cooling air to  $6.0 \pm 1.0$  NI/min.

Cooling air flow equivalent circuit diagram



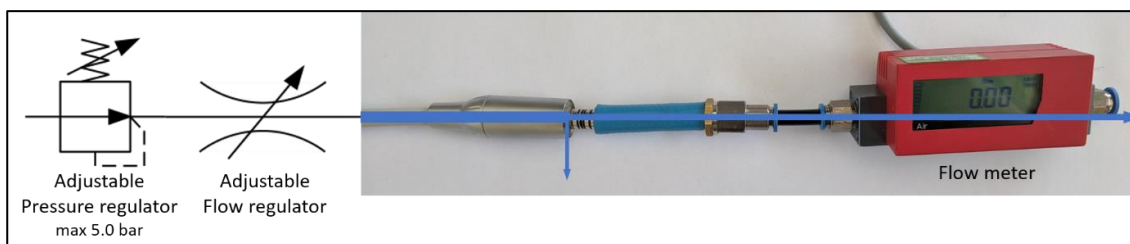
Setting handpiece cooling air with pressure regulator



The handpiece cooling air is set with an adjustable pressure regulator as follows:

- ▶ Attach the flow meter to the ISO 3964 handpiece coupling.
- ▶ Change the pressure by adjusting the pressure regulator until the desired flow rate is achieved.

Handpiece cooling air setting with pressure regulator and restrictor



The handpiece cooling air is set with a pressure regulator and an adjustable restrictor as follows:

- ▶ The upstream pressure regulator must not be set above 4.5 bar!
- ▶ Attach the flow meter to the ISO 3964 handpiece coupling.
- ▶ Change the pressure by adjusting the restrictor until the desired flow rate is achieved.



## 5.2 Spray adjustment

Spray water and spray air must be adjusted so that a spray mist is formed.

The minimum flow rates according to ISO 14457 must be observed.

The pressure of the spray water and spray air is measured at the supply side of the motor line.

### Setting the spray air

Set the spray air pressure according to the specifications in the respective dental motor Instructions for Use.

The spray air pressure must therefore be set between 1.0 and 2.5 bar.

### Setting the spray water

Set the spray water pressure according to the information in the relevant dental motor Instructions for Use.

The spray water pressure must therefore be set between 0.8 and 2.0 bar.

## 6 Safety check

The following safety checks according to EN 62353 are provided for this medical device:

- ▶ The dental motor together with motor cable and motor control must be tested together with the dental treatment unit.
- ▶ The test interval is 24 months

The following checks must be carried out.

- ▶ Check the motor and motor cable for damage
- ▶ Presence of the Instructions for Use
- ▶ Leakage current test according to IEC 60601-1
- ▶ Faultless functioning of the components

All results of the safety test must be documented in the medical devices book.

Products with damage that may cause danger to patients, users or third parties must not be used any longer. The defective parts must be professionally repaired or replaced.

## 7 Technical data

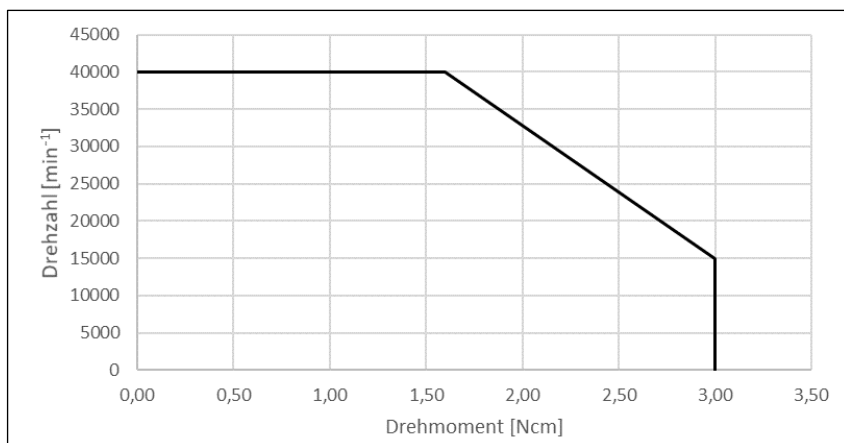
### Electrical data

|  | Type SycoDrill | Type SycoSLM   | Type SycoSLX   |
|--|----------------|----------------|----------------|
| Rated voltage                            | 22.0 V         | 22.0 V         | 22.0 V         |
| Max. speed                               | 40,000 rpm     | 40,000 rpm     | 40,000 rpm     |
| Max. torque                              | 3.0 Ncm (-10%) | 3.0 Ncm (-10%) | 3.0 Ncm (-10%) |
| Generator voltage (EMF)<br>at 40,000 rpm | 12.9 V         | 15.6 V         | 15.2 V         |
| Torque constant                          | 0.53 Ncm/A     | 0.64 Ncm/A     | 0.62 Ncm/A     |
| Resistance Ph-Ph                         | 1.45 Ohm       | 1.31 Ohm       | 1.61 Ohm       |

|         | Type SycoDrill          | Type SycoSLM | Type SycoSLX |
|---------|-------------------------|--------------|--------------|
| Torque: | Maximum operating time* |              |              |
| 0.6 Ncm | unlimited               | unlimited    | unlimited    |
| 1.0 Ncm | 100 s                   | 120 s        | unbegrenzt   |
| 2.0 Ncm | 10 s                    | 10 s         | 15 s         |
| 3.0 Ncm | 4 s                     | 4 s          | 6 s          |

\*maximum operating time at a continuous torque before the temperature management of the motor control reduces the torque. Operating times refer to a cold dental motor with normal cooling air supply of 6 NI/min. Operating times may vary depending on the motor control used.

## Speed/torque characteristic curve of the dental motors



Characteristic may vary depending on motor control and power supply used.

## Classification according to IEC 60601-1

|                      |        |  |
|----------------------|--------|--|
| Applied part (Class) | Type B | Class of the applied part must be attached to the treatment unit when installing the dental motor. |
| Protection class     | II     |  |

## Requirements for the place of operation:

|                     |                            |
|---------------------|----------------------------|
| Place of operation  | Permitted in indoor spaces |
| Ambient temperature | 10 – 35°C (50 – 95°F)      |
| Relative humidity   | 30 – 75%, non condensing   |
| Max. altitude       | 2,000 m                    |
| Ambient pressure    | 700 hPa – 1,060 hPa        |

## Further technical data

See Instructions for Use of the respective dental motor.