

Universal Battery Charger II

User Manual



Table of Contents

Introduction	General Information	3
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Description of the Device	• Front view	7
	• Rear view	7

Operating the Device	Starting the System	8
	Charging the Battery	9
	• Charger bay	9
	• Charging the battery	10
	• Temperature monitoring	11
	• Charging new batteries or batteries not recently used	11
	• Errors during charging	11
	Checking and Refreshing Batteries	12
	• Battery Power Line and SBD batteries	12
	• Battery Power Line II and SBD II batteries	14
• Trauma Recon System power module	16	

Care and Maintenance	Storing Batteries	17
	30% State of Charge	18
	Cleaning	19

Care and Maintenance	Repair and Technical Service	20
	Disposal	21

Troubleshooting		22
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Technical Data	Device Specifications	25
	Minimum required Firmware version of UBC II	26
	Environmental Conditions	27
	Applicable Standards	28
	Electromagnetic Compatibility	29
	Permissible Battery Types	33
	• Battery for Battery Power Line	33
	• Battery for Battery Power Line II	33
	• Power module for Trauma Recon System	33
	• Batteries for Small Battery Drive	34
• Battery for Small Battery Drive II	34	

Explanation of Symbols Used	Symbols for Operating the Charger	35
	Symbols on the Charger	36

Ordering Information	37
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Introduction

General Information

Introduction

Associated device systems with these instructions for use are the Universal Battery Charger II (05.001.204).

The Universal Battery Charger II consists of the charger (05.001.204). This charger is also supplied with a country-specific power cord and four slot cover sets (05.001.228). The charger may only be used with the supplied power cord.

Refer to section 'Ordering Information' for specific devices in scope.

The Universal Battery Charger II (UBC II), allows the following Synthes batteries/power modules to be automatically charged and manually checked. The below table further also highlights the compatibility between handpieces and batteries/power modules.

System	Handpieces	Battery/Power Module
Battery Power Line	530.605	530.620* (14.4 V, NiMH)
	530.610	
	530.615	
Battery Power Line II	530.705	530.630 (14.8 V, Li-Ion)
	530.710	
	530.715	
Trauma Recon System	05.001.201 05.001.240	05.001.202 (25.2 V, Li-Ion)
Small Battery Drive	532.001/532.010	532.003* (12 V, NiCd) 532.033* (14.4 V, NiCd)
Small Battery Drive II	532.101/532.110	532.103 (14.4 V, Li-Ion)

If required, Battery Power Line battery (530.620*) and Small Battery Drive II/Small Battery Drive batteries (532.003*, 532.033*) can also be refreshed with the charger.

Warning: The battery for the Power Drive (530.200) cannot be charged with the UBC II. Please use the UBC item number 530.600 or 530.601.

Intended Use

The Universal Battery Charger II (05.001.204) is intended for charging and/or conditioning of authorized Synthes batteries and power modules.

* Phased-out and no longer available for order.

Indications

There are no device specific indications associated with the UBC II device as it is not patient contacting and is not used during a surgical procedure.

Contraindications

There are no device specific contraindications associated with the UBC II device as it is not patient contacting and is not used during a surgical procedure.

Potential Adverse Events, Undesirable Side Effects and Residual Risks

The UBC II device is not patient contacting and is not used during a surgical procedure.

DePuy Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The adverse events/side effects are based upon the implant devices rather than the instruments. Specific adverse events/side effects for the implants can be found in the respective Synthes implant instructions for use.

Patient Target Group

There are no restrictions on patient population as the UBC II device is not patient contacting and is not used during a surgical procedure.

Intended User

The Universal Battery Charger II is intended to be used by qualified health care professionals.

Expected Clinical Benefits

Not applicable. The device is an accessory which is used to enable specific Synthes batteries/power modules to meet their function.

Treatment before Device is Used

Warning: For safety reasons, please read the IFU carefully before using UBC II.

Combination of Medical Devices

The UBC II is a standalone device, the compatible batteries/power modules which can be charged and refreshed, as well as the power cords are listed in the section: 'Ordering Information'.

General Warnings and Precautions

Warnings:

- Do not use the device in the direct vicinity of radiators or other heat emitting devices, as these can affect the device.
- The device must not come into direct or indirect contact with the patient. As the charger is not a sterile product, it must not be used in the sterile area of the operating room. However, the device may be used in the non-sterile part of the operating room.
- The use of high frequency (HF) equipment for tissue coagulation can cause electromagnetic interferences – in this case the cables should be separated as far as possible.
- Do not sterilize, wash, rinse, drop or apply force to the UBC II. This will destroy it with possible secondary damage.
- Do not expose the device to direct sunlight or moisture.
- Do not dismantle, open, short-circuit or manipulate the device.
- Before operating the device, visually inspect the device for damage and wear (e.g. unrecognizable markings, missing or removed part numbers, corrosion, etc.). Do not use any component if damage is apparent.

Precautions:

- The device may only be used with the supplied power cord. Only connect to a power supply with grounding, a rated voltage between 100 V and 240 V and a network frequency range of 50 or 60 Hz.
- The device may only be operated on an even, dry surface that is sufficiently strong to hold its weight. Place the device on a non-slip, stable base.
- Do not dismantle, open, short-circuit or manipulate the device. Risk of electric shock!
- The charging station should always be turned on when a battery is in the charging bay. This ensures availability and prevents discharge.
- If the device drops on the floor, fragments may split off. This represents a danger for the user as these fragments may be sharp.
- Should the device have corroded parts, do not use it anymore and send it to the DePuy Synthes Service Center.
- If the device is damaged, contact the DePuy Synthes representative. Do not use damaged or faulty devices. Send the device to the DePuy Synthes representative for repairs.

Storage and Transport

All batteries/power modules should be removed for transporting the charger.

The UBC II with a minimum of Firmware 17.2 allows the user to charge specific DePuy Synthes Lithium Ion batteries to 30% of their capacity for transportation in aircraft cargo bays. Please refer to the section 30% State of Charge within this IFU for detailed information.

Use the original packaging for shipping and transport. If this is no longer available, please contact the DePuy Synthes representative.

The same environmental conditions apply for transport as for storage.

Warnings:

- **The device is designed to be operated and stored in closed rooms. Do not use the device in the direct vicinity of radiators or other heat emitting devices, as these can affect the device.**
- **Do not store/use the device in the presence of oxygen, nitrous oxide or a mixture consisting of flammable anesthetics and air.**

Warranty

The warranty for the device is null and void if the device has not been used properly or the guarantee seal has been damaged. The manufacturer does not accept liability for damage resulting from repairs or maintenance carried out by unauthorized sites. For a complete warranty statement, please contact DePuy Synthes Customer Service.

Description of the Device

Front view

- 1 Charger bays (24)
- 2 Symbols for battery type
- 3 ON/OFF blue LED
- 4 Control symbols for each charging bay
- 5 Ventilation holes



Rear view

- 6 Ventilation holes
- 7 Power switch
- 8 Fuses: 225 AT/250 V
- 9 Power cord connection



The Slot Covers Set (05.001.228) consists of three plastic elements which can be used to cover the non-used slots of the charger.



Operating the Device

Starting the System

Before starting for the first time, ensure that the power switch is set to ①. The device can only be connected to the power supply using the supplied power cord. Set the power switch to I to turn the device on (fig. 1). The ON/OFF blue LED on the front of the device shows that it is working properly (fig. 2). If the blue LED flashes, the device must be sent in for control.

If the symbol ⚠ for a single charger bay is red (fig. 3) before the battery is inserted, this charger bay is faulty. In this case, batteries/power modules can still be charged in the other charger bays, but it is recommended that the device be sent to the local DePuy Synthes representative for repairs.

Warning: Ensure that the ventilation holes in the base and side of the device are not covered by towels or other objects.

Precaution: Ensure that the power cord can always be disconnected immediately from mains supply.



Fig. 1

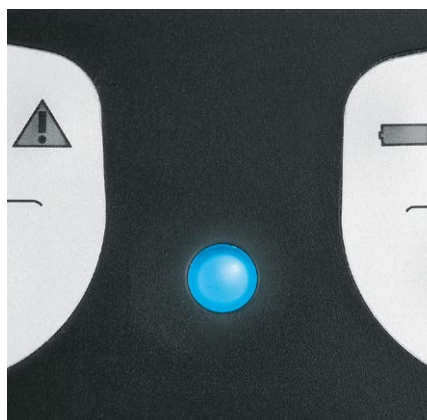


Fig. 2



Fig. 3

Operating the Device

Charging the Battery

Charger bay

The device is fitted with four independent charger bays. Each of these has three slots for the following batteries (fig. 1):

- 1** Battery Power Line and Battery Power Line II batteries (530.620, 530.630)
- 2** Trauma Recon System Power Module (05.001.202)
- 3** Small Battery Drive /SBD and Small Battery Drive II/SBD II batteries (532.003, 532.033, 532.103)

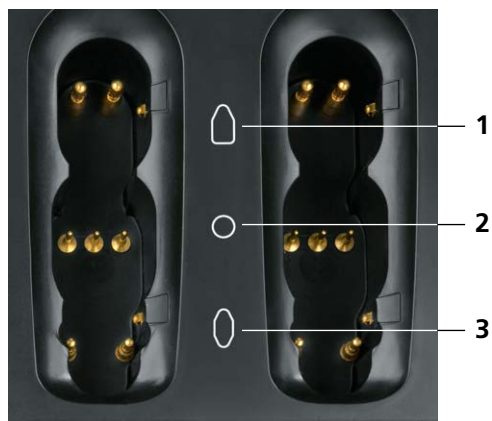



Fig. 1

Charging the battery

Place the battery to be charged in the proper direction into the corresponding slot of an empty charger bay. Ensure that the battery is fitted correctly and is identified by the device (symbol  is yellow). See fig. 2.

Only one battery can be charged in each charger bay at a time. All charger bays can, however, be used simultaneously with any combination of battery types.


Warnings:

- **Insert the battery into the correct slot.**
- **Do not charge damaged batteries with UBC II.**
Inspect battery for cracks and damage.
- **Do not insert any objects other than authorized Synthes batteries into the charger, as the contacts may otherwise be damaged.**

Precaution:

- **If the symbol does not light up after the battery is inserted, remove the battery and insert again or insert into another charger bay.**
- **Only use fully charged batteries to avoid delays during surgery.**

Depending on the charge status and type of battery, it can take from about 15 minutes to around 60 minutes to charge.

Once the battery is fully charged, the symbol  is green and the charger switches to maintenance charge (fig. 3). The battery can be left in the charger. Leave the device switched on to ensure that the battery is always fully charged.


If the battery is removed from the charger before the symbol  lights up green, it will not be fully charged.





Fig. 2



Fig. 3

Temperature monitoring

The battery and the charger heat up during the charging process. The ventilation holes should therefore not be covered.

If the battery temperature is too high, the symbol  starts flashing (fig. 4). To protect the battery, the device stops charging until the battery has cooled down. Do not remove the battery from the charger if this occurs until the symbol  stops flashing and stays yellow. The charging time will be longer in this case.

Warning: Always control the temperature of the device to prevent overheating and possibly harming.

Charging new batteries or batteries not recently used

Battery Power Line battery (530.620) or Small Battery Drive/SBD batteries (532.003, 532.033) that have not been used for a long period of time and that have not been stored in an activated charger do not reach their maximum performance for several charging and discharging cycles. The charger can be used to check the battery status and to refresh the battery (see page 11).

Errors during charging

The following errors may occur while charging a battery:

Symbol flashes (fig. 4)

The battery is too hot and has to cool down before the charging process can be automatically resumed. The battery should be left in the charger until the battery symbol lights up green. Otherwise, it is not ensured that the battery is fully charged.

Symbol is red (fig. 5)

The battery is faulty and has to be replaced.

No symbol lights up

The battery has not engaged in the charging bay or has not been recognized by the device. Remove the battery and insert again or use another charger bay.



Fig. 4



Fig. 5

Checking and Refreshing Batteries

1. Battery Power Line and Small Battery Drive II/SBD batteries

The charger enables Battery Power Line battery (530.620) and Small Battery Drive/SBD batteries (532.003, 532.033) to be refreshed and checked.

It will be indicated if the battery performance is sufficient or if the battery needs to be replaced.

The following factors will affect the battery performance:





- Unused, new battery
- Battery not used for a longer period

In these cases a battery will only reach its maximum performance after several charging and discharging cycles. The check and refresh function ensures that the battery regains its maximum performance again.

- Old battery

The battery performance declines with age and usage. With the check function it can be seen if the battery performance is sufficient. In some cases, batteries that are too old can no longer be refreshed.

When required, the check and refresh function is started manually, as outlined below.

After the battery is inserted, the symbol  lights up yellow. To refresh and check the battery, press the button with the exclamation mark  for at least 2 seconds (fig. 1) until the symbol  lights up yellow (fig. 2). The device then carries out the process. The symbol  is yellow throughout this time.

Precautions:





- To recharge batteries normally, do not press the exclamation mark button .
- Do not remove the battery from the charger bay as long as the symbol  is yellow. Wait until the process has ended and the symbols  or  light up. Only then is the battery status clearly assessed.





Fig. 1



Fig. 2

Completion of the process is indicated as follows:

- Symbol  is green (fig. 3): Battery has been successfully refreshed, checked and charged.
- Symbol  is red (fig. 4): Either the battery is faulty or performance is insufficient. The battery must be disposed of.

The entire process (refreshing and checking battery status) takes around 10 hours and should only be carried out if there is enough time to do so.

A battery can be charged, checked or refreshed independently in each charger bay.

Precautions:

- **Checking the battery status and refreshing the battery have an impact on the battery. If this is carried out frequently the lifespan of the battery can be affected.**
- **The process is interrupted if there is a power cut or a switch to the emergency power supply and will then have to be restarted.**



Fig. 3







Fig. 4

2. Battery Power Line II and Small Battery Drive II/SBD II batteries

The charger enables Battery Power Line II and Small Battery Drive II/SBD II batteries (530.630, 532.103) to be checked. It will be indicated if the battery performance is sufficient or if the battery needs to be replaced.

Due to the very low self-discharging rate of Lithium-based batteries a refresh function is not required.

When required, the check function is started manually, as outlined below.

After the battery is inserted, the symbol  lights up yellow. To check the battery, press the button with the exclamation mark  for at least 2 seconds (fig. 5) until the symbol  lights up yellow (fig. 6). The device then carries out the process. The symbol  is yellow throughout this time.

Precautions:





- To recharge batteries normally, do not press the exclamation mark button .
- Do not remove the battery from the charger bay as long as the symbol  is yellow (fig. 6). Wait until the process has ended and the symbols  or  light up. Only then is the battery status clearly assessed.





Fig. 5



Fig. 6

Completion of the process is indicated as follows:

- Symbol  is green (fig. 7): Battery has been successfully checked and charged.
- Symbol  is red (fig. 8): Either the battery is faulty or performance is insufficient. The battery must be disposed of.

The entire process (checking battery status) takes around 3 hours and should only be carried out if there is enough time to do so.

A battery can be charged or checked independently in each charger bay.

Precautions:

- **Checking the battery status has an impact on the battery. If this is carried out frequently the lifespan of the battery can be affected.**
- **The process is interrupted if there is a power cut or a switch to the emergency power supply and will then have to be restarted.**



Fig. 7







Fig. 8



3. Trauma Recon System power module

To ensure that the Trauma Recon System (05.001.201, 05.001.240) can operate safely and reliably, the Trauma Recon System power module (05.001.202) has to be checked at periodical intervals. It will be indicated if the power module performance is sufficient or if the power module needs to be replaced.

The charger will indicate the necessity, but the user can choose a convenient time to check the power module, as this can take around 4 hours.

When it needs to be checked, the symbol  flashes (fig. 9). The check needs to be carried out within the next 3 charging cycles. This is done by pressing the exclamation mark button  for at least 2 seconds (fig. 10). The symbol light  goes out and the symbol  stops flashing and stays yellow (fig. 11). If the check is not carried out within the next 3 charging cycles, the device carries out the check automatically.

Completion of the process is indicated as follows:

- Symbol  is green (fig. 7 on previous page): power module has been checked, charged and is ready to use.
- Symbol  is red (fig. 8 on previous page): power module has been checked, is not charged and cannot be used; the red service indicator lamp on the power module lights up. Send in the power module for servicing.

A power module can be charged or checked independently in each charger bay.



Fig. 9



Fig. 10



Fig. 11

Operating the Device

Storing Batteries

Immediately recharge batteries and the power module after each use.

Any Small Battery Drive/SBD batteries (532.003, 532.033) or Battery Power Line battery (530.620) that are not used should always be stored in the activated charger (maintenance charge). This guarantees that the batteries are always fully charged and ready to use.

It is not necessary to store Trauma Recon System power module (05.001.202), Battery Power Line II battery (530.630) and Small Battery Drive II/SBD II battery (532.103) in the charger. Once charged they can be stored outside the charger without any noticeable charge difference due to a very low self-discharging rate of Lithium-based batteries.

Warning: Unusable or faulty batteries/power modules must not be reused and should be disposed of in an environmentally friendly manner and in accordance with national regulations. For further information, refer to the section 'Disposal' in this IFU.

Operating the Device







30% State of Charge

When transporting Lithium Ion batteries in aircraft cargo bays, rules and regulations require batteries to only have a maximum of 30% state of charge.

The UBC II with a minimum firmware version 17.2 allows the user to charge the following Synthes Lithium Ion batteries to 30% of their capacity for transportation:

- Battery Power Line II Battery (530.630)
- Small Battery Drive II Battery (532.103)

Operation Instructions

1. Insert the battery into the corresponding charger bay.
As soon as the battery is placed in the UBC II, the symbol  will light up yellow (Fig. 1).
2. To charge the battery to 30% state of charge (SOC), the button with the exclamation mark  has to be pressed five times (5x) within 5 seconds (Fig. 1).
3. As a confirmation for the start of the 30% SOC, all LED's flash four times (4x) (Fig. 2).
4. When the yellow symbols  and  light up, the UBC II is performing the 30% SOC function. This will take between 30 and 90 minutes depending on the charge status and type of battery (Fig. 3).
5. Once the battery has been charged to 30% SOC, the green symbol  lights up and the red symbol  flashes (Fig. 4).
6. The batteries are now ready for transportation. They must not be used in the OR in this status as they are not fully charged. Once the battery has been removed from the charger, the SOC function switches off.

Notes:

- If the battery has been left in the bay since the last charge, the 30% SOC function can only be started if the battery is removed from the charger and placed once again into the charger bay by the user.
- If the exclamation mark was not pressed five times (5x) within 5 seconds, then the step must be repeated.
- If the battery is removed during the 30% SOC function, then the process needs to be restarted.
- Please note that during the SOC function the other charging bays can be used as usual.



Fig. 1



Fig. 2



Fig. 3



Fig. 4

Care and Maintenance

Cleaning

The device must be unplugged before it is cleaned. To clean the charger, wipe it off with a clean, soft and lint-free cloth dampened with deionized water and dry prior to reprocessing.

Then wipe the charger with a new, clean, soft and lint-free cloth dampened with a minimum of 70% alcohol-based disinfectant for thirty (30) seconds. A disinfectant that is VAH (Verbund für Angewandte Hygiene) listed, EPA (Environmental Protection Agency) registered or locally recognized is recommended. This step has to be repeated two (2) additional times using a new, clean, soft and lint-free cloth dampened with a minimum 70% alcohol-based disinfectant each time. Please follow the safety instructions given by the manual of the disinfectant manufacturer which is selected.

Whenever it is cleaned, the device should be checked to ensure it is working properly and is not damaged.

Maintenance of the device is not required.

If there are any faults, please send the device to a DePuy Synthes representative (see next section).

Precautions:

- **Danger of electric shock! Unplug before cleaning.**
- **Do not sterilize, wash, rinse, drop or apply force to the UBC II. This will destroy it with possible secondary damage.**
- **If necessary, clean the contacts in the charger bays using utmost care.**
- **Do not to spray the contacts or touch both contacts at the same time with the damp cloth due to danger of short circuiting. Avoid contact of the device with fluids.**

Warning: Make sure that no solution enters the device.



Care and Maintenance

Repair and Technical Service

The device should be sent to the DePuy Synthes representative for repair if it is faulty or malfunctions.

The same applies if the ON/OFF blue LED does not light up or flashes when the device is switched on.

To prevent damage of the charger during shipping use the original packaging to return devices back to DePuy Synthes. If this is not possible, please contact the DePuy Synthes representative.

When shipping Synthes batteries in aircraft carrier bays, please follow the instructions in the section 30% State of Charge of this IFU as well as the IFU of the device used.

Precautions:

- **The manufacturer shall assume no responsibility for damage resulting from unauthorized repair.**
- **Users or third parties should not carry out repairs themselves.**

Disposal

In most cases faulty chargers can be repaired (see previous section "Repair and Technical Service").



The European directive 2012/19/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 DePuy Synthes representative. This ensures that they are disposed of in accordance with the national application of the respective directive.

Faulty batteries may not be reused and should be disposed of in an environmentally friendly manner and in accordance with national regulations.

Only return Trauma Recon System power module (05.001.202) to the DePuy Synthes representative, observing the applicable instructions for use.


Warnings:





- **Do not dispose of contaminated products with household waste.**
- **Unusable or faulty batteries/power modules must not be reused and should be disposed of in an environmentally friendly manner and in accordance with national regulations.**



Precaution: The UBC II should be disposed of in an environmentally friendly manner and in accordance with national regulations.

Troubleshooting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Problem	Possible cause	Solution
ON/OFF blue LED does not light up.	Charger is switched off.	Switch on power switch.
	Power cord is not plugged in.	Connect power cord to the connection on the charger and plug into the wall socket. Then switch on the power switch on the charger.
	Power supply is interrupted (e.g. faulty fuse).	Check power supply. Replace fuse if necessary.
	Charger is faulty.	Send the charger to the DePuy Synthes representative for repairs.
ON/OFF blue LED flashes.	Charger is faulty.	Send the charger to the DePuy Synthes representative for repairs.
Although the battery/power module is inserted, no symbol lights up on the charger bay.	Battery/power module is not fully inserted.	Ensure that the battery/power module is inserted properly.
	Contacts in the charger bay are dirty.	Carefully clean contacts.
	Battery/power module was not recognized by the charger.	Use another free charger bay.
	Battery/power module is faulty.	Test the battery/power module in another charger bay and dispose of if necessary.
	Charger bay is faulty.	Send the charger to the DePuy Synthes representative for repairs.
The symbol  is red when the battery/power module is inserted.	Battery/power module is faulty.	Replace battery/power module.
	Firmware has to be updated	Check firmware version on the sticker, which is visible on the underside of the charger and compare with the minimum required firmware listed on page 25. Send the charger to DePuy Synthes representative for a software update.

Problem	Possible cause	Solution
The symbol  is red when the charger is switched on before the batteries/power modules are inserted.	Charger bay is faulty.	Use another free charger bay. Send the charger to the DePuy Synthes affiliate for repairs as soon as possible.
Symbol  flashes yellow during the charging process.	Battery/power module is too hot.	Leave battery/power module inserted in the charger bay. Charger automatically continues the charging process once the battery/power module has cooled down.
Symbol  does not light up yellow when the button  is pressed.	Button was released too soon.	Hold button down for at least 2 seconds.
	Charger bay is faulty.	Select another free charger bay. Send the device to the DePuy Synthes representative for repairs as soon as possible.
	Charger has an error.	Switch off charger, then switch back on after 5 seconds. If the ON/OFF blue LED flashes, send the device to the DePuy Synthes representative for repairs.
It is not possible to insert the battery/power module into the slot.	Wrong slot.	Select correct slot and re-insert battery/power module.
	Non-authorized battery/power module.	Check battery/power module type.
	Contacts in the slot bent.	Use another free charger bay. Send the charger to the DePuy Synthes representative for repairs as soon as possible.
Charger makes loud noises.	Ventilation holes on the sides, back or base are covered and/or the device is next to a heat source. Automatic cooling is on full power.	Expose ventilation holes and/or ensure that the device is not next to a heat source.

Problem	Possible cause	Solution
Battery/power module performance is low.	Insufficient battery/power module status.	Refresh battery (see page 11 ff). Only possible with Battery Power Line battery (530.620) and Small Battery Drive/SBD batteries (532.003, 532.033).
	Expected battery/power module life is reached.	Test battery/power module (see page 11 ff). If the red display  lights up, replace battery/power module.
	Battery/power module is not ready for use.	Charge battery/power module until symbol  is green.
	Power Tool or attachment is sluggish, i.e. as a result of insufficient maintenance.	Send Power Tool and attachments to DePuy Synthes representative to be checked.
Battery/power module is visibly damaged.	Battery/power module was exposed to excessive heat.	Replace battery/power module.
	Battery/power module was washed, disinfected or sterilized.	Replace battery/power module.
	Battery/power module was short-fused by metal objects.	Replace battery/power module.
	Battery/power module fell on the floor.	Replace battery/power module.
UBC II is visibly damaged.	UBC II was exposed to excessive heat.	Replace UBC II.
	UBC II was washed, disinfected or sterilized.	Replace UBC II.
	UBC II was short-fused by metal objects.	Replace UBC II.
	UBC II fell on the floor.	Replace UBC II.

Please also observe the instructions for use of the corresponding Power Tools.

If the recommended solutions do not work, please contact your DePuy Synthes representative.

Technical Data

Device Specifications

Performance Characteristics of the Device

DePuy Synthes has established the performance and safety of UBC II and that it represents a state of the art medical surgical power tool and performs as intended for the function according to its instructions for use and labeling.

Universal Battery Charger II

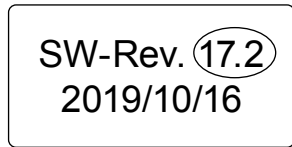
Dimensions (L2B2H)	310 mm 2 220 mm 2 175 mm
Weight	4.8 kg
Operating voltage	100 V – 240 V, 50/60 Hz
Operating current	1.2–2.8 A AC
Mains rated input	250 W
Protection class	I, EN/IEC 60601-1
Protection type by casing	IPX0, EN/IEC 60601-1
Fuses	225 AT/250 V
Operating mode	Continuous operating mode
Sterilization	Device must not be sterilized

Minimum required Firmware version of UBC II







In order that the different battery types can be recognized and charged by UBC II, the correct Firmware version is required. The table below outlines the requirements for each battery type. If required, send the charger to a DePuy Synthes representative for a firmware update.

System	Battery/power module	Minimum required Firmware version of UBC II
Battery Power Line	530.620 (14.4 V, NiMH)	2.0 (no sticker on the underside of the charger)
Trauma Recon System	05.001.202 (25.2 V, Li-Ion)	2.0 (no sticker on the underside of the charger)
Small Battery Drive	532.003 (12 V, NiCd)	2.0 (no sticker on the underside of the charger)
	532.033 (14.4 V, NiCd)	2.0 (no sticker on the underside of the charger)
Small Battery Drive II	532.103 (14.4 V, Li-Ion)	11.0 (sticker visible on the underside of the charger*)
Battery Power Line II	530.630 (14.8 V, Li-Ion)	14.0 (sticker visible on the underside of the charger*)
30% State of Charge	532.103 (14.4 V, Li-Ion)	17.2 (sticker visible on the underside of the charger*)
	530.630 (14.8 V, Li-Ion)	

* The UBC II device features a sticker on the underside which indicates the latest firmware version applicable to the device.



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	 500 hPa 1060 hPa	 500 hPa 1060 hPa
Altitude	0–5000 m	0–5000 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

Technical Data

Applicable Standards

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 General Medical Equipment as to electrical shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES60601-1(2005) + AMD 1(2012) CAN/CSA – C22.2 No. 60601-1(2014)

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 (2013)

Electromagnetic Compatibility

Table 1: Emissions

Guidelines and manufacturer’s declaration – electromagnetic emissions

The Synthes Universal Battery Charger II is intended for use in the electromagnetic environment specified below. The customer or the user of the Synthes Universal Battery Charger II should assure that it is used in such an environment.

Emission tests	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Synthes Universal Battery Charger II uses RF energy only for its internal function. Therefore, its RF emission is very low and it is not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The emissions characteristic of this equipment make it suitable for use in professional environment in industrial areas and hospitals. If it is used in a residential environment this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2: Immunity (all devices)

Guidelines and manufacturer's declaration – electromagnetic immunity

The Synthes Universal Battery Charger II is intended for use in the electromagnetic environment specified below. The customer or the user of the Synthes Universal Battery Charger II 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 the 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	±2 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 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5 % U_T (0.5 cycle) 40 % U_T (5 cycles) 70 % U_T (25 cycles) <5 % U_T for 5 s	<5 % U_T (0.5 cycle) 40 % U_T (5 cycles) 70 % U_T (25 cycles) <5 % U_T for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Synthes Universal Battery Charger II requires continued operation during power mains interruptions, it is recommended that the Synthes Universal Battery Charger II is powered from an UPS.
Note: U_T is the A.C. mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	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.

Table 3: Immunity (not life-supporting devices)

Guidance and manufacturer’s declaration – electromagnetic immunity

The Synthes Universal Battery Charger II is intended for use in the electromagnetic environment specified below. The customer or the user of the Synthes Universal Battery Charger II should assure that it is used in such an environment.

Warning: Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device 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 Synthes Universal Battery Charger II, 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
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:

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 Synthes Universal Battery Charger II is used exceeds the applicable RF compliance level above, the Synthes Universal Battery Charger II should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Synthes Universal Battery Charger II.

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

Table 4: Recommended separation distances (not life-supporting devices)

Recommended separation distances between portable and mobile RF communications equipment and the Synthes Universal Battery Charger II

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 0.35 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 6.2 GHz $d = 0.7 \sqrt{P}$
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.

Technical Data

Permissible Battery Types

Battery for Battery Power Line

Part NO.	530.620*
Operating voltage (rated)	14.4 V
Battery capacity	2 Ah/28.8 Wh
Battery	NiMH
Typical charging time	<60 min



Battery for Battery Power Line II

Part NO.	530.630
Operating voltage (rated)	14.8 V
Battery capacity	1.5 Ah/22.2 Wh
Battery	Li-Ion
Typical charging time	<60 min



Power module for Trauma Recon System

Part NO..	05.001.202
Operating voltage (rated)	25.2 V
Battery capacity	1.2 Ah/30.24 Wh
Battery	Li-Ion
Typical charging time	<60 min



* Phased-out and no longer available.
Subject to technical modifications.

Batteries for Small Battery Drive/Small Battery Drive

Part NO.	532.003*	532.033*
Operating voltage (rated)	12 V	14.4 V
Battery capacity	0.5 Ah/6 Wh	0.5 Ah/7.2 Wh
Battery	NiCd	NiCd
Typical charging time	<60 min	<60 min



Battery for Small Battery Drive II/Small Battery Drive II

Part NO.	532.103
Operating voltage (rated)	14.4 V
Battery capacity	1.2 Ah/17.28 Wh
Battery	Li-Ion
Typical charging time	<60 min





Warning: The device may only be used for the authorized Synthes batteries. The battery for the Power Drive (530.200) cannot be charged with the UBC II. Please use the UBC item number 530.600 or 530.601.


* Phased-out and not longer available.
Subject to technical modifications.


Explanation of Symbols Used


Symbols for Operating the Charger


 Battery is charged. The charger has switched to maintenance charge and checks that the battery is always fully charged and ready to use.


 Yellow symbol: the battery is partially charged. The charging process is not completed. Flashing yellow symbol: the battery is too hot.


 The battery is faulty and has to be replaced or the charger bay is faulty.

 Button to check and refresh batteries and to check Battery Power Line II, Small Battery Drive II/SBD II batteries or power modules. Button to start the 30% state of charge feature.

 Symbol is yellow: the process to check and refresh batteries and to check Battery Power Line II, Small Battery Drive II/SBD II batteries or power modules is ongoing. Flashing yellow symbol: the inserted Trauma Recon System power module should be checked.

 Symbol for Battery Power Line and Battery Power Line II batteries (530.620, 530.630)

 Symbol for Trauma Recon System power module (05.001.202)

 Symbol for Small Battery Drive/SBD and Small Battery Drive II/SBD II batteries (532.003, 532.033, 532.103)

Explanation of Symbols Used

Symbols on the Charger



Read the provided instructions for use before operating the device.



Caution



The European directive 2012/19/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. See section entitled "Disposal".



Legal manufacturer



Manufacturing date



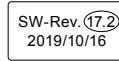
Product is UL Classified to the requirements of both the United States and Canada.



The device meets the requirements of the Medical Device Regulation (EU) 2017/745.



Environment-friendly use period according to China RoHS.



Firmware version of UBC II



Fuses: 225 AT/250 V



Non sterile



Temperature



Relative humidity



Atmospheric pressure



Do not use if package is damaged



Reference number



Lot number



Serial number



Packaging unit



INMETRO Ord. 350 certified

Ordering Information

Battery charger		Device(s)	Material(s)	Standard(s)
05.001.204	Universal Battery Charger II	UBC II	Stainless Steel (AU Plated) Aluminium Copper-zinc(AU Plated) ABS PE Silicone	n/a DIN EN 573 n/a n/a n/a n/a
Batteries				
05.001.202	Power Module, for Trauma Recon System			
530.630	Battery for Battery Power Line II			
532.103	Battery for Nos. 532.101 and 532.110	Batteries	Stainless Steel Copper-zinc (AU-plated) ABS PPSU PEEK POLYESTER PVS-G PA	ISO7153-1 n/a n/a n/a n/a n/a n/a
Power cord				
05.001.140	Power Cord, three-pole (North America)	Power Cord(s)	Copper-zinc (nickel-plated) PBTP PVC	n/a n/a n/a
Slot Covers Set				
05.001.228	Slot Covers Set, for Universal Battery Charger II	Slot Covers	TPE	n/a

Note: For additional information, please refer to the package insert or www.e-ifu.com.

For detailed cleaning and sterilization instructions, please refer to www.depuy-synthes.com/hcp/cleaning-sterilization or sterilization instructions, if provided in the instructions for use.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.
Some devices listed in this technique guide may not have been licensed in accordance with Canadian law and may not be for sale in Canada.
Please contact your sales consultant for items approved for sale in Canada.
Not all products may currently be available in all markets.



Manufactured or distributed by:

Synthes USA, LLC
1101 Synthes Avenue
Monument, CO 80132

Synthes GmbH
Luzernstrasse 21
4528 Zuchwil, Switzerland

To order (USA): 800-523-0322
To order (Canada): 844-243-4321

Note: For recognized manufacturer, refer to the product label.

www.depuysynthes.com

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