



Instructions for use

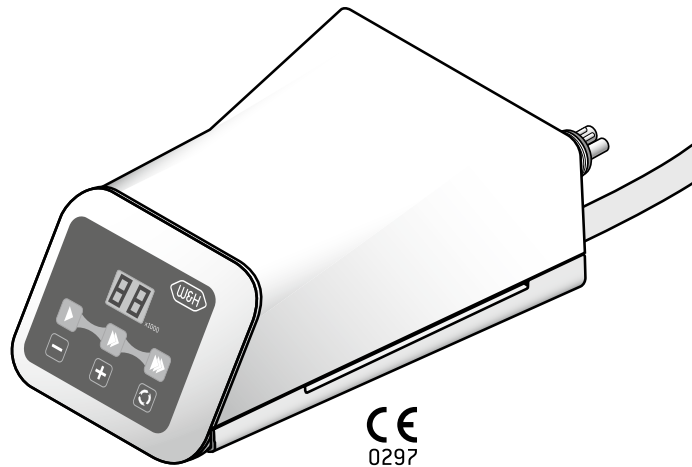


Table-Top Control
EM-E6 TP

Contents

W&H Symbols	3
1. Introduction	4 – 5
2. Equipment supplied	6
3. Safety notes	7 – 8
4. Description of front panel / Display	9
5. Description of rear panel	10
6. Starting operation – General	11
7. Control unit operation	12 – 13
8. Hygienic maintenance	14
9. W&H Accessories	15
10. Service	16
11. Technical data	17 – 18
12. Recycling and Disposal	19
Letter of indemnity	21
Authorized W&H service partner	23

W&H Symbols

Symbols in the Instructions for use



WARNING!
(Risk of injury)



ATTENTION!
(To prevent damage occurring)



General explanations, without risk to persons or objects

Only for USA

Caution: Federal law restricts this device to sale by or on the order of a dentist, physician or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of the device.

Symbols on the control unit (rear panel)



Consult Instructions for use



Do not dispose of with domestic waste

REF Catalogue number



Date of manufacture



Data Matrix Code, for product identification e.g. in hygienic maintenance process

SN Serial number



Not suitable for intracardiac application – Type B appliance



Classification mark, that this product is in compliance with the American and Canadian safety requirements

rpm Revolutions per minute

1. Introduction



For your safety and the safety of your patients

These Instructions for use explain how to use your W&H product. Please read and follow the advice herein to avoid potentially hazardous situations. Your safety and the safety of your team and your patients are of paramount importance to us.



It is therefore essential to read the safety notes on Pages 7 to 8.

Intended use


Control unit with light supply connecting the dental unit and electric motor. Motor can be operated in two rotary directions, with speed ranges which can be set by the user.

Misuse can damage the control unit and involves risk and danger to the user and third parties.

Skilled application


The control unit is intended only for skilled application in the dental or medical field according to its purpose of use in compliance with the valid health and safety at work regulations, the valid accident prevention regulations as well as in compliance with these Instructions for use. The control unit should be maintained according to the manufacturer's recommendations and in line with infection control procedures for the safety and well-being of patients. Improper use, e.g. poor hygienic maintenance, non-compliance with our Instructions or the use of accessories and spare parts which are not approved by W&H, invalidates all claims under warranty and any other claims.

Introduction


 **Production according to EU-Directive**
0297 EU Directive 93/42/EEC has been used as a basis in the design and manufacture of this medical product and this applies to the control unit

> **EM-E6 TP**

in the condition as supplied by W&H. This declaration does not apply to unapproved fixtures, mountings etc.

 **Responsibility of the manufacturer**
The manufacturer can only accept responsibility for the safety, reliability and performance of the control unit when there is compliance with the following directions:

- > The control unit must be used in accordance with these Instructions for use.
- > The control unit has no components which can be repaired by the user. Assembly, modifications or repairs must only be undertaken by an authorized W&H service partner (see page 23).
- > The electrical installation at the premises must comply with the regulations of ÖVE-EN 7 (»Installation of electrical equipment in rooms used for medical purposes«) or with the regulations applicable in your country.

 **HF communication equipment**
Do not use any portable and mobile HF communication equipment (e.g. mobile telephones) during operation. These may affect medical electrical equipment.

2. Equipment supplied

Content of set EM-E6 TP

REF 10531600

- Transformer REF 04479500
- Mains cable REF 01343700 (Europa)

Optional:

W&H Electric motor EM-E6

W&H Instruments

3. Safety notes



Please ensure that you carry out the following instructions

- > Only use the power supply Globtek GT-500160-30 B for the control unit.
- > Only connect the mains cable to a grounded socket outlet.
- > The control unit is not provided with holder monitoring; this function must be provided by the dental unit manufacturer.
[When the motor is in the handpiece holder, the drive air must be disabled.]
- > Always ensure the correct operating conditions and cooling function.
- > Check the control unit for damage and loose parts prior to use.
- > Check that sufficient air and water coolants are supplied.



Inappropriate use

Improper use, in addition to incorrect assembly, installation, modification or repairs of the control unit or non-compliance with our instructions invalidates all claims under warranty and any other claims.

Cardiac pacemaker function

Use of this device generates magnetic fields. Measured levels of field intensity are below the threshold limit for interference according to EN 50061 Ad1. Even under adverse conditions, there is no likelihood of serious harm to the patient.

Intermittent operation mode S6 (2 min / 3 min)

The permissible relative load time is 2 minutes to 3 minutes idle time.

Safety notes



According to IEC 60601-1 / UL 60601-1, the control unit must not be used in potentially explosive atmospheres or in potentially explosive mixtures of anesthetics with air, oxygen or nitrous oxide, or at locations where concentrations of such gases could occur (closed rooms).

Control unit

The control unit is classified as »conventional equipment« (closed equipment without protection against the ingress of water).



The control unit should only be used with the W&H electric motor EM-E6. The use of other dental motors could lead to electrical damage and/or injury to patients or operators.

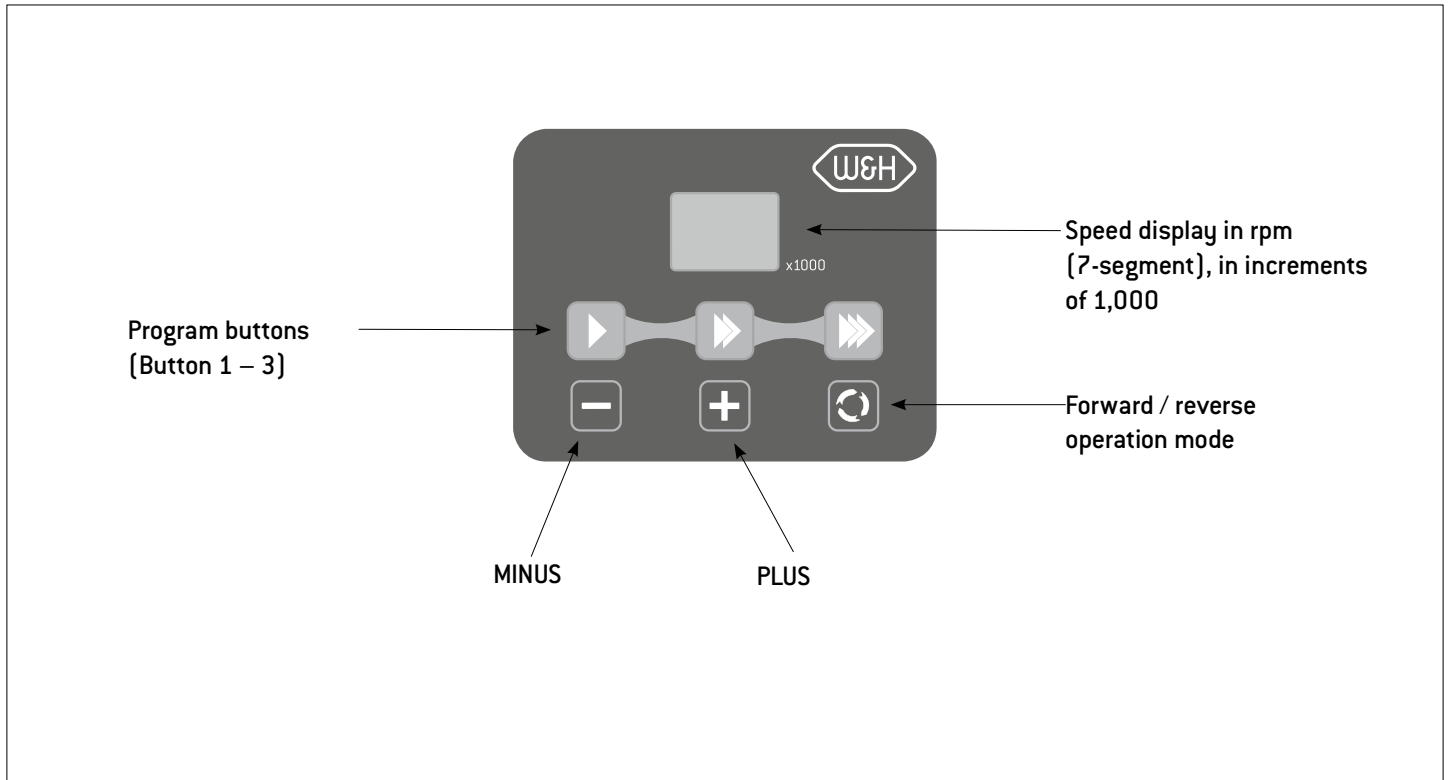
Power failure

If the power supply fails or the control unit is shut off, or when switching between the programs 1 to 3, the last settings saved will be activated in the forward operating mode.

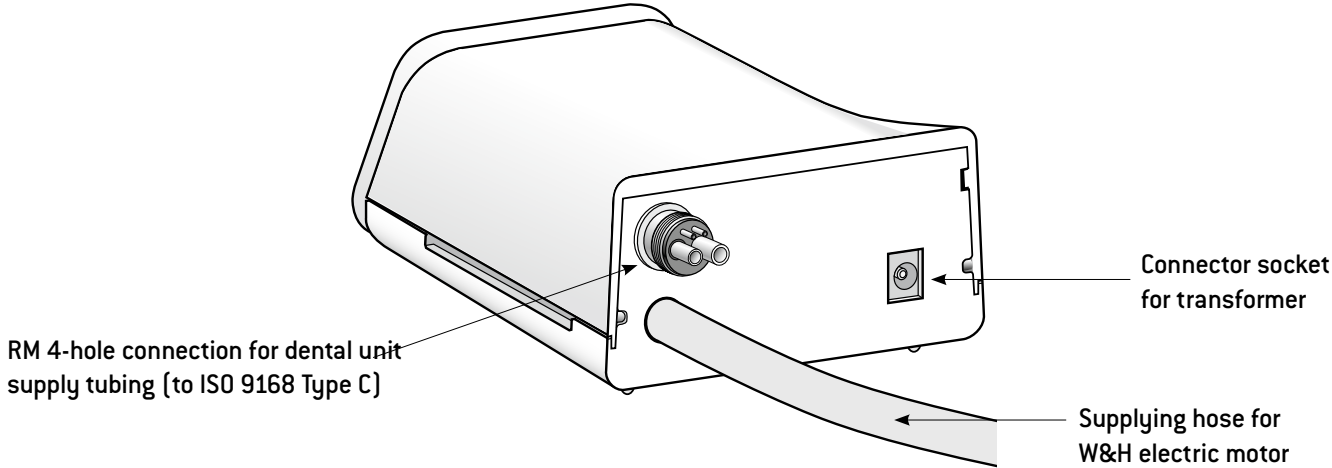
System failure

A total system failure does not constitute a critical fault.

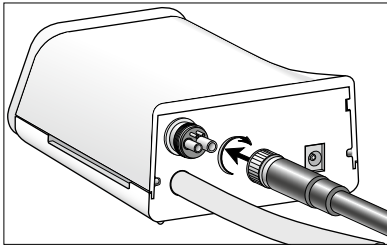
4. Description of front panel / Display



5. Description of rear panel



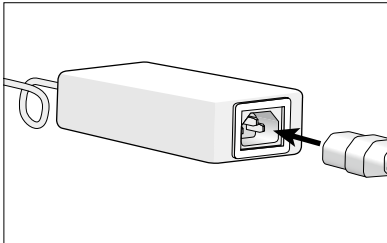
6. Starting operation – General



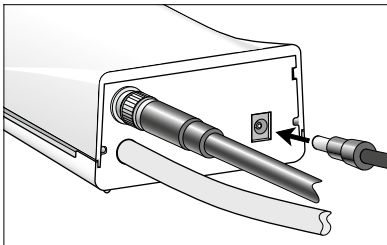
Screw on tubing of the dental unit. (ISO 9168 Type C)

Pressure settings, see Page 17.

Using W&H electric motor:
> EM-E6



Mains cable with the power pack stick on.








Connect power supply.


7. Control unit operation – Factory settings

When the display is switched on, a two-second LED test is performed, in which all bars of the two 7-segment displays (88) as well as the LEDs in the program buttons light up. The last values saved during forward running (program and speed) are activated.

All the programs shown below are factory settings.

-  **Program 1 – Display 2**
2,000 rpm, forward running, adjustable from 2,000 to 40,000 rpm
-  **Program 2 – Display 20**
20,000 rpm, forward running, adjustable from 2,000 to 40,000 rpm
-  **Program 3 – Display 36**
36,000 rpm, forward running, adjustable from 2,000 to 40,000 rpm

-  **PLUS / MINUS buttons**
These buttons increase or reduce the speed. Holding down these buttons actuates the repeat function and the speed is continuously increased or decreased in steps of 1000.
- 

-  This button switches over from forward to reverse running.

Control unit operation – Changing speed, program



Speeds between 2,000 and 40,000 rpm can be selected and/or saved.



① Press any program button



② Increase speed



③ Reduce speed




④ You can save the changed speed by holding the program button selected for 1.5 sec.



You can return to the factory settings at any time by:

- > holding down all 3 program buttons simultaneously until the display shows »- -«
- > holding down the program buttons for a further 3 sec. until the display shows »FS«
- > you can then release the buttons and the factory settings will reappear

8. Hygienic maintenance


 Follow your country-specific directives, standards and guidelines for cleaning and disinfection.

-  > Wear protective clothing.
> Clean and disinfect the control unit **immediately after every treatment!**


Control unit

Pre-disinfection

> If heavily soiled: Clean first with disinfectant cloths.

 Only use disinfectants that have no protein fixing effects.

Manual cleaning and disinfection


 The display of the control unit is sealed and may be wiped clean.

> Disinfection with disinfectants, wiping disinfection is recommended.

> Use only disinfectants which do not contain chlorine and which are certified by officially recognized institutes.

For USA: Use EPA registered surface disinfectants.

> Note the manufacturer's specifications for the use of the disinfectants.

 **Before starting operation again**
Wait until the control unit is completely dry.

Moisture in the plug can lead to a malfunction! (Risk of short circuit)

9. W&H Accessories

Use only original W&H accessories/spare parts
or accessories approved by W&H

Accessories and spare parts

10530601	Electric motor EM-E6
04479500	Transformer
01343700	Mains cable (Europa)

10. Service



Regular checkup of control unit

Regular servicing of function and safety is necessary and must be carried out at least once every three years, unless shorter intervals are prescribed by law. Checking must be carried out by a person/organization qualified to do so and must include the following steps as a minimum:

- > External visual inspection and a check on changes relevant to safety
- > Measurement of leakage current
- > Visual inspection of internal components and electronic boards on suspicion of a safety hazard, e. g. mechanical damage on the housing or signs of overheated or burned (electronic) components
- > Check whether the power supply unit is being used as prescribed.

We recommend that this checkup should be performed by an authorized W&H service partner (see page 23) or by the unit manufacturer only.

11. Technical data

EM-E6 TP

Rated voltage:	30 VDC
Rated current:	≈ 2 A
Fuse (F1):	5A T in the unit
Operating mode:	S6 (2min/3min)
Dimensions in mm (WxDxH):	100 x 160 x 58

Connection for supply ISO 9168 Type C

Drive air pressure:	0 – 350 kPa* (Switch-on threshold of the motor is approx. 100 kPa)
Water pressure:	50 – 300 kPa*
Chip air pressure:	50 – 300 kPa*

* 100 kPa = 1 bar

Classification according to § 5 of the General Specifications for the Safety of Medical Electrical Equipment according to IEC 60601-1 / UL 60601-1



Type B appliance (not suitable for intracardiac application)

Technical data

Physical characteristics

Temperature in storage:

-40 °C (-40 °F) to +70 °C (+158 °F)

Air humidity in storage:

8 % to 80 % [relative], non-condensing at +40 °C (+104 °F)

Temperature in operation:

+10 °C (+50 °F) to +40 °C (+104 °F)

Air humidity in operation:

+15 % to +80 % [relative], non-condensing at +40 °C (+104 °F)

Altitude:

up to 3,000 m above sea level

12. Recycling and Disposal

Recycling

W&H considers that it has a special duty towards the environment. The control unit along with its packaging has been designed to be as environmentally friendly as possible.



Disposal of the control unit

Follow your country-specific laws, directives, standards and guidelines for the disposal of used electrical devices.



Ensure that the control unit is not contaminated when disposing of it.

Disposal of the packaging material

All packaging materials have been selected according to environmentally compatible and disposal aspects and can be recycled. Please send old packaging materials to the relevant collection and reprocessing system. In this way, you will contribute to the recycling of raw materials and the avoidance of waste.

Letter of indemnity

This W&H product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee faultless operation. Please note that claims under warranty can only be validated when all the directions in the Instructions for use have been followed.

As manufacturer, W&H is liable for material or manufacturing defects within a warranty period of 12 months from the date of purchase.

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by W&H!

Claims under warranty – accompanied by proof of purchase – must be sent to the vendor or to an authorized W&H service partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

12 months warranty

Authorized W&H service partner

Find you nearest W&H service partner at <http://wh.com>

Simply go to the menu option »Service« for full details. Alternatively please contact:

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