PEOPLE HAVE PRIORITY

Instructions for Use

Display

D-2.0

(Optional in combination with Piezo scaler Built-in)

Contents

Symbols in the Instructions for use

WARNING!
(risk of injury)

ATTENTION!
(in cases where something could be damaged)

General explanations, without risk to persons or property

Symbols on the product


Consult instructions for use

Catalogue number


DataMatrix Code for product information including UDI (Unique Device Identification)


Follow instructions for use

Serial number


Date of manufacture


Do not dispose of with domestic waste

Supply voltage of the device

UL Component Recognition Mark indicates compliance with Canadian and U.S. requirements


Electrostatic sensitive devices


Manufacturer

Symbols on the packaging

This way up

Fragile, handle with care

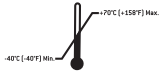
Keep dry

»Der Grüne Punkt« (The Green Dot)
trademark of Duales
System Deutschland GmbH

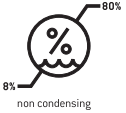
Trademark of RESY OfW GmbH for
identification of recyclable
transport and outer packaging
of paper and cardboard

DataMatrix Code
for product information including UDI
(Unique Device Identification)

Data structure in accordance with
Health Industry Bar Code



Permitted
temperature range



Humidity,
Limitation

Caution! According to Federal law restricts this device to sale by or on the order of a physician, dentist, veterinarian or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.

1. Introduction

For your safety and the safety of your patients
These Instructions for use explain how to use your device. However, we must also warn against possible hazardous situations. Your safety, the safety of your team and, of course, the safety of your patients are of paramount importance to us.

Observe the safety notes on pages 10 to 12.

Intended use
Component for displaying and setting parameters for controlling devices.

Misuse may damage the device and hence cause risks and hazards for patient, user and third parties.

Qualifications of the user
We have based our development and design of the device on the dentists, dental hygienists, dental employees (prophylaxis) and dental assistants target group.

1. Introduction

Responsibility of the manufacturer
The manufacturer can only accept responsibility for the safety, reliability and performance of the device when it is used in compliance with the following directions:

> The device must be used in accordance with these Instructions for use.
> The device has no components that can be repaired by the user. Assembly, modifications or repairs must only be undertaken by an authorised W&H service partner (page 33).
> The electrical installation at the premises must comply with the regulations laid out in IEC 60364-7-710 (»Installation of electrical equipment in rooms used for medical purposes«) or with the regulations applicable in your country.
> Unauthorised opening of the equipment invalidates all claims under warranty and any other claims.

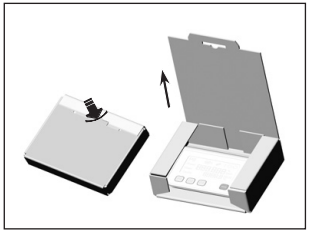
2. Electromagnetic compatibility (EMC)

Medical electrical equipment is subject to particular precautions with regards to EMC and must be installed and put into operation in accordance with the EMC notes included.

W&H guarantees the compliance of the device with the EMC requirements only when used with original W&H accessories and spare parts. The use of accessories and spare parts not approved by W&H can lead to an increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.

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

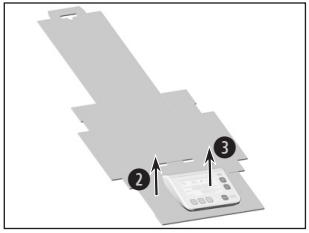
3. Unpacking



❶ Open the packaging.

W&H packaging is environmentally friendly and can be disposed of by industrial recycling companies.

However, we recommend that you keep the original packaging.



❷ Remove the foil.
❸ Remove the display with cable.

4. Scope of delivery

REF 30243000	**D-2.0 Display**
	(Optional in combination with Piezo scaler Built-in)

5. Safety notes

> Before using the device for the first time, store it at room temperature for 24 hours.
> Check the device with cable for damage and loose parts each time before using.
Correct any faults or refer to an authorised W&H service partner (see page 33).
> Check the settings every time the device is restarted.
> Do not operate the device if it is damaged.

> Operation is only permitted on dental units that conform to the IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2) standards.

Inappropriate use
In addition to unauthorised assembly, installation, modification or repairs to the device and non-compliance with our instructions, invalidates all claims under warranty and any other claims.

Device
The device is classed as »conventional equipment« closed equipment without protection against the ingress of water).

5. Safety notes

Danger zones M and G
In accordance with IEC 60601-1 / ANSI/AAMI ES 60601-1, the device is not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.

The device is not suitable for use in oxygen-enriched atmospheres.

Zone M, also referred to as the »medical environment«, includes the part of a room in which potentially explosive atmospheres may occur as a result of the use of analgesics or medical skin cleaning or disinfectant agents, but only in small quantities and only for a short time.
Zone M comprises a truncated pyramid below the operating table which is tilted outwards at a 30° angle.

Zone G, also referred to as an »enclosed medical gas system«, comprises not necessarily fully enclosed cavities in which permanent or temporary potentially explosive mixtures may be generated, supplied or used in small quantities.

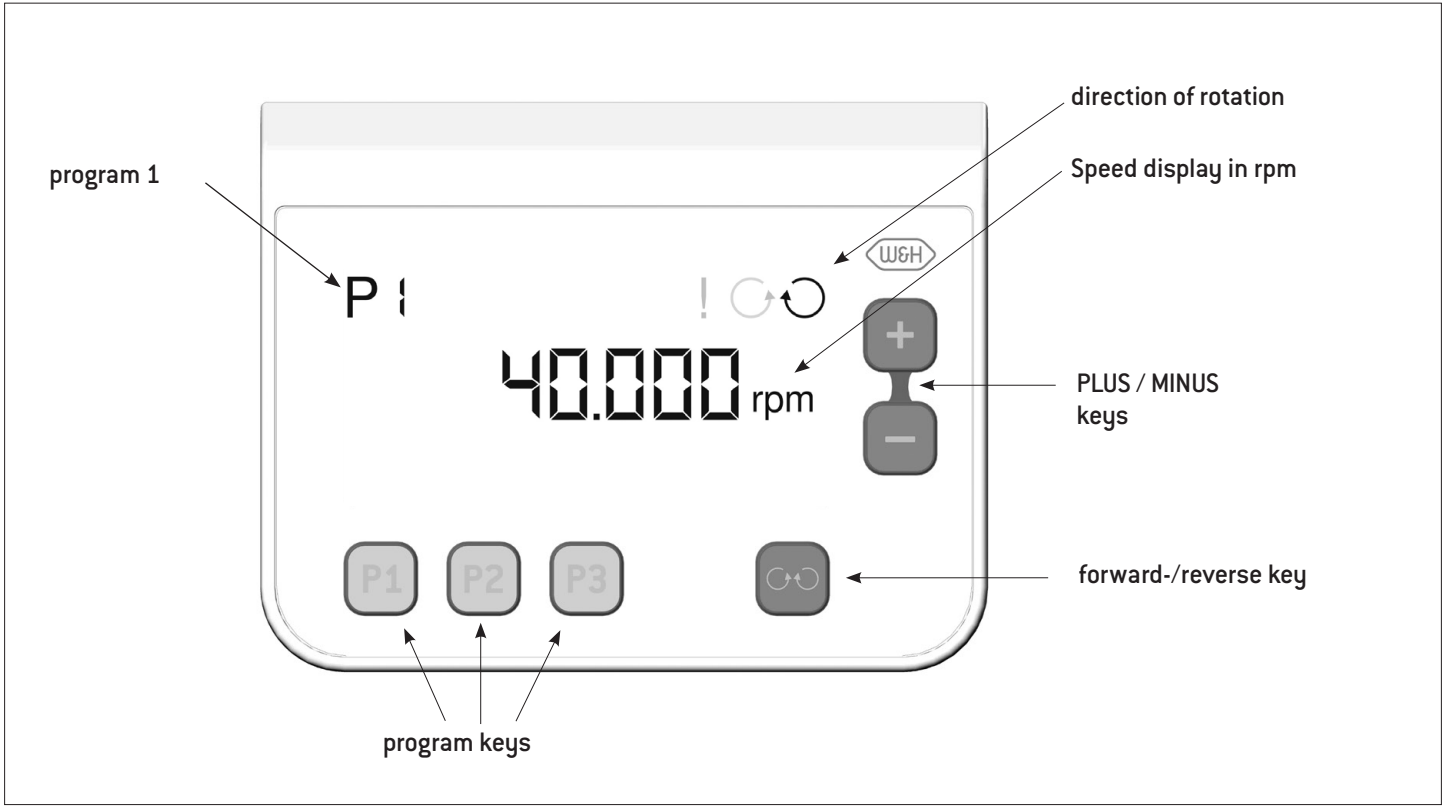
5. Safety notes

Risks due to electromagnetic fields

The functionality of implantable systems, such as cardiac pacemakers and implantable cardioverter defibrillator (ICD) can be affected by electric, magnetic and electromagnetic fields.

> Find out if patient and user have implanted systems before using the device and consider the application.
> Weigh the risks and benefits.
> Keep the device away from implanted systems.
> Make appropriate emergency provisions and take immediate action on any signs of ill-health.
> Symptoms such as raised heartbeat, irregular pulse and dizziness can be signs of a problem with a cardiac pacemaker or ICD.

6. Overview of the front electric motor display



7. Factory settings electric motor

Program 1 – Display shows P1:
Forward drive 40,000 rpm

Program 2 – Display shows P2:
Forward drive 20,000 rpm

Program 3 – Display shows P3:
Forward drive 2,000 rpm

The display shows the speed of the motor.

Note the transmission / reduction ratio of the transmission instrument.
> The speed of the instrument (e. g. rotary instrument) depends on the transmission instrument used.

PLUS key

Increase speed, maximum 40,000 rpm, possible during use

MINUS key

Reduce speed, minimum 2,000 rpm, possible during use

Forward/reverse operation key

Changing from forward to reverse operation, not possible during use

8. Operation – Changing / saving speed electric motor

The speed can be set at P1, P2, P3 from minimum 2,000 rpm to maximum 40,000 rpm.

❶ Press the program key (P1, P2 or P3).

❷ Increase speed

❸ Reduce speed

❹ Press the program key (P1, P2 or P3) for approximately 2 seconds to save.

The set values flash and an acoustic signal is emitted to confirm that all the settings have been saved.

9. Operation – Changing from forward to reverse operation electric motor

Factory setting = Forward operation

❶ Press the forward/reverse operation key.

»!« and ↻ appear on the display and an acoustic signal is emitted.
»!« and ↻ flash continuously.

An acoustic signal is emitted three times in succession before the motor is started in reverse operation via the foot control.

❷ Press program key (P1, P2 oder P3) for approximately 2 seconds to save.

If the program settings are not saved in reverse operation, the device will switch back to forward operation automatically when you change programs.

10. Operation – General set-up menu

You can return to the set-up menu from any program by pressing on the PLUS and MINUS keys at the same time.

❶ PLUS and MINUS keys simultaneously for approximately 3 seconds.
»Setup« appears on the display.

❷ Press program key P1 to navigate in the set-up menu.

❸ Press the PLUS / MINUS key to change the settings in the respective set-up menu item.

❹ Press program key P1 for approximately 2 seconds to save.

The set values flash and an acoustic signal is emitted to confirm that all the settings have been saved.

11. Operation – Back to original program

Press the PLUS and MINUS keys simultaneously for approximately 3 seconds to exit the set-up menu.

The original program appears on the display.

12. Reset factory settings

Press program keys P1, P2 and P3 simultaneously for approximately 3 seconds (see page 16).

13. Operation – Set-up menu

»Pedal«

> Pedal: ON/OFF
> Pedal STEP: variable from 2,000 rpm to value set (maximum 40,000 rpm)
Piezo Scaler: power variable from 1 to maximum 40

»Sound«

> Sound: ON
> Sound: OFF

»Speed«

> rpm = absolute speed in rpm
> % = speed displayed as a percentage
P1 100 %
P2 50 %
P 3 5 %

Speed rpm	%
40.000	100 %
30.000	75 %
20.000	50 %
10.000	25 %
4.000	10 %
2.000	5 %

»LED«

> Setting for fade-out time: from 0 to maximum 60 seconds
Factory setting = 5 seconds

14. Standby mode

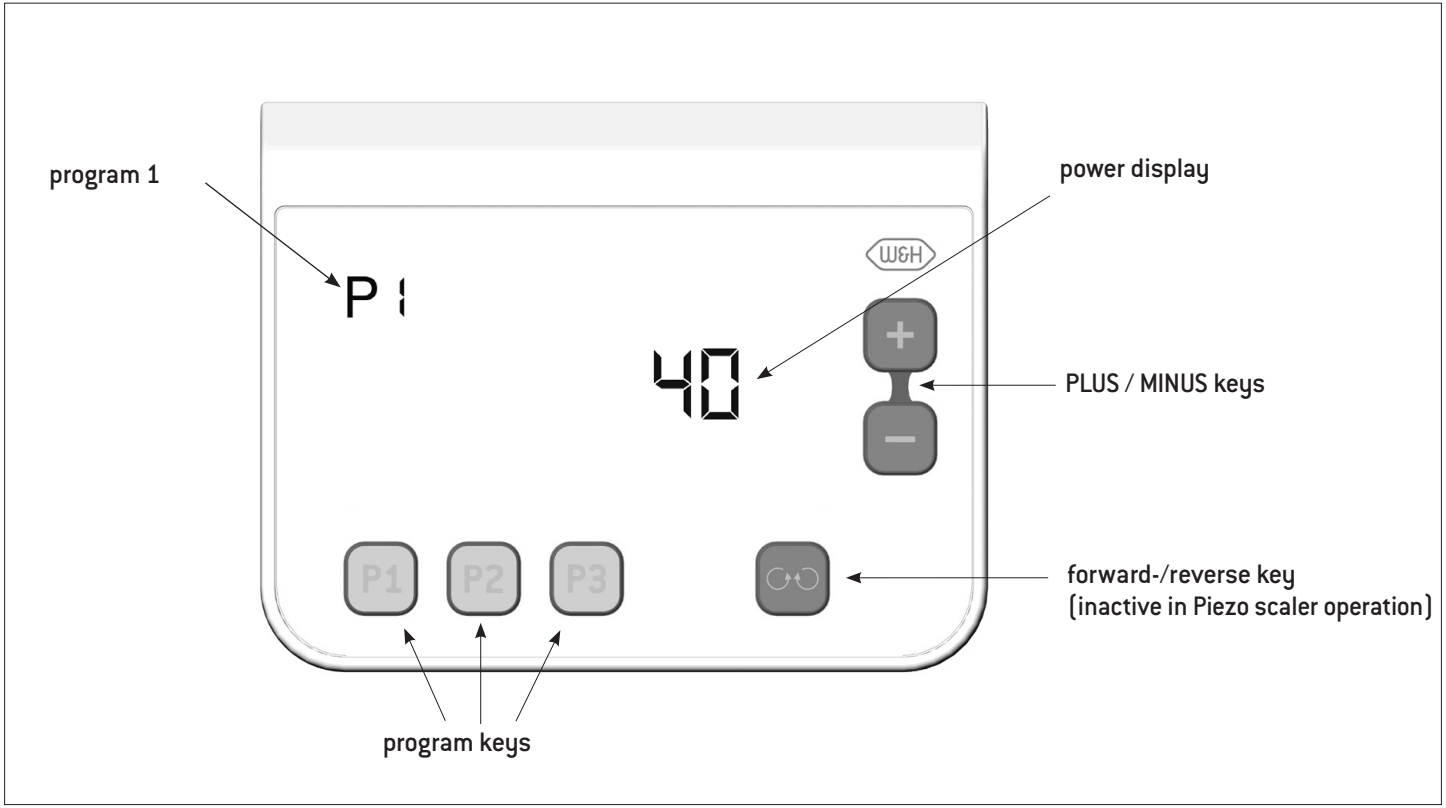
The standby mode is automatically activated after 3 minutes.
> You can exit standby mode by actuating the foot control or pressing the keys.

15. Error messages electric motor/ Piezo Scaler

Display	Description of error	Solutions
Error 1	Overheating / overloading of electronics	> ❶ Disconnect device from power supply ❷ Wait 5 minutes and allow the system to cool ❸ Switch the device back on again and restart the function
Error 2	Pedal of the foot control pressed during switching on	> Do not press the pedal of the foot control
Error 4	Display keys pressed during switching on	> Do not press the display keys
Error 5	Running time limiter as a result of 15 minutes of continuous operation	> Check the pedal of the foot control > Do not press the pedal of the foot control any more (release completely)
Error 6	Error with »Electric motor / Piezo scaler«	> ❶ Check that electric motor is correctly attached to the supply hose coupling > ❷ Electric motor / replace tip
Reboot		> Switch the power supply off and on again > Restart system
Error	z. B.: 05 6303	> Contact an authorised W&H service partner immediately (see page 33).

If the error messages described cannot be resolved a check by an authorised W&H service partner is required (see page 33).

16. Overview of the front Piezo scaler display



17. Factory settings / keys Piezo scaler

Program 1 – Display shows P1:
30

Program 2 – Display shows P2:
20

Program 3 – Display shows P3:
15

The display shows the speed of the scaler.

PLUS key Increase power, maximum 40, possible during use

MINUS key Reduce power, minimum 1, possible during use

By holding PLUS / MINUS key the values are continuously increased / decreased

Forward/reverse operation key (inactive in Piezo scaler operation)

18. Operation – Changing / saving the power Piezo scaler

The power can be set at P1, P2, P3 from minimum 1 to maximum 40.

❶ Press the program key (P1, P2 or P3).

❷ Increase speed

❸ Reduce speed

❹ Press the program key (P1, P2 or P3) for approximately 2 seconds to save.

The set values flash and an acoustic signal is emitted to confirm that all the settings have been saved.

19. Hygiene and maintenance

Follow your local and national laws, directives, standards and guidelines for cleaning and disinfection.

> Wear protective clothing.
> Clean and disinfect the device **immediately after every treatment.**

> The device is not approved for mechanical cleaning (thermo washer disinfector) and sterilization.
> Do not immerse the device in water or clean it under running water.

Pre-disinfection

> If heavily soiled, clean first with disinfectant cloths.

Only use disinfectants that have no protein-fixing effects.

> Use only disinfectants which do not contain chlorine and which are certified by officially recognized institutes.
> Note the manufacturer's specifications for the use of the disinfectants.

Before resuming operation
Wait until the device is completely dry.
Moisture in the plug can lead to a malfunction! (Risk of short circuit).

Do not twist or kink the cable! Do not coil it too tightly!

20. Service

Regular checking
Regular servicing including the accessories is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law.
The inspection must be undertaken by a qualified organisation and must include the following procedures:

> Visual inspection for external damage
> Check for any changes which could jeopardise safety
> Measurement of the device leakage current
> Measurement of the patient leakage current
> Visual inspection of internal components on suspicion of safety interference, , mechanical damage of the enclosure or indicators of overheating
> Check of whether the correct power supply unit is being used

The regular service must only be performed by an authorised W&H service partner (see page 33).

Repair
If a defect occurs, always return all the equipment, as it is also necessary to inspect all of the control electronics!

Returns
> Refer all questions to an authorized W&H service partner (see page 33).
> Always return equipment in the original packaging!
> Do not coil the cable around the display and do not kink the cable! (Risk of damage)

21. Technical data

Model:	D-2.0
Power supply:	5 V DC ± 10%, from W&H Controller ⎓
Power consumption:	1,5 VA
Dimensions in mm (WxDxH):	155,5 x 29 x 122
Weight:	280 g

Ambient conditions

Temperature during storage and transport:	-40 °C to +70 °C (-40°F to +158°F)
Humidity during storage and transport:	8% to 80% (relative), non-condensing
Temperature during operation:	+10 °C to +35 °C (+50°F to +95°F)
Humidity during operation:	15% to 80% (relative), non-condensing
Permitted ambient pressure:	70 – 106 kPa
Pollution level:	2
Overvoltage category:	II
Altitude:	up to 3,000 m above sea leve

Classification according to Paragraph 6 of the General Specifications for the Safety of Medical Electrical Equipment according to IEC 60601-1 / ANSI/AAMI ES 60601-1

22. Disposal

Ensure that the parts are not contaminated on disposal.

Follow your local and national laws, directives, standards and guidelines for disposal.
> Waste electrical equipment
> Packaging

Explanation of warranty terms

This W&H device has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantees 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 the manufacturer, W&H is liable for material or manufacturing defects within a warranty period of 24 months from the date of purchase. Accessories and consumables (RM seal) are excluded from the warranty.

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.

24 months warranty

Authorised service partners

Please contact the appropriate dental unit manufacturer or its authorized service partner network.

Manufacturer

W&H Dentalwerk Bürmoos GmbH
Ignaz-Glaser-Straße 53, 5111 Bürmoos, **Austria**

t +43 6274 6236-0, **f** +43 6274 6236-55
office@wh.com **wh.com**

Form-Nr. 50895 AEN
Rev. 001 / 19.05.2020
Subject to alterations