

MAINTENANCE UNIT

For Electric Pen Drive and
Air Pen Drive



This publication is not intended for distribution in the USA.

INSTRUCTIONS FOR USE

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INTRODUCTION

GENERAL INFORMATION

Intended use

The Maintenance Unit is an electrically- and compressed air powered device for maintaining handpieces and attachments for Electric Pen Drive and Air Pen Drive.

Safety instructions

The Maintenance Unit is only to be used after careful consultation of the instructions for use.

The Maintenance Unit is designed for use by reprocessing department, Synthes service center or production personnel.

DO NOT use this equipment in the presence of oxygen, nitrous oxide or a mixture consisting of flammable anesthetics and air.

To ensure the proper operation of the maintenance unit, only use Synthes original accessories.

Only use Synthes Maintenance Oil, 40 ml, for EPD and APD, 05.001.095. Other oils can have a toxic effect and can lead to sticking.

The user of the product is responsible for proper use of the equipment.

For important information regarding electromagnetic compatibility (EMC), please refer to the chapter "Electromagnetic Compatibility" in this manual.

To ensure the proper operation of the Maintenance Unit, Synthes recommends the device to be regularly (every five years) serviced by the original manufacturer or an authorized site. The manufacturer assumes no responsibility for damage resulting from improper operation and from neglected or unauthorized maintenance or repair of the Maintenance Unit.

Precautions:

- To avoid injuries, the lid of the Maintenance Unit has to be closed during the lubrication process.
- Never use oxygen to run the Maintenance Unit (danger of explosion!); only use compressed air or compressed nitrogen.
- Set the air pressure to 5–10 bars. Do not exceed the pressure.
- If the Maintenance Unit drops on the floor, fragments may split off. This represents danger for the user as these fragments may be sharp.
- If the Maintenance Unit has visible defects or does not function properly, do not use it anymore and send it to the Synthes service center.
- If solid, wrong or expired oil is in the tank, do not use the Maintenance Unit anymore and send it back to the Synthes service center.
- The Maintenance Unit must not be sterilized.
- Do not expose the Maintenance Unit to moisture.

Warning: The Synthes Maintenance Unit must not be stored or operated in an explosive atmosphere.

Warranty / Liability

The warranty for the Maintenance Unit and its accessories does not cover any damage resulting from improper use, damaged seals or improper storage and transportation.

The manufacturer excludes liability for damage resulting from repairs or maintenance carried out by unauthorized sites.

Accessories / Scope of delivery

The Maintenance Unit consists of the unit itself, the pneumatic connection, the power supply, a country specific power cord as well a bottle of maintenance oil and the filter.

Location, storage and transport

The Synthes Maintenance Unit is only permitted for storage and operation outside the operating room (OR).

For operation and storage place the maintenance unit on a straight and solid surface.

Empty the tank and use the original packaging for dispatch and transport. If the packaging material is no longer available, please contact the Synthes office. For storage and transport environmental conditions, see page 21.

THE LUBRICATION PROCESS

1

Installation

Install the provided Power Supply in the power supply connection, then connect the country specific Power Cord to the Power Supply and to a plug socket.



Plug the end of the Pneumatic Connection into the air connector on the back of the module; then connect the nipple for the Pneumatic Connection to the air supply. Set the air pressure of the air supply to 5–10 bars.



Fill the oil tank with Synthes Maintenance Oil, 40 ml for EPD and APD (05.001.095), as described in the chapter Care and Maintenance.

Precaution

- **To completely disconnect from AC mains disconnect the power supply.**
- **Make sure the air supply is turned off prior to connect or disconnect the Pneumatic Connection from the Maintenance Unit.**
- **Ensure that the power cord can always be disconnected immediately from mains supply.**

2

Start the Maintenance Unit

Push the ON/OFF button ① on the keypad to turn on the Maintenance Unit. The POWER ON LED should stay lit up.

If the ERROR ⚠ LED flashes or lights up, consult the chapter Troubleshooting.



3 Connect the Electric Pen Drive Handpiece (05.001.010)

The connector for handpieces is on the left side of the unit. To connect the Electric Pen Drive handpiece, open the release sleeve for attachments on the handpiece. Place it with the coupling for attachments pointing forward, then push the handpiece with light pressure towards the connector fitting until the handpiece locks in place.



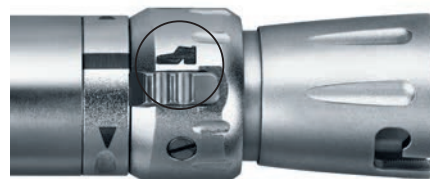
Connect the Air Pen Drive Handpiece (05.001.080)

To connect the Air Pen Drive handpiece, the Adapter for Maintenance Unit for Air Pen Drive (05.001.089) has to be used. Place the female side of the Adapter onto the connector on the left of the Maintenance Unit, making sure that the pins on the connector engage in the slotted link on the Adapter and then turn the Adapter clockwise. To apply the handpiece, set the adjustment sleeve to the foot switch position. Then mount the air hose coupling side of the handpiece to the connector by fitting the pins into the grooves of the Adapter and turn the handpiece clockwise.



Precaution

- The Air Pen Drive must be set to foot switch position during the lubrication process. Otherwise the lubrication process is blocked.
- The Air Pen Drive has to be lubricated through the air inlet/outlet, not through the attachment coupling!



Connect the Attachments

The remaining connectors can be used for attachments. To connect the attachments, carefully push the attachment with the cone coupling pointing towards the connector fitting and turn the attachment counterclockwise to lock it in place.

Connect the Burr Attachments XL and XXL 20°

To connect Burr Attachment XL 20° (05.001.063) and XXL 20° (05.001.055) the Adapter for Maintenance Unit for Burr Attachments XL and XXL (05.001.064) has to be used. Place the male side of the Adapter onto the second connector from the left, making sure that the pins on the Adapter engage in the slotted link on the connector and then turn the Adapter counterclockwise.

Precaution: Burr Attachments (05.001.045 – 05.001.050, 05.001.063 and 05.001.055) and Craniotome Attachment (05.001.059) must be lubricated in lock position. Otherwise the lubrication procedure stops.




4

Start the Lubrication Process

Before starting the lubrication process the Lid must be closed. After closing the Lid, push the START button to start the lubrication procedure. The lubrication procedure will take approximately three minutes when all connectors are loaded.

The READY LED will flash up when the lubrication loop is successfully completed.

If the ERROR  LED flashes or lights up, consult the chapter Troubleshooting.

Note: Make sure the oil tank is filled up before you start the lubrication process.



5

Remove the Handpieces and Attachments

To remove the Electric Pen Drive handpiece, turn the release sleeve as indicated by the arrow and remove the handpiece.

To remove the Air Pen Drive handpiece, simply turn the handpiece anticlockwise and remove from the Adapter. When the Maintenance Unit is only used for maintaining the Air Pen Drive it is possible to keep the Adapter in the Maintenance Unit.


The attachments can be removed by turning them clockwise in the connector and carefully pulling them out.

After the sterilizing process the handpiece and the attachments will be ready to use.

CARE AND MAINTENANCE

1

Fill the Oil Tank

If the oil tank is empty, the ERROR  LED will stay lit up; oil should then be refilled. Open the oil tank by turning the cap counterclockwise and refill only with Synthes Maintenance Oil, 40 ml, for EPD and APD, 05.001.095.

Precaution:

- Only use Synthes Maintenance Oil, for EPD and APD, 05.001.095 until the expiration date printed on the label. Lubricants with other compositions can cause jamming, can have a toxic effect or can have a negative impact on the sterilization results.
- Make sure that the lid is closed properly before operating the Maintenance Unit.
- As soon as the tank is empty refill one bottle of Maintenance Oil, 40 ml for EPD and APD, 05.001.095. Do not overfill the tank.



2

Change the Filter

If oil can be detected in the filter in the inspection window (1), the filter has to be changed. We recommend changing the filter every time the oil has to be filled up.

To change the filter, open the lid, remove the old filter and fit the new filter into the bottom of the Maintenance Unit.

The old filter and the empty bottle of Synthes Maintenance Oil, for EPD and APD, should be disposed according to national regulations.

Note: The Maintenance Kit 05.001.094 contains 1 bottle of Synthes Maintenance Oil 05.001.095 and 1 spare filter.



Cleaning

By unscrewing the fixing bolts on both sides of the unit, it is possible to remove the lid in order to get easier access for cleaning. When mounting the lid again, make sure that both fixing bolts are properly inserted and tightened.

The device must be unplugged before it is cleaned. To clean the Maintenance Unit and the Adapters, wipe them off with a clean, soft and lintfree cloth dampened with ph-neutral detergent or with an alcohol based disinfectant that is either VAH listed, EPA registered or locally recognized. Follow the instructions provided by the manufacturer. Dry well.

Precaution:

- **Never sterilize the Maintenance Unit.**
- **Do not expose the Maintenance Unit to moisture.**
- **Should the Maintenance Unit have corroded parts, do not use it anymore and send it to the Synthes service center.**



Repairs and Technical Service

If the Maintenance Unit malfunctions, do not use it anymore and send it back to Synthes for repair.

If it is no longer possible or feasible to repair the tool it should be disposed off (refer to the following section "Disposal").

Other than the above-mentioned care and maintenance procedures, no further maintenance must be carried out by the user or by third parties.

The Maintenance Unit requires regular maintenance service, at least every 5 years, in order to maintain its functionality. This service has to be performed by the original manufacturer or an authorized service provider.

Warranty/Liability: The manufacturer takes no responsibility for damage resulting from neglected or unauthorized maintenance.

Disposal





In most cases faulty devices can be repaired (cf. previous chapter "Maintenance").

The European directive 2002/96/EC on waste electrical and electronic equipment (WEEE) applies to this device. This device contains materials that should be disposed of in accordance with environment protection requirements. Please observe national and local regulations.

Please send devices that are no longer used to the local Synthes representative. This ensures that they are disposed of in accordance with the national application of the respective directive. The tool may not be disposed of with household waste.



TROUBLESHOOTING

Problem	Possible Causes	Remedy
After pushing the start button the ERROR  LED lights up.	The START button only works when the Lid is closed.	Close the Lid and push the START button again.
	A Burr Attachment (05.001.045–05.001.050, 05.001.063 and 05.001.055) or Craniotome Attachment (05.001.059) is placed on the connectors, but the release sleeve is in the unlock position. This blocks the lubrication procedure.	Turn the release sleeve of the attachment (05.001.045–05.001.050, 05.001.063 and 05.001.055 or 05.001.059) into lock position and push the START button again.
	The fixing bolts are not properly inserted or tightened into the housing of the Maintenance Unit.	Insert both fixing bolts proper and tighten them.
The Maintenance Unit stops during the lubrication procedure and the ERROR  LED lights up.	The Lid has been opened during the lubrication procedure.	Close the Lid and repeat the lubrication procedure.
	The air pressure falls (<5 bar) during the lubrication procedure.	Open the Lid, set the pressure to 5–10 bars and close the Lid. Push the START button again.
ERROR  LED stays lit.	The oil level is too low.	Fill up oil.
	The air pressure is too low (<5 bar).	Set the air pressure to 5–10 bars.
	The Air Pen Drive is being lubricated through the attachment coupling.	The Air Pen Drive has to be lubricated with the Adapter for Maintenance Unit for Air Pen Drive (05.001.089) and through the air inlet/outlet.
	The Air Pen Drive is not set to the foot switch position during lubrication.	Set the Air Pen Drive to the foot switch position during lubrication.
ERROR  LED flashes.	The Maintenance Unit is faulty.	Send the Maintenance Unit to your Synthes Service Centre.
Lubrication procedure does not start, despite pushing the start button. The POWER ON LED lights up.	No handpiece or attachment is plugged to the Maintenance Unit or is detected.	Reconnect the handpiece or attachments (entirely). Push the start button again.

EXPLANATION OF SYMBOLS



Caution



This is a recognised component by UL.



Read the Instructions for Use before operating the device



The European directive 2002/96/EC on waste electrical and electronic equipment (WEEE) applies to this device. This device contains materials that should be disposed of in accordance with environment protection requirements. Please observe national and local regulations.



Manufacturer



Date of manufacture



Non sterile



Do not immerse device in liquids



Non sterile



The product is double insulated



Range of temperature



Indoor use only



Range of relative humidity



Air intake



Range of atmospheric pressure



Polarity of the supply voltage connector



Product is UL classified to the requirements of both the United States and Canada



The device meets the requirements of directive 93/42/EEC for medical devices.

It is authorized by an independent named site for which it bears the CE symbol.

SYSTEM SPECIFICATIONS

The device meets the following standards:

Medical electrical equipment – Part 1:
General requirements for basic safety and essential performance:

IEC 60601-1 (2012) (Ed. 3.1),
EN 60601-1 (2006) + A11 + A1 + A12,
ANSI/AAMI ES60601-1:2005/(R)2012,
CAN/CSA-C22.2 NO. 60601-1:14

Medical electrical equipment – Part 1-2:
Collateral Standard: Electromagnetic disturbances –
Requirements and tests:

IEC 60601-1-2 (2014) (Ed. 4.0),
EN 60601-1-2 (2015)

Medical electrical equipment – Part 1-6:
Collateral Standard: Usability:
IEC 60601-1-6 (2010) (Ed. 3.0) + A1 (2010)



UL classified with respect to electrical shock, fire and mechanical hazard only in accordance with ANSI/AAMI ES60601-1 and CAN/CSA-C22.2 No. 60601-1

Technical Data*

Maintenance Unit


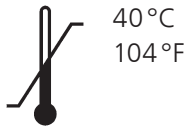


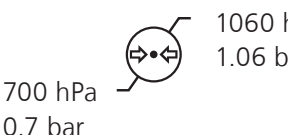
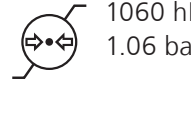
Weight:	~ 4700 g
Dimensions:	342 mm/205 mm/162 mm
Operating voltage:	24 VDC
Degree of protection against the penetration of water:	IP X0
Intake air pressure:	5 – 10 bar/70– 145 psi
Intake air quality:	Filtered air 5 µm, unoiled
Noise level in the operating position:	approx. 65 dB(A)

Power Supply

Weight:	~130 g (including cable)
Dimensions:	92 mm/40 mm/28 mm
Operating voltage:	100 VAC – 240 VAC, 50/60 Hz
Output voltage:	24 VDC
Output current:	500 mA
Degree of protection:	IP X0

*Technical data is subject to tolerances. Specifications are approximate and may vary from one device to another or as a result of power supply fluctuations.

Environmental Conditions

	Operation	Storage
Temperature	 10 °C 50 °F 40 °C 104 °F	 10 °C 50 °F 40 °C 104 °F
Relative humidity	 30 % 90 %	 30 % 90 %
Atmospheric pressure	 700 hPa 0.7 bar 1060 hPa 1.06 bar	 700 hPa 0.7 bar 1060 hPa 1.06 bar
Altitude	0–3000 m	0–3000 m

Transportation*

Temperature	Duration	Humidity
–29 °C; –20 °F	72 h	uncontrolled
38 °C; 100 °F	72 h	85 %
60 °C; 140 °F	6 h	30 %

*products have been tested according to ISTA 2A

Precautions:

- **Never sterilize the Maintenance Unit.**
- **The Maintenance Unit may not be stored or operated in an explosive atmosphere.**
- **Do not expose the Maintenance Unit to moisture.**

ELECTROMAGNETIC COMPATIBILITY

ACCOMPANYING DOCUMENTS ACCORDING TO

IEC 60601-1-2, 2014, Ed. 4.0

Emissions

Guidance and manufacturer's declaration – electromagnetic emissions

The Maintenance Unit 05.001.099 is intended for use in the electromagnetic environment specified below. The customer or the user of the Maintenance Unit 05.001.099 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Maintenance Unit 05.001.099 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Maintenance Unit is suitable for use in professional healthcare facility environment but not in home healthcare or special environment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Immunity (all devices)**Guidance and manufacturer's declaration – electromagnetic immunity**

The Maintenance Unit 05.001.099 is intended for use in the electromagnetic environment specified below. The customer or the user of Maintenance Unit 05.001.099 should assure that it is used in such an environment.

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 3 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1.5 kV line to line not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply lines	< 5% UT (0,5 cycle)	< 5 % UT (0.5 cycle)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Maintenance Unit 05.001.099 requires continued operation during power mains interruptions, it is recommended that the Maintenance Unit 05.001.099 is powered from an UPS.
IEC 61000-4-11	40% UT (5 cycles)	40 % UT (5 cycles)	
	70% UT (25 cycles)	70 % UT (25 cycles)	
	< 5% UT for 5s	< 5 % UT for 5 s	
Note: UT is the a.c.mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field	30 A/m	200 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-8			

Immunity (not life-supporting devices)**Guidance and manufacturer's declaration – electromagnetic immunity**

The Maintenance Unit 05.001.099 is intended for use in the electromagnetic environment specified below. The customer or the user of the Maintenance Unit 05.001.099 should assure that it is used in such an environment.

Precaution: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Electromagnetic Environment – Guidance

Portable and mobile RF communications equipment should be used no closer to any part of the Maintenance Unit 05.001.099, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test standard	IEC 60601 test level	Compliance level	Recommended separation distance c
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V1 = 10 Vrms 150 kHz to 230 MHz	$d = 0.35 \sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz	E1 = 10 V/m 80 MHz to 800 MHz	$d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 800 MHz to 2.7 GHz	E2 = 10 V/m 800 MHz to 6.2 GHz	$d = 0.7 \sqrt{P}$ 800 MHz to 2.7 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b

Interference may occur in the vicinity of equipment marked with the following symbol:



Immunity test standard	IEC 60601 test level	Compliance level	Recommended separation distance c
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Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Maintenance Unit 05.001.099 is used exceeds the applicable RF compliance level above, the Maintenance Unit 05.001.099 or the device, which contains it should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device containing the Maintenance Unit 05.001.099.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

c Possible shorter distances outside ISM bands are not considered to have a better applicability of this table.

Recommended separation distances (not life-supporting devices)**Recommended Separation Distances between portable and mobile RF Communications Equipment and the Maintenance Unit 05.001.099**

The Maintenance Unit 05.001.099 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Maintenance Unit 05.001.099 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Maintenance Unit 05.001.099 as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter		
	m		
w	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 6.2 GHz
	$d = 0.35 \sqrt{P}$	$d = 0.35 \sqrt{P}$	$d = 0.7 \sqrt{P}$
0,01	3.5 cm	3.5 cm	7 cm
0,1	11 cm	11 cm	23 cm
1	35 cm	35 cm	70 cm
10	1.1 m	1.1 m	2.3 m
100	3.5 m	3.5 m	7 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

ORDERING INFORMATION

Maintenance Unit and Adapters

05.001.099	Maintenance Unit, for EPD and APD (includes 05.001.094)
05.001.095	Synthes Maintenance Oil, 40 ml, for EPD and APD
05.001.089	Adapter, for Maintenance Unit, for APD
05.001.064	Adapter, for Maintenance Unit, for Burr Attachment XL and XXL

Spare parts

05.001.094	Maintenance kit with oil and filter, for EPD and APD
60032599	Lid, for Maintenance Unit 05.001.099
50160470	Fixing bolt, for Maintenance Unit 05.001.099
50160473	Pneumatic connection, for Maintenance Unit 05.001.099
50160471	Oil cap, for Maintenance Unit 05.001.099
50161414	Power Supply
05.001.130	Power Cord, two-pole (AT, BE, BG, CH, CN, CZ, DE, DK, ES, FI, FR, GR, HU, ID, IT, NL, NO, PL, PR, PT, RO, RU, SE, SK, TR)
05.001.131	Power Cord, two-pole (Argentina, Brazil, Canada, Colombia, Korea, Mexico, Taiwan, USA)
05.001.132	Power Cord, two-pole (Great Britain, Ireland, Hong Kong, Malaysia, Singapore)
05.001.133	Power Cord, two-pole (Australia, New Zealand, Uruguay)
05.001.134	Power Cord, two-pole (Japan)
05.001.135	Power Cord, two-pole (India, South Africa)

Precaution: The device shall only be operated with the country specific Power Cord provided by the supplier. One power cord is supplied with each Maintenance Unit.

