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 0JL7001

TT BIO

Thor 700 +

Electric Handpiece System Operating Instructions

電動手機系統操作說明書

1. Important information

English

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.
The operating instructions should be read by the user before starting up the unit for the first time in order to avoid incorrect operation or damage. Duplication and /or distribution of these operating instructions requires the manufacturer's prior consent.

■ Packing List

Thor 700+

- Thor 700+ System unit
- Operating instructions
- P812 Dental drive device
- Power supply AC 100~240 V
- Power supply cord set
- Mounting bracket

Thor 700i+

- Thor 700i+ Operation unit
- Control tube
- 24 AC cable
- P812 Dental drive device
- Solenoid valve
- Operating instructions
- Disply panel
- Cross-type hose barb
- Water tube
- Mounting bracket

All specifications, information and properties of the product described in these operating instructions correspond to the status upon going to press. 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

> **!** Repair and maintenance work – apart from the activities described in these operating instructions- may be performed only by qualified technical staff.
> - In the event of modifications by third parties, existing medical device licences become null and void.
> - Only use original parts and spare parts.

■ Intended Use

> **!** This medical device is:
> - The Thor 700+ series Electric Handpiece system are intended to convert pneumatic output from a dental treatment center to electrical energy for operation of electrically-driven dental handpiece.
> - Only intended for dental treatment. Any other type of use or alteration to the product is impermissible and can be hazardous. The medical device is intended for the following use: Removal of carious material, cavities and crown preparations, removal of fillings, processing of tooth and restoration surfaces.
> - A medical device according to relevant national statutory regulations.

This medical product:

- Includes a low-voltage electric dental drive device (Model: P812) in accordance with ISO 11498 type 2
- In not approved for use in areas with an increased risk of explosion. (It is not suitable to use the dental unit in an atmosphere of flammable mixtures)

Definition (Intended purpose)	Meaning
Main function	Dental treatment
Use	For dental treatment of crowns and roots
Main functional specification	Mains powered additional component for dentist's unit
Duration of use	Approx. 30-40 minutes with individual interruptions per day

Population: all patients (all age-groups)

According to these provisions, the medical device 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
- The operating instructions

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

■ **Improper handling of handpieces:**
Incorrect handling can result in injury to persons
- Follow the separate user instructions for the attachments.

■ **Target group:**
This document is for dentists and office personnel.

■ **Disposal**

Consumables:
The wastes incurred are to be recycled or disposed of in a way that is harmless for human beings and the environment; in doing so, the national valid regulations are to be observed.
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 centers. Additional information can be obtained from the manufacturer or your dental supplier.

■ **Service**

Send the product every 2 years for a service check.
The safety checks in different countries can vary in compliance with country specific regulations and requirements for medical devices. The national valid regulations are to be observed.

■ **Operating Suggestion**

30 seconds operating time and 9 minutes interval is the feasible limit load of the drive device (full load at maximum speed).
In practice, it is realistic for impulse loading to last a number of seconds and intervals to last anywhere between a number of seconds to a number of minutes, with the maximum drive device current not usually being reached. This will extend the lifetime of drive device.

■ **Safety Precautions**

Risk from 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 caused by incorrectly connecting third-party system to the medical device.
- When installing and operating the medical device 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.

■ **Risk from 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.
- In addition, the accompanying documents must refer to them due to responsibilities arising from safety, reliability and performance.

■ **Premature wear and tear; malfunctions caused by improper care and maintenance:**
Foreshortened product life:
- Perform proper care and maintenance operations on a regular basis.

■ **Malfunctions from electromagnetic fields:**
The product meets the applicable requirements regarding electromagnetic fields.
Given the complex interactions between equipment and cell phones, the product may be influenced by a cell phone that is in use.
- Do not use cell phones in medical offices, hospitals, or laboratories.
- Turn off electronic devices such as computer storage media, hearing aids, etc. during operation.

■ **Damaged cord / brittle cord / no ground wire:**
Electric shock
- Inspect the cord before use.

■ **Instrument tubing damage as a result of adhesive labels:**
The instrument tubing may break
- Do not attach adhesive labels or tape to the tubing.

■ **Endangering of the practitioner and the patient:**
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.

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

■ **Applied Symbols**
Appearing on the packaging


Fragile


Stacking restrictions

Humidity


Keep dry

Temperature range

Serial number


Transport upright

Air pressure


Disposal information

Applied Symbols

A potential hazard to the operator

Important information

Appearing on the unit /on the drive device

Sterilizable up to 135°C (275°F)

Type B : applied part

Disposal information, see important information "Disposal"

Date of manufacture

CE label

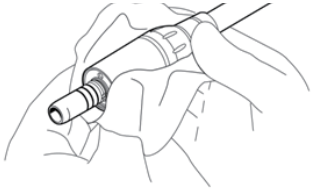
Observe operator's manual

Supply of spare parts, service and maintenance may only be carried out by authorized personnel. TTBio Healthcare Inc. shall assume no liability for accidental, special or consequential damage caused by maintenance or service of the Thor 700+/Thor 700i+ by third parties, or for use of equipment or parts manufactured by third parties, including loss of profit, any commercial loss, economic loss or loss incurred by personal injury. Never remove the cover of the device and never insert objects through the holes or openings on the case. Non-compliance may cause damage to the device and/or may endanger the user.

2. Cleaning and Maintenance and Sterilization

■ **Cleaning**

Disinfect the drive device by wiping after each treatment.



Use only disinfectants approved within the market of use.
Disinfect with a clean, damp cloth using isopropyl alcohol – see illustration below.
- Do not use products containing acetone, chlorine or bleach as disinfecting agents.
- Never immerse in solvent.
- Not suitable for cleaning in an ultrasonic bath.

■ **Maintenance**

Repair and maintenance work on the electrical part of Thor 700+/Thor 700i+ must be performed only by specialists or by persons trained in the factory and familiarized with the safety regulations.
DO NOT OPEN CONTROL UNIT. There are no serviceable parts inside the control unit. Open control unit can result in damage to product or injury to person.

3. Installation and Commissioning

Operate the medical device Thor 700+/Thor 700i+ exclusively with dental drive device P812 and power supply type FSP105-KEAM1.

■ **Connection**

Damage as a result of incorrect pressures. Medical device or drive device defect.
- Connection in accordance with operating instruction (refer to chapter 3 Installation and commissioning)

■ **Damage as a result of poor quality media.**

Defect of drive device or attachment.
- ISO 7494-2 states that compressed air must be clean, dry and free from oil.

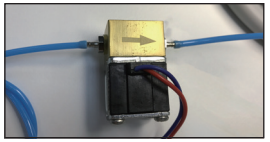
If necessary, insert a filter, water trap or air dryer.
Air requirements (refer to chapter 7 Specifications)

■ **Connect Operation Unit (Thor 700i+)**

Connect the cable to the controller.

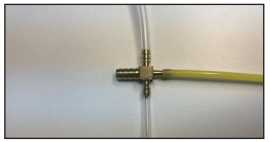
■ **Connect Solenoid Valve (Thor 700i+)**

Connect the solenoid valve connector to the controller. Connect the chip water tube (blue) to the solenoid valve and dental unit.



■ **Connect Control Tube (Thor 700i+)**

Connect the connector to the controller. Connect motor cooling tube (transparent), chip air tube (yellow), drive air tube (transparent) and dental unit drive air to the cross-type hose barb.



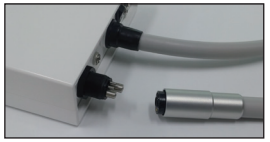
■ **Connect Power Cable (Thor 700i+)**

Plug the power connector to the controller. Connect that cable with electric supply AC24V from dental unit.

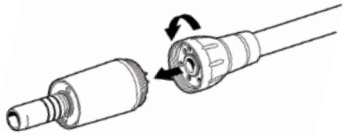
■ **Connect Power Supply (Thor 700+)**

The power supply must be connected in compliance with country specific regulations and requirements for medical devices.
- Connect the power supply to the back of the unit.
- When switching off the dental unit, unplug the power supply cord.

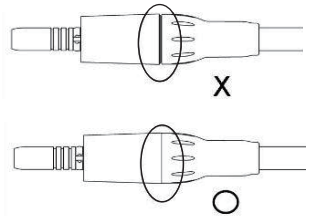
■ **Connect Control Unit (Thor 700+)**
- Connect the 4-hole, 5-hole or 6-hole(according to ISO 9168) to the control unit four-hole connection.



■ **Connect Drive Device (Model : P812)**
- Connect the drive device with the drive device tube.



- Correctly connect to the drive device like shown below.



4. Operation and Setting

■ Parameters configured incorrectly

Damage as a result of incorrect air pressure

- Check and set up air pressure before use.
- In normal operation, the drive speed is shown on the display according to the speed increase or reduction.

■ Damage resulting from use of a non authorized transformer

Damage of product

- Only operate the medical device with the power supply supplied (Model: FSP105-KEAM1)

■ Infection Control

- After treatment of a patient, leak spray air and spray water for at least 20 seconds.
- Because of stagnation, water- or air-conveying lines in treatment units must be flushed or blown through before initial operation and after standing times (weekend, public holiday, vacation, etc.)

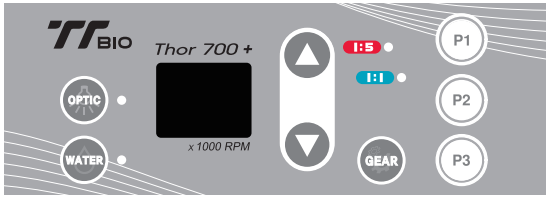
■ Switch on medical device

- Plug into the electrical circuit and switch on power at the back of unit.
- After switch on, LED of speed will illuminate.

Power Symbol	
I	O
On	Off

■ Drive motor speed on the display:

Arabic numerals which are shown on the display is the handpiece burr speed.



Operating Foil keypad

Button	Function	Description
OPTIC	Motor LED on/off	Turn on and off the motor LED illumination
WATER	Spray on/off	Turn on and off the handpiece water spray
GEAR	Gear select	Gear Ratio select
▲ ▼	Speed adjustment	▲ Increase speed ▼ Reduce speed

Button	Function	Description
P1 P2 P3	Start P1、P2 and P3 mode	Select a saved program
1:1 1:5	Current speed ratio	2 setting options : 1 : 1 (Blue) 1 : 5 (Red)
200	Burr speed display	1 : 1 (Display x 1000 rpm) 1 : 5 (Display x 1000 rpm)

■ Setting Gear Ratios Of Handpiece

- The gear ratio can be set to 1:5 or 1:1 depending on the gear ratio of the handpiece in use on the control display.
- The gear ratio is set to 1:5 or 1:1 sequentially whenever GEAR button is pressed once.
- The selected ratio is highlighted.

■ Setting Optic LED On/Off

- The LED installed in the P812 motor can be turned on or off by pressing the OPTIC button on the control display.

■ Setting Water Spray On/Off

- The water spray on the handpiece can be turned on or off by pressing the WATER button on the control display.

■ Operation Mode Setting

- Three memory functions, P1, P2 and P3 are available on the control display depending on the program to be used.
- Save a program: select the customized settings of optic, water and gear ratio and press a program switch P1, P2 or P3 for 3 seconds or longer.
- Select a program: Select a desired program by pressing P1, P2 or P3.

5. Exceptions and exclusions

Common exceptions and debugging methods

Breakdown	Reason	Exclusion Method
Screen or LED down	Power off	Turn on power
	Power supply not connected	Check connection
	Fuse burnt	Contact dealer
Driving device not work	Pipeline or power supply not connected	Check connection
	Insufficient air pressure	Check air supply
Rotating speed cannot increase	Insufficient air pressure	Check air supply
	Abnormal controller	Contact dealer
Operating Driving device overheat	Insufficient air pressure, result in poor heat dissipation	Check air supply
	Abnormal driving device	Contact dealer
Cooling water leakage	Leak from back-end of driving device	Check driving device correctly connect with pipeline
	Leak from controller	Contact dealer

Error Code

Error Code	Description	Reason	Exclusion
E1	Driving device connection error	Incorrect driving device connection	Check the connection.
E2	Driving device defect	Damage to the driving device connection	Replace the driving device if the connection has no damage.
E3	Driving device overload	Driving device stop due to overload.	Stop running the driving device and reuse it after cooling it down for 3 minutes or longer.

6. Information on electromagnetic Compatibility

The medical device is suitable for use in the specified electromagnetic environment. The purchaser or user of the medical device should ensure that it is used in an electromagnetic environment as described below:

Emission Test	Compliance	Electromagnetic Environment
Radio-Frequency Emissions CISPR 11	Group 1	The medical device uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
Radio-Frequency Emissions CISPR 11	Class A	The medical device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Immunity tests	IEC 60601-test level	Conformance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood or ceramic tiles. If floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ bursts IEC 61000-4-4	± 2 kV for power lines ± 1 kV for signal lines	± 2 kV for power lines ± 1 kV for signal lines	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges IEC 61000-4-5	± 1 kV Push-pull voltage ± 2 kV common mode voltage	± 1 kV Push-pull voltage ± 2 kV common mode voltage	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage interruptions, short-term interruptions and fluctuations of the supply voltage IEC 61000-4-11	<5% UT for 0.5 periods 40% UT for 5 periods 70% UT for 25 periods <5% UT for 250 periods	<5% UT for 0.5 periods 40% UT for 5 periods 70% UT for 25 periods <5% UT for 250 periods	The quality of the supply voltage should correspond to that of a typical business or hospital environment. When the user of the medical device needs continued operation even when the power supply is interrupted, it is recommended to supply the medical device from an uninterrupted power supply or a battery.
Magnetic field with a supply frequency (50/60 Hz) per IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial hospital.
Conducted HF disturbances IEC 61000-4-6	3 Veff 150 kHz to 80 MHz outside of the ISM bandsa	3 Vrms	Portable and mobile radio devices should not be used closer to the medical device (including the electrical lines) than the recommenced safe distance calculated using the equation for the transmission frequency. Recommended safe distance: $d = 1.2\ \sqrt{P}$ $d = 1.2\ \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\ \sqrt{P}$ for 800 MHz to 2.5 GHz with P as the maximum rated power of the transmitter in Watts (W) according to the transmitter manufacturer, and d as the recommended safe distance in meters (m). bThe field strength of stationary radio transmitters should be less than the conformance level at all frequencies in an on-site checkc. dDisturbances are possible close to devices that have the following symbol.
Radiated HF disturbances IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE: UT is the alternating mains voltage before the test level is used.
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not be applicable in every case. The spread of electromagnetic waves is absorbed and reflected by buildings, objects and people.

a. The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHZ to 27.283 MHz and 40.66 MHz to 40.70 MHz.
b. The conformance levels in the ISM frequency bands between 150 kHz and 80 MHz and the frequency range of 80 MHz and 2.5 GHz are intended to reduce the probability that mobile and portable communications equipment will produce disturbances when they are unintentionally brought near the patient. For this reason, the additional factor of 10/3 is used when calculating the recommended safe distances within these frequency ranges.
c. The field strength of stationary transmitters such as base stations of mobile telephones and land mobile radio devices, amateur radio stations, AM and FM, radio and television broadcasters cannot be theoretically predetermined. To determine the electromagnetic environment of stationary transmitters, a study of the location should be considered. When the measured field strength at the site where the medical device is used exceeds the above conformance level, the medical device should be monitored to demonstrate proper function. When unusual performance features are observed, additional measures may be necessary such as realigning or moving the medical device.
d. Within the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 Veff V/m.

Recommended safe distance between portable and mobile HF telecommunications equipment and the medical device.

The medical device is intended for use in an electromagnetic environment in which HF disturbances are controlled. The customer or the user of the medical device can help prevent electromagnetic disturbances by maintaining the minimum distance between portable and mobile HF telecommunications devices (transmitters) and the medical device depending on the output of the communication device as indicated below.

Rated power of the transmitter / W	Safe distance depending on the transmission frequency:		
	150 kHz to 80 MHz d=1.2 √P	80 MHz to 800 MHz d=1.2 √P	800 MHz to 2.5 GHz d=2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximum rated power is not in the above table, the recommended safe distance d in meters (m) can be calculated using the equation for the respective gap, where P is the maximum rated power of the transmitter in Watts (W) according to the manufacturer's information.
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not be applicable in every case. The spread of electromagnetic waves is absorbed and reflected by buildings, objects and people.

7. Specification

Controller

Drive device speed range:	1000 ~ 40,000	rpm
Output torque:	max. 3.0	Ncm
Drive device voltage:	36 ~ 38	V DC
Operating Suggestion:	Duty cycle: 0.5 on / 9 off	min
Weight:	0.43	Kg
Dimensions (Width/Height/Depth):	113 x 45 x 170	mm
Rotation:	clockwise	
Sound level:	< 40	dBa
Instrument connection:	ISO 3964	
Protection class:	Class I system	
Overvoltage category:	II	
Pollution degree:	P2	
Device classification of applied part (EN 60601):	Type B	
Protection category (Dust-proof; water-proof):	IP X1	

Power Supply

Rated voltage:	100 ~ 240	V AC
Frequency:	47 ~ 63	Hz
Frequency range:	0.7 ~ 1.4	A
Operating mode:	Duty cycle (1 on / 9 off)	min
Weight:	0.59	kg
Dimensions (Width/Height/Depth):	75.2 x 39.0 x 146.2	mm
Protection class:	Class I system	
Overvoltage category:	II	
Pollution degree:	P2	
Protection category (Dust-proof; water-proof):	IP 40	

Media Supply Data to Control Unit

System pressure:	1.8 ~ 4.0 (26 ~ 58)	bar (psi)
Spray air:	1.0 ~ 2.5 (14.5 ~ 36.2)	bar (psi)
Spray water:	0.8 ~ 2.0 (17.4 ~ 29)	bar (psi)
Air requirements:	Dry, free from oil, clean, uncontaminated according ISO 7494-2	
Air filter:	50	µm
Water quality:	Tap water	
Ph-value:	7.2 ~ 7.8	
Water quality:	80	µm

Recommended Setting

System pressure :	3.0 (43.5)	bar (psi)
Spray air :	1.0 (14.5)	bar (psi)
Spray water :	0.8 (11.6)	bar (psi)

Ambient Conditions of Control Unit and Power Supply

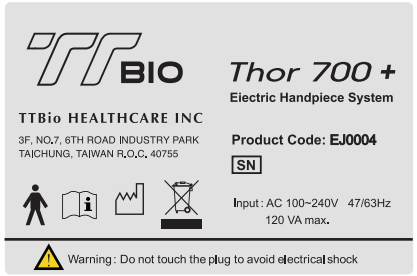
Location:	Permitted in interior rooms	
Ambient temperature:	10 ~ 35 (50 ~ 95)	°C (°F)
Relative humidity:	30 ~ 80	%
Air pressure:	700 ~ 1,060	hPa

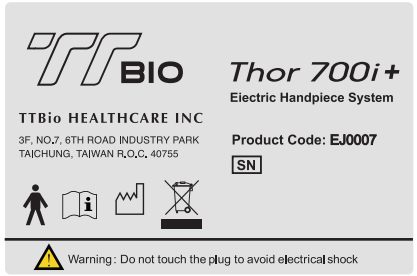
Storage and Transport Conditions of Control Unit and Power Supply

⚠ Danger when start-up the medical device after storage in very cold conditions. This can cause an operational failure of the medical device. Very cold devices must be brought to a temperature of 20 ~ 25°C (68 ~ 77°F) before being started up.		
Ambient temperature:	0 ~ 50 (32 ~ 122)	°C (°F)
Relative humidity:	10 ~ 80	%
Air pressure:	500 ~ 1,060	hPa
Keep dry!		

We reserve the right to make technical modifications.

Label





The explanations of the symbols are described in chapter 1 - Important information.

8. Disclaimer

- Information in this operation manual were carefully reviewed. We cannot assume any liability for any damage arising from improper use of the device or from use of this manual.
- Products must be operated by qualified practitioners and in dental treatment. Use for other purposes may damage the device and cause severe consequence.
- Products are subject to change without notice.
- Rx only.

9. Quality and Service

All of our products have passed strict QC procedures before delivery. Please note that improper use or not using the recommended parts and accessories or modifying our products without our approval may shorten the lifetime of the product or cause damage. Please contact our dealers with proof of purchase for consultation whenever you have any questions.

1. 重要資訊 繁體中文

親愛的使用者：

我們希望您能充分使用您的新產品。為了確保您能夠充分、正確、安全的使用此產品，請按照以下的指示進行。為了避免不正確的操作或損害，使用者在第一次使用之前應充分閱讀這份操作說明書，複製或是銷售這份操作說明書必須事先得到製造商的同意。

■ 產品明細

Thor 700+

- Thor 700+ 控制主機
- P812 驅動裝置
- 電源線
- 操作說明書
- 電源供應器 AC 100 240 V
- 安裝支架

Thor 700i+

- Thor 700i+ 操作主機
- P812 驅動裝置
- 控制面板
- 安裝支架
- 控制管線
- 電磁閥
- 十字形四通接頭
- 電源線 AC 24V
- 操作說明書
- 水管

新的技術發展有可能對此產品進行改良與提升，恕無法更新舊設備。
製造商對於以下原因所造成的損害不負擔任何責任：

- 外在的影響 (不當的安裝或是水、氣供應品質不良)
- 使用不正確的資訊
- 不正確的使用
- 不正確的維修

! 維修和保養–說明書中的產品拆解只能由符合資格的技術人員執行。
- 經由第三方的維修，本產品的認證與保固將會失效。
- 只能使用原廠的維修零件與備用零件。

■ 預期用途

! 此醫療設備：
- 只能作為牙科治療使用，任何其他形式的使用會造成危險。此醫療設備可用在下列牙科治療：移除蛀牙物質，牙齒窩洞的準備，移除填充物，牙齒處理和修復表面。
- 此醫療設備依循相關國際醫療法規的規定。

此醫療產品：
- 包含低電壓的電動驅動裝置（型號：P812），依據ISO 11498 Type 2
- 禁止在有爆炸高風險性的環境使用。（不適合在有可燃物的環境中使用）

定義(可預期的目的)	意義
主要功能	牙齒治療
使用	齒冠與齒根的治療
主要功能規格	附加於牙科治療台的動力裝置
使用時間	每位病患大約30-40分鐘

治療對象：所有病患（所有年齡族群）。

根據規定，此醫療設備只能由有經驗的使用者依據下列說明進行使用：
- 適當的健康和安全法規
- 適時的意外防範法規
- 操作說明

根據法規，使用者被要求必須：
- 只能在機器良好的狀況下正確使用
- 只為了適當的目的使用設備
- 保護自己、病患和第三者免於危險
- 避免產品污損

■ **不適當的手機操作：**
不當的操作可能會傷及別人
- 參閱操作手冊進行操作

■ **目標族群：**
這份文件適用於牙醫師和相關工作人員

■ **處理**

消耗品：
廢棄物必須在不傷害人類和環境的方法下回收處理；可遵照國家法規進行。
到了使用期限時，機器和配件的處置：
根據 2002/96/EC 廢電氣電子設備指令，指出本產品目前遵守標籤規定，但尚未受限於此指令處置要求。然而，本產品可能由歐洲特殊廢棄物管理中心處理 ，其他的資訊可透過製造商或牙科供應商取得。

■ **服務**

每兩年將產品送回檢查。
安全檢查會依據每個國家醫療裝置法規而不同。可遵照各國家法規進行。

■ **操作建議**

30秒的操作時間和9分鐘的間隔是電動驅動裝置最合適的負荷限度（最大速度的負荷）。
實際上，在數秒鐘至數分鐘的操作過程中，持續數秒的衝擊負載會間歇產生，因此電動驅動裝置的最大電流通常不會達到，可增加使用壽命。

■ **安全預防**

電磁場產生的風險：植入型裝置（例如-心律調節器）的功能會被電磁場影響。
- 在開始治療前詢問病患，並且告知病患相關風險。

■ **電力**

不正確的連接醫療系統於本裝置將會導致電擊。
- 與其他醫療裝置連結安裝和操作時，請根據IEC 60601-1注意 "電擊防護"， "洩漏電流" 與 "應用部件非接地"。
- 為避免觸電的風險, 此設備必須連接到有接地線的電源。
- 接觸病患的部件(觸身部件) – 牙科手機

■ **控制設備功能喪失的風險**
如果控制設備對於改變速度和改變轉動方向無作用時將會產生危險。
- 連接的牙科治療裝置必須要有控制系統來改變速度和轉動方向。
- 除此之外，基於安全性、可靠性與功能性的考量，必須隨附相關文件。

■ **過早的磨損–不當使用及保養所引起的故障**
產品壽命縮短：
- 依照說明書進行適當的保養。

■ **因電磁場而產生的故障**
產品符合電磁場使用要求。
產品和行動電話同時使用的情形下，可能會被正在使用的行動電話所影響。
- 不要在醫療辦公室、醫院、實驗室裡使用行動電話。
- 在操作期間請關掉電子裝置，如：數位儲存媒體、助聽器...等。

■ **已受損的電線／易損壞的電線／未接地**
電擊傷害
- 使用之前請檢查電線。

■ **儀器的管件可能因為黏貼標籤造成損壞**
儀器的管件可能破損
- 不要在管件上黏貼標籤。

■ **對於醫師和病患造成危險**
有以下情況立即停止使用：不尋常的異音、過度的震動、不尋常的發熱或是鑽針沒有鎖緊。

連同牙科治療裝置，此醫療裝置符合 IEC 60601-1-2 的要求。
唯有被製造商認可訓練過的人員才可以維修及保養此醫療裝置。
在沒有雷祥生技的授權下，由顧客或第三方對產品做修改而造成的損害，並不在保固條件內。

■ **使用符號**

包裝上的符號

易碎
疊放規定
溼度
保持乾燥
溫度範圍
序號
垂直運輸
氣壓
廢棄資訊
參照重要資訊 "廢棄"

使用手冊的符號

對於操作者
潛在的危險

重要資訊

產品 / 驅動裝置上的符號

可承受
高溫135°C 滅菌 (275°F)

應用部件：Type B

廢棄資訊
參照重要資訊 "廢棄"

生產日期

CE 標籤

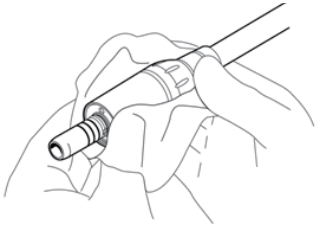
注意操作手冊

除外責任
配件的供應，服務和維修只能由雷祥生技授權的人員負責。
由第三方對Thor 700+ / Thor 700i+ 進行維修，導致造成意外、特殊或相應的損害；或是使用第三方製造的設備或零件，造成利益損失，任何商業損失、經濟損失或人身傷害的損失，雷祥生技不承擔任何責任。千萬不要拆開主機的外殼，也不要經由孔洞插入任何東西到主機內，未經授權任意地打開外殼，將會使外殼的機構損壞，此行為造成的損壞並不在保固條件範圍內。
任何的不遵守都可能造成儀器的損害或是人員的傷害。

2. 清潔與維護

■ 清潔
電動驅動裝置每次使用後藉由擦拭來滅菌。

只可使用市場上核准的消毒劑。
使用有異丙醇酒精的乾淨溼抹布來消毒 – 如下方的圖片所示。
- 不要使用含有丙酮、氯或是漂白劑的消毒媒介。
- 不要浸入溶劑裡。
- 不適合在超音波容器裡清洗。



■ 維護

修理和維護Thor 700+ / Thor 700i+ 的人員必須是專業人員或經過原廠訓練且熟悉安全法規的人員。
不要打開控制主機，控制主機裡並沒有可以用的備份零件。
任意的打開可能造成儀器的損害或是人員的傷害。

3. 安裝

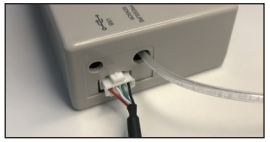
Thor 700+ / Thor 700i+ 僅可搭配P812電動驅動裝置進行操作；Thor 700+ 使用FSP105-KEAM1電源供應器進行電力供應。

■ 連接
不正確的連接會造成主機或電動驅動裝置損壞
- 請依照說明書進行連接設定 (參考第3章 安裝)。

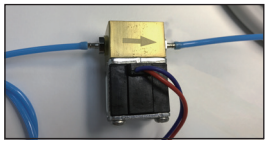
■ 品質不良的媒介造成損壞
電動驅動裝置或配件的損壞
- 依據 ISO 7494-2 標準，壓縮空氣必須乾淨、乾燥並且不含油質。

如有需要，可安裝過濾器、排水器或是空氣乾燥器。
空氣需求 (參考第7章 規則)

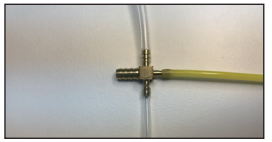
■ **連接控制面板 (Thor 700i+)**
連接控制面板通訊線到主機板。



■ **連接電磁閥 (Thor 700i+)**
連接電磁閥通訊線到主機板。連接牙椅冷卻水管(藍色)及控制管線的冷卻水管(藍色)到電磁閥。



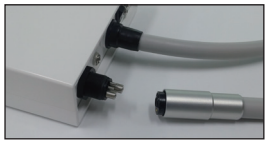
■ **連接控制管線 (Thor 700i+)**
連接控制管線到主機板。連接驅動裝置散熱氣管(透明)、冷卻氣管(黃色)、驅動空氣管(透明)及牙椅驅動氣管到十字形軟管接頭。



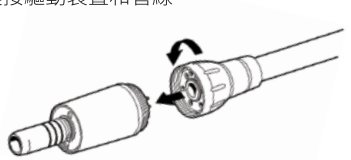
■ **連接電源線 (Thor 700i+)**
連接電源線到主機板，並連接牙椅供應之AC24V電源。

■ **電源供應器連接 (Thor 700+)**
電力供應必須符合國家規格和醫療裝置的需求。
- 從儀器的後面連接電力供應。
- 當關閉治療台電源時，電源線必須從機體拔除。

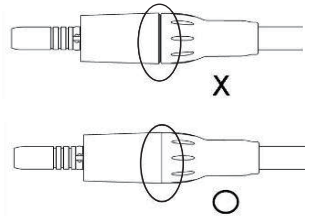
■ **控制器連接 (Thor 700+)**
- 連接4孔、5孔或是6孔管線(ISO 9168)到控制器4孔接頭。



■ **連接電動驅動裝置 (型號: P812)**
- 連接驅動裝置和管線。



- 驅動裝置連接是否正確的判別。



4. 操作與設定

■ 參數設定不正確

不正確的空氣氣壓值會造成產品損害或無法作動。

- 使用之前檢查並設定氣壓值。
- 在正常操作下，驅動器速度會根據增速或減速顯示在顯示屏上。

■ 使用未經認可的電源轉換造成損害

產品損壞

- 只能使用原廠提供的電源供應器 (型號: FSP105-KEAM1)。

■ 感染控制

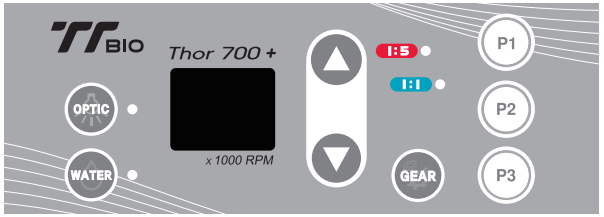
- 治療病人後，讓冷卻空氣和冷卻水至少持續噴霧20秒。
- 為避免淤塞，在每次開始使用之前或是固定時間後 (周末、國定假日、假期...等)，必須清潔水或空氣管線使之順暢。

■ 啟動醫療裝置

- 插上電源，按下儀器後方的電源開關啟動儀器。
- 啟動後，轉速顯示屏燈號會亮起。

電源符號	
I	O
開	關

■ 操作面板配置



圖示	功能	說明	圖示	功能	說明
OPTIC	LED開關	驅動器LED開關 燈號燈亮表示為開啟	P1 P2 P3	P1、P2或P3 記憶模式選擇	可記憶3組操作模式 短按切換
WATER	水霧開關	手機水霧開關 燈號燈亮表示為開啟			
GEAR	手機速比切換	有1:1、1:5二種速比 短按循環切換	1:1 1:5	手機速比顯示	二種速比及燈號顯示 1:1(藍色)、1:5(紅色)
	速度調整	向上符號為〝加速〞 向下符號為〝減速〞	200	手機鑽針速度 顯示	鑽針實際轉速如下 1:1(顯示 X 1000 rpm) 5:1(顯示 X 1000 rpm)

■ 手機速比設定

- 依照手機速比選擇控制面板上之速比，共有1:1、1:5二種速比可供選擇。
- 按壓 GEAR 按鍵切換1:1或1:5手機速比。
- 設定之手機速比將由燈號顯示。

■ LED照明開關

- P812驅動裝置內建LED照明，按壓 OPTIC 按鍵開啟或關閉LED照明。
- LED照明開啟時將由燈號顯示。

■ 手機水霧開關

- 按壓 WATER 按鍵開啟或關閉手機水霧。
- 手機水霧開啟時將由燈號顯示。

■ 記憶模式設定

- 共3組記憶模式P1、P2或P3可供設定。
- 儲存記憶模式: 選擇所要設定的手機速比、轉速、LED燈開/關、水霧開/關後，長按P1按鍵3秒，完成P1記憶模式設定。P2、P3記憶模式設定流程與P1相同。
- 選擇記憶模式: 按壓P1按鍵後，即選定P1記憶模式。P2、P3記憶模式選擇與P1相同。

5. 異常及排除

常見異常及排除方法

故障	原因	排除方法
顯示屏或LED不亮	電源未開	打開電源
	電源供應器未連接	確認連接是否正確
	保險絲燒毀	請與經銷商連絡
驅動裝置無法運轉	管線或電源供應器未連接	確認連接是否正確
	氣壓不足	確認氣壓供給系統
轉速無法提升	氣壓不足	確認氣壓供給系統
	控制器異常	請與經銷商連絡
驅動裝置過熱	氣壓不足，導致散熱不良	確認氣壓供給系統
	驅動裝置內部異常	請與經銷商連絡
冷卻水洩漏	從驅動裝置後端流出	確認驅動裝置與管線連接是否正確
	從控制主機流出	請與經銷商連絡

故障碼

故障碼	說 明	原 因	排除方式
E1	驅動裝置連結錯誤	驅動裝置未正確連接	請檢查驅動裝置之連接。
E2	驅動裝置故障	驅動裝置連結故障	請與經銷商聯絡。
E3	驅動裝置過載	驅動裝置因過載而停止	暫停使用驅動裝置，並靜置 3分鐘(或以上)讓驅動裝置降溫。

6. 電磁相容性資訊

The medical device is suitable for use in the specified electromagnetic environment. The purchaser or user of the medical device should ensure that it is used in an electromagnetic environment as described below:

Emission Test	Compliance	Electromagnetic Environment
Radio-Frequency Emissions CISPR 11	Group 1	The medical device uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
Radio-Frequency Emissions CISPR 11	Class A	The medical device is for use in all facilities including residential facilities and facilities that are directly connected to a public power supply that also supplies residential buildings.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Immunity tests	IEC 60601-test level	Conformance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood or ceramic tiles. If floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ bursts IEC 61000-4-4	± 2 kV for power lines ± 1 kV for signal lines	± 2 kV for power lines ± 1 kV for signal lines	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges IEC 61000-4-5	± 1 kV Push-pull voltage ± 2 kV common mode voltage	± 1 kV Push-pull voltage ± 2 kV common mode voltage	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage interruptions, short-term interruptions and fluctuations of the supply voltage IEC 61000-4-11	<5% UT for 0.5 periods 40% UT for 5 periods 70% UT for 25 periods <5% UT for 250 periods	<5% UT for 0.5 periods 40% UT for 5 periods 70% UT for 25 periods <5% UT for 250 periods	The quality of the supply voltage should correspond to that of a typical business or hospital environment. When the user of the medical device needs continued operation even when the power supply is interrupted, it is recommended to supply the medical device from an uninterrupted power supply or a battery.
Magnetic field with a supply frequency (50/60 Hz) per IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial hospital.
Conducted HF disturbances IEC 61000-4-6	3 Veff 150 kHz to 80 MHz outside of the ISM bandsa	3 Vrms	Portable and mobile radio devices should not be used closer to the medical device (including the electrical lines) than the recommenced safe distance calculated using the equation for the transmission frequency. Recommended safe distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.5 GHz with P as the maximum rated power of the transmitter in Watts (W) according to the transmitter manufacturer, and d as the recommended safe distance in meters (m). bThe field strength of stationary radio transmitters should be less than the conformance level at all frequencies in an on-site checkc. dDisturbances are possible close to devices that have the following symbol.
Radiated HF disturbances IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE: UT is the alternating mains voltage before the test level is used.
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not be applicable in every case. The spread of electromagnetic waves is absorbed and reflected by buildings, objects and people.

a. The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHZ to 27.283 MHz and 40.66 MHz to 40.70 MHz.
b. The conformance levels in the ISM frequency bands between 150 kHz and 80 MHz and the frequency range of 80 MHz and 2.5 GHz are intended to reduce the probability that mobile and portable communications equipment will produce disturbances when they are unintentionally brought near the patient. For this reason, the additional factor of 10/3 is used when calculating the recommended safe distances within these frequency ranges.
c. The field strength of stationary transmitters such as base stations of mobile telephones and land mobile radio devices, amateur radio stations, AM and FM, radio and television broadcasters cannot be theoretically predetermined. To determine the electromagnetic environment of stationary transmitters, a study of the location should be considered. When the measured field strength at the site where the medical device is used exceeds the above conformance level, the medical device should be monitored to demonstrate proper function. When unusual performance features are observed, additional measures may be necessary such as realigning or moving the medical device.
d. Within the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 Veff V/m.

Recommended safe distance between portable and mobile HF telecommunications equipment and the medical device.

The medical device is intended for use in an electromagnetic environment in which HF disturbances are controlled. The customer or the user of the medical device can help prevent electromagnetic disturbances by maintaining the minimum distance between portable and mobile HF telecommunications devices (transmitters) and the medical device depending on the output of the communication device as indicated below.

Rated power of the transmitter / W	Safe distance depending on the transmission frequency:		
	150 kHz to 80 MHz d=0.35 √P	80 MHz to 800 MHz d=0.35 √P	800 MHz to 2.5 GHz d=0.70 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximum rated power is not in the above table, the recommended safe distance d in meters (m) can be calculated using the equation for the respective gap, where P is the maximum rated power of the transmitter in Watts (W) according to the manufacturer's information.
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not be applicable in every case. The spread of electromagnetic waves is absorbed and reflected by buildings, objects and people.

7. 規格

控制器

驅動裝置速度範圍：	1000 ~ 40,000	rpm
輸出扭矩：	max. 3.0	Ncm
驅動裝置電壓：	36 ~ 38	V DC
操作模式：	Duty cycle : 0.5 on / 9 off	min
重量：	0.43	Kg
規格（寬／高／深）：	113 x 45 x 170	mm
旋轉方向：	順時針	
噪音：	< 40	dBa
手機連接接頭：	ISO 3964	
防護等級：	第一等級系統	
防電擊分類：	II	
污染程度：	P2	
應用部件電擊防護等級：	Type B	
保護等級（防塵防水）：	IP X1	

電源供應器

電壓範圍：	100 ~ 240	V AC
頻率：	47 ~ 63	Hz
電流範圍：	0.7 ~ 1.4	A
操作模式：	Duty cycle (1 on / 9 off)	min
重量：	0.59	kg
規格（寬／高／深）：	75.2 x 39.0 x 146.2	mm
防護等級：	第一等級系統	
防電擊分類：	II	
污染程度：	P2	
保護等級（防塵防水）：	IP 40	

水、氣供應要求

系統壓力：	1.8 ~ 4.0 (26 ~ 58)	bar (psi)
噴霧空氣：	1.0 ~ 2.5 (14.5 ~ 36.2)	bar (psi)
噴霧水：	0.8 ~ 2.0 (17.4 ~ 29)	bar (psi)
空氣需求：	乾燥, 無油, 乾淨, 無污染（依據 ISO 7494-2）	
空氣過濾器：	50	µm
水質：	可飲用水	
酸鹼值：	7.2 ~ 7.8	
水質過濾：	80	µm

水、氣建議壓力

系統壓力：	3.0 (43.5)	bar (psi)
噴霧空氣：	1.0 (14.5)	bar (psi)
噴霧水：	0.8 (11.6)	bar (psi)

控制器與電源供應器環境要求

位置：	只允許在室內使用	
環境溫度：	10 ~ 35 (50 ~ 95)	°C (°F)
相對溼度：	30 ~ 80	%
大氣壓力：	700 ~ 1,060	m

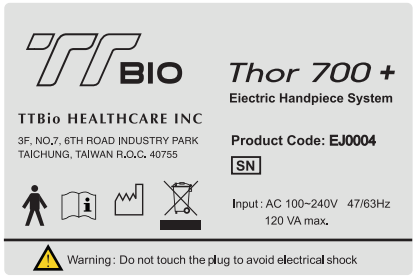
控制器與電源供應器的儲存及運輸環境

⚠ 在低溫環境儲存之後立刻使用此醫療裝置可能會有危險
可能導致此醫療裝置操作的錯誤
使用之前必須先放置於室溫 20 ~ 25°C (68 ~ 77°F) 之間

環境溫度：	0 ~ 50 (32 ~ 122)	°C (°F)
相對溼度：	10 ~ 80	%
大氣壓力：	500 ~ 1,060	hPa
保持乾燥！		

我們保留技術規格變更的權利。

標籤



符號的說明在第 1 章節 重要資訊中有描述。

8. 聲明

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- 本產品只有適用在牙科口腔治療用，不可轉用其他用途，否則有發生危險的可能性。
- 製造商保有尺寸、規格更改權利，不另行通知。

9. 品質政策與售後服務

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