

UNIVERSAL BATTERY CHARGER II

Instructions for Use



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General Information

Introduction

The Universal Battery Charger II (05.001.204) is 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 Batteries, Power Module and Power Unit to be automatically charged and manually checked, as shown in the table below.

Devices	Handpieces	Battery/Power Module/Power Unit
Battery Power Line II	530.705 530.710 530.715	530.630 (14.8 V, Li-Ion)
Trauma Recon System	05.001.201 05.001.240	05.001.202 (25.2 V, Li-Ion)
Colibri II/Small Battery Drive II	532.101/532.110	532.103 (14.4 V, Li-Ion)
UNIUM™	05.001.601 05.001.611	05.001.602 (10.8 V, Li-Ion) in combination with the UNIUM™ Adapter for UBC II (05.001.604)

▲ WARNING:

The UBC II may only be used for authorized Batteries, Power Module and Power Unit.

Intended Use

The Universal Battery Charger II is intended for charging and/or conditioning of authorized Batteries, Power Module and Power Unit.

Indications

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

Intended User

The UBC II is intended to be used by qualified health care professionals.

Expected Clinical Benefits

Not applicable. The UBC II is a device which is used to enable authorized Batteries, Power Module and Power Unit to function.

Treatment before Device is Used

▲ WARNING:

For safety reasons, please read the Instructions for Use carefully before using UBC II.

Latex Information

Not made with natural rubber latex.

Combination of Medical Devices

The UBC II is a standalone device which is used to automatically charge and manually check authorized Batteries, Power Module and Power Unit.

It is supplied with a country-specific power cord and four slot cover sets.

The UNIUM Adapter for UBC II is a mechanical device that is inserted into one of the charger bays to allow the UNIUM Power Unit to be charged. The adapter is not delivered with the UBC II and needs to be ordered separately.

Storage and Transport

All Batteries, Power Modules and Power Units should be removed when transporting the charger.

A UBC II with a minimum firmware version of 17.2 allows the user to charge specific Li-Ion batteries up to 30% of their capacity for transportation in aircraft cargo bays. This is a requirement of the International Air Transport Association (IATA) regulation (UN 3480 PI 965). Please refer to the section “30% State of Charge” within this Instructions for Use for detailed information.

Use the original packaging for shipping and transport as damage may occur otherwise. If the original packaging materials are no longer available, please contact your DePuy Synthes Representative.

Please follow information in this Instructions for Use as well as that provided in the Instructions for Use of the device itself. Furthermore, ensure that the packaging and documentation requirements for shipping a Battery, Power Module or Power Unit are followed.

Please refer to the chapter “Environmental Conditions” to see both transport and storage conditions.

▲ WARNINGS:

- The device is designed to be operated and stored in closed rooms.
- Do not store/use the device in the presence of oxygen, nitrous oxide or a mixture consisting of flammable anesthetics and air.

Warranty and Liability

The warranty for the device does not cover damage or wear of any kind resulting from improper use, improper care and maintenance, damaged guarantee seal or improper storage and transport. The manufacturer excludes liability for damage resulting from repairs and maintenance carried out by unauthorized sites. In such cases the product will no longer be accepted or repaired by DePuy Synthes. For further information on the warranty and return policy please contact your local DePuy Synthes Office.

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. Risk of electric shock.
- 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 damaged, corroded or faulty devices and send them to the DePuy Synthes Representative.

▲ 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 main 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.
- The charging station should always be turned on when an authorized Battery, Power Module or Power Unit 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.
- United States Federal law restricts this device to sale by or on order of a physician or other licensed healthcare provider.

Glossary

The following abbreviations are used in the UBC II IFU.

Abbreviations UBC II

W	Watt	°F	Degrees Fahrenheit	Wh	Watt hour
kg	Kilogram	hPa	Hectopascal	Hz	Hertz
lbs	Pound	Li-Ion	Lithium-Ion	AC	Alternating current
mm	Millimeter	V	Volt	DC	Direct current
m	Meter	A	Ampere	PE	Protective Earth
L × W × H	Length × Width × Height	mA	Milliamperere	N	Neutral
min	Minute	µA	Microampere	P	Phase
h	Hour	mΩ	Milliohm	NC	Normal condition
°C	Degrees Celsius	Ah	Ampere hour	SFC	Single fault condition

Description of the Device

Front View

- 1 Charger bays (×4)
- 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: 2×5 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. Four Slot Cover Sets are supplied with the charger.



The UNIUM™ Adapter for UBC II (05.001.604) is a mechanical device that is inserted into one of the charger bays to allow the UNIUM™ Power Unit (05.001.602) to be charged. The adapter is not delivered with the UBC II and needs to be ordered separately.



Starting the Charger

Before starting for the first time, ensure that the power switch is set to **O**. 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 a Battery, Power Module or Power Unit is inserted, this charger bay is faulty. In this case, they can still be charged in the other charger bays. However, it is recommended that the device be sent to the local DePuy Synthes Service Center 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 main supply.



Fig. 1

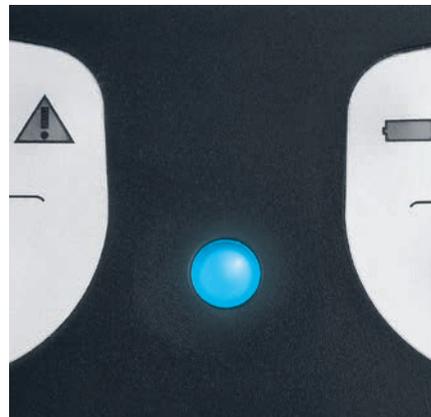


Fig. 2



Fig. 3

Operating the Device

Charging Batteries, Power Module and UNIUM™ Power Unit

Charger Bay

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

1. Slot for Battery Power Line II battery (530.630)
2. Slot for Trauma Recon System Power Module (05.001.202) or the UNIUM Adapter for UBC II (05.001.604) as described below.
3. Slot for Colibri II / Small Battery Drive II battery (532.103)

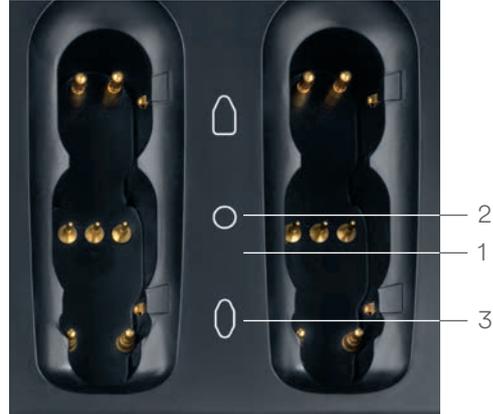


Fig. 1

The image shows the UNIUM™ Adapter for UBC II (05.001.604) inserted into one of the charger bays and the UNIUM™ Power Unit (05.001.602) connected to it. When inserting the adapter care must be taken to correctly orientate it so that the DePuy Synthes logo is next to the control symbols on the charger.

Furthermore, the Power Unit illustration on the adapter shows which way round the Power Unit is to be inserted.

Up to four Power Units can be charged simultaneously in separate bays, each equipped with an adapter.



Universal Battery Charger II (05.001.204)

Charging Procedure

Place the Battery, Power Module or Power Unit to be charged into the slot of an empty charger bay. Ensure that it is fitted correctly and is identified by the charger (symbol  is yellow). See fig. 2.

Only one battery, power module or power unit can be charged in each charger bay at a time. All charger bays can, however, be used simultaneously with any combination of battery, power module or power unit type. For the UNIUM™ Power Unit (05.001.602) first the UNIUM™ Adapter for UBC II (05.001.604) needs to be placed in the proper direction into the corresponding slot of an empty charger bay. Afterwards connect the Power Unit to the Adapter for UBC II.

▲ WARNINGS:

- Ensure that the Battery, Power Module or Power Unit (using the adapter) is correctly inserted into the slot of the charger bay.
- Do not charge damaged Batteries, Power Modules or Power Units with UBC II. Inspect them for cracks and damage.
- Do not insert any objects other than authorized Batteries, Power Modules or Power Units into the charger, as the contacts may otherwise be damaged.

▲ Precautions:

- If the symbol  does not light up after a Battery, Power Module or Power Unit (using the adapter) has been inserted, remove it and insert it again or use another charger bay.
- Only use fully charged Batteries, Power Modules and Power Units 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, power module and power unit is fully charged, the symbol  is green and the charger switches to maintenance charge (fig. 3). The battery, power module, power unit and adapter for UBC II can be left in the charger. Leave the device switched on to ensure that they are always fully charged.

If they are removed from the charger before the symbol  lights up green, they will not be fully charged.



Fig. 2



Fig. 3

Temperature Monitoring

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

If the battery, power module and power unit temperature is too high, the symbol  starts flashing (fig. 4). To protect them, the device stops charging until they have cooled down. Do not remove them 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.

Storage

Do not store an empty battery, power module or power unit as this will shorten the lifetime and void warranty coverage. Any batteries, power modules or power units that are not used should always be stored in an activated UBC II. This guarantees that they are always fully charged and ready to use.

Errors during Charging

The following errors may occur while charging:

Symbol Flashes (fig. 4)

The battery, power module or power unit is too hot and has to cool down before the charging process can be automatically resumed. They should be left in the charger until the symbol lights up green . Otherwise, they may not be fully charged.

Do not insert a battery, power module or power unit directly into the charger after use. They must be allowed to cool down to room temperature before being charged.

Symbol is Red (fig. 5)

The battery, power module or power unit is faulty and has to be replaced.

No Symbol Lights Up

The battery, power module or power unit (using the adapter) has not engaged in the charging bay or **has not been recognized by the device**. Remove it and insert again or use another charger bay.

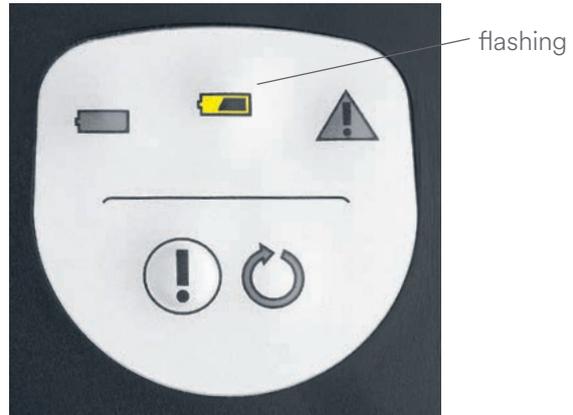


Fig. 4



Fig. 5

Checking Function

1. Battery Power Line II and Colibri II / Small Battery Drive II (SBD II) Batteries

The charger enables Battery Power Line II and Colibri 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.

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. 1) until the symbol  lights up yellow (fig. 2). The device then carries out the process. The symbol  is yellow throughout this time.

▲ Precautions:

- Do not remove the battery from the charger bay as long as the symbol  is yellow (fig. 2). Wait until the process has ended and the symbols  or  light up. Only then is the battery status clearly assessed.

Completion of the process is indicated as follows:

- Symbol  is green (fig. 3): Battery has been successfully 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 (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 will have an impact on it. this is carried out frequently the lifespan of the battery can be affected.
- The process is interrupted if there is a power outage or a switch to an internal power generator and will then have to be restarted.



Fig. 1



Fig. 2



Fig. 3



Fig. 4

2. Trauma Recon System Power Module and UNIUM™ Power Unit

To ensure that the Trauma Recon System (05.001.201, 05.001.240) and UNIUM™ Handpieces (05.001.601, 05.001.611) can operate safely and reliably, the Trauma Recon System Power Module (05.001.202) and UNIUM™ Power Unit (05.001.602) have to be checked at periodical intervals. It will be indicated if the performance is sufficient or if they need to be replaced.

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

When it needs to be checked, the symbol  flashes (fig. 5). 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. 6). The symbol light  goes out and the symbol  stops flashing and stays yellow (fig. 7). 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. 3 on previous page): power module or power unit has been checked, charged and is ready to use.
- Symbol  is red (fig. 4 on previous page): power module or power unit has been checked, is not charged, cannot be used and must be replaced; the red service indicator lamp on the power module or power unit lights up.

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

▲ Precautions:

- Do not remove the Power Module or Power Unit from the charger bay as long as the symbol  is yellow (fig. 7). Wait until the process has ended and the symbols  or  light up. Only then is the Power Module or Power Unit status clearly assessed.
- The process is interrupted if there is a power outage or a switch to an internal power generator and will then have to be restarted.

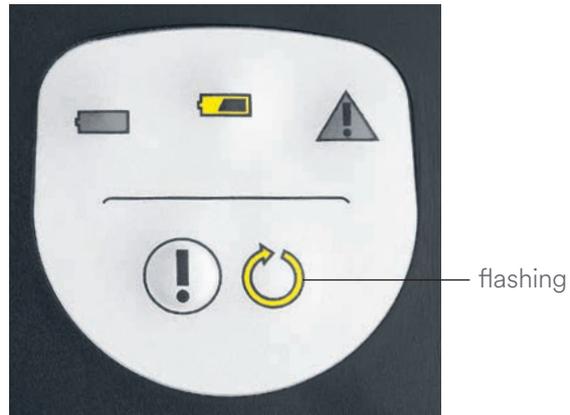


Fig. 5



Fig. 6



Fig. 7

30% State of Charge

The International Air Transport Association (IATA) regulation (UN 3480 PI 965) requires Li-Ion batteries shipped by aircraft cargo bays to have a maximum of 30% stage of charge.

A UBC II with a minimum firmware version of 17.2 allows the user to charge the following Li-Ion batteries up to 30% of their capacity for transportation in aircraft cargo bays:

- Battery Power Line II Battery (530.630)
- Colibri II/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 operating room in this status as they are not fully charged. Once the battery has been removed from the charger, the SOC function switches off.



Fig. 1



Fig. 2



Fig. 3



Fig. 4

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.
- The Trauma Recon System Power Module (05.001.202) and UNIUM Power Unit (05.001.602) are not affected by this regulation as they are not classified as a Li-Ion battery. They are covered by UN 3481 PI 967 (Li-Ion Battery Contained in Equipment).

Precaution:

Do not remove the battery from the charger bay as long as the yellow symbols  and  light up (fig. 3). Wait until the process has ended and the green symbol  lights up and the red symbol  flashes. Only then has the 30% state of charge been reached.

Care and Maintenance

Cleaning and Disinfection

The UBC II must be unplugged before it is cleaned. To clean the UBC II and UNIUM™ Adapter for UBC II, wipe them off with a clean, soft and lint-free cloth dampened with deionized water until no visible soil remains on the devices. If any visible soil remains, repeat the step with a new dampened cloth. Dry them off using a clean, soft, lint-free single-use cloth prior to disinfection.

To disinfect the UBC II and adapter wipe them off 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.

Whenever it is cleaned and disinfected, 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 and disinfecting.
- Do not spray the contacts in the charger bays. If necessary, clean the contacts in the charger bays using utmost care.
- Inspect the UBC II and UNIUM™ Adapter for UBC II for cracks and damage. Do not use a damaged device.

▲ WARNINGS:

- Make sure that no solution enters the device.
- Do not sterilize, wash, rinse, drop or apply force to the UBC II and UNIUM™ Adapter for UBC II. This will destroy them with possible secondary damage.



Repair and Technical Service

The device should be sent to the DePuy Synthes Service Center 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.

A device may have reached its end of life if there is evidence of damage and wear. This may include but is not limited to corrosion, discoloration, excessive scratches, flaking and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed part numbers, damaged and excessively worn devices should not be used.

To prevent damage to 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 a Battery, Power Module and UNIUM™ Power Unit in aircraft cargo bays, please follow the information in this Instructions for Use as well as that provided in the Instructions for Use of the device itself. Furthermore, ensure that the packaging and documentation requirements for shipping them are followed.

▲ Precautions:

- Do not use a damaged, corroded or faulty device. In this case return it to the DePuy Synthes Service Center.
- The manufacturer shall assume no responsibility for damage resulting from unauthorized repair. In such cases the product will no longer be accepted or repaired by DePuy Synthes.
- Users or third parties should not carry out repairs themselves.

Disposal of Waste

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



The European Directive 2012/19/EU 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.

The devices must not be disposed of with household waste. Please send chargers 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 European Directive.

Faulty Batteries, Power Modules and Power Units may not be reused and should be disposed of in an environmentally friendly manner and in accordance with national and local regulations.

▲ WARNINGS:

- Do not dispose of contaminated products with household waste.
- Unusable or faulty Batteries, Power Modules and Power Units must not be reused and should be disposed of in an environmentally friendly manner and in accordance with national and local and local regulations.

▲ Precaution:

The UBC II and UNIUM™ Adapter for UBC II should be disposed of in an environmentally friendly manner and in accordance with national and local regulations.

Troubleshooting

For a patient/user/third party in the European Union and in countries with identical regulatory framework (Regulation (EU) 2017/745 on Medical Devices): if during the use of this device or as a result of its use, a serious incident has occurred, please report to the manufacturer and to 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/power unit (using the adapter) is inserted, no symbol lights up on the charger bay.	Battery/power module/power unit (using the adapter) is not fully inserted.	Ensure that the battery/power module/power unit (using the adapter) is inserted properly.
	Contacts in the charger bay are dirty.	Carefully clean contacts.
	Battery/power module/power unit (using the adapter) was not recognized by the charger.	Use another free charger bay.
	Battery/power module/power unit (using the adapter) is faulty.	Test the battery/power module/power unit (using the adapter) 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/power unit (using the adapter) is correctly inserted.	Battery/power module/power unit is faulty.	Do not further use the battery/power module/power unit as it must be replaced.
	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 21. Send the charger to DePuy Synthes Representative for a firmware update.

Problem	Possible Cause	Solution
The symbol  is red when the charger is switched on before the batteries/power modules/power unit 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/power unit is too hot.	Leave battery/power module/power unit inserted in the charger bay. Charger automatically continues the charging process once the battery/power module/power unit 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/power unit (using the adapter) into the slot.	Wrong slot.	Select correct slot and re-insert battery/power module/power unit (using the adapter).
	Non-authorized battery/power module/power unit.	Check battery/power module/power unit 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/power unit performance is low.	Expected battery/power module/power unit life is reached.	Test battery/power module/power unit (see page 10). If the red display  lights up, replace battery/power module/power unit.
	Battery/power module/power unit is not ready for use.	Charge battery/power module/power unit until symbol  is green.
	Power Tool or attachment is under-performing, i.e. as a result of insufficient maintenance.	Send Power Tool and attachments to DePuy Synthes Representative to be checked.
Battery/power module/power unit is visibly damaged.	Battery/power module/power unit was exposed to excessive heat.	Do not further use the battery/power module/power unit as it must be replaced.
	Battery/power module/power unit was washed, incorrectly disinfected or steam sterilized.	Do not further use the battery/power module/power unit as it must be replaced.
	Battery/power module/power unit was short-fused by metal objects.	Do not further use the battery/power module/power unit as it must be replaced.
	Battery/power module/power unit fell on the floor.	Do not further use the battery/power module/power unit as it must be replaced.
UBC II or Adapter for UBC II is visibly damaged.	UBC II or Adapter for UBC II was exposed to excessive heat.	Do not further use the UBC II or Adapter for UBC II as it must be replaced.
	UBC II or Adapter for UBC II was washed, incorrectly disinfected or steam sterilized.	Do not further use the UBC II or Adapter for UBC II as it must be replaced.
	UBC II or Adapter for UBC II was short-fused by metal objects.	Do not further use the UBC II or Adapter for UBC II as it must be replaced.
	UBC II or Adapter for UBC II fell on the floor.	Do not further use the UBC II or Adapter for UBC II as it must be replaced.
	Markings on the UBC II or Adapter for UBC II are unrecognizable, missing or have been removed.	Replace UBC II or Adapter for 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 and Materials

Performance Characteristics of the Device

Synthes has established the performance and safety of the UBC II. It represents a state of the art medical device and performs as intended when used according to the Instructions for Use and associated labeling.

Universal Battery Charger II

Dimensions (L × W × H)	310 mm × 220 mm × 175 mm
Weight	4.8 kg/10.6 lbs
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	2 × 5 AT/250 V
Operating mode	Continuous operating mode
Sterilization	Device must not be sterilized

Materials

Device(s)	Material(s)	Abbreviation(s)	Standard(s)
UBC II	Acrylnitril-Butadien-Styrol-Copolymere	ABS	n/a
	Copper zinc with gold plating	CuZn gold plated	n/a
	Aluminium	Aluminium	DIN EN 573
	Stainless Steel	SSt	ISO 7153-1
	Polycarbonate	PC	n/a
	Polyester	PVS-G	n/a
	Elastomer	Elastomer	n/a
UNIUM™ Adapter for UBC II	Polyamid 12	PA 12	n/a
	Copper zinc with gold plating	CuZn gold plated	n/a
	Stainless Steel	SSt	ISO 7153-1
Power Cord(s)	Copper zinc with nickel plating	CuZn nickel plated	n/a
	Polybutylenterephthalat	PBTP	n/a
	Polyvinylchloride	PVC	n/a
Slot Covers	Thermoplastic elastomer	TPE	n/a

Subject to technical modifications.

Minimum Required Firmware Version of UBC II

In order that the different authorized Batteries, Power Module and UNIUM™ Power Unit can be recognized and charged by UBC II, the correct Firmware version is required. The table below outlines the requirements for each device type. If required, send the charger to a DePuy Synthes Service Center for a firmware update.

Device/feature	Battery/Power Module/	Minimum required Firmware version of UBC II Power Unit
Trauma Recon System	05.001.202 (25.2 V, Li-Ion)	2.0 (no sticker on the underside of the charger)
Colibri II/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*)
UNIUM™	05.001.602 (10.8 V, Li-Ion)	16.0 (sticker visible on the underside of the charger*)
30% State of Charge	532.103 (14.4 V, Li-Ion) 530.630 (14.8 V, Li-Ion)	17.2 (sticker visible on the underside of the charger*)

* The UBC II 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 or ISTA 3A.

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 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)



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)

Electromagnetic Compatibility

Table 1: Emissions

Guidelines and manufacturer’s declaration – electromagnetic emissions

The Universal Battery Charger II is intended for use in the electromagnetic environment specified below. The customer or the user of the 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 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.
Harmonic emissions IEC 61000-3-2	Class A	If it is used in a residential environment this equipment might not offer adequate protection to radio-frequency communication services.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 2: Immunity (all devices)

Guidelines and manufacturer's declaration – electromagnetic immunity

The Universal Battery Charger II is intended for use in the electromagnetic environment specified below. The customer or the user of the 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 Universal Batter Charger II requires continued operation during power mains interruptions, it is recommended that the 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 Universal Battery Charger II is intended for use in the electromagnetic environment specified below. The customer or the user of the 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 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 Universal Battery Charger II is used exceeds the applicable RF compliance level above, the 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 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 Universal Battery Charger II

The 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 Universal Battery Charger II can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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 m		
	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

Electrical Safety Check of the UBC II

The UBC II has been factory tested for electrical safety. Depending on national regulations, the operating companies are responsible for regular safety checks of medical electrical equipment. Below instructions should be followed and only be carried out by adequately trained personal.

1. Visual inspection

Check the device for visible damage to the housing and contacts. Damaged devices are not safe and must not be used.

2. Protective Earth Connection

By measuring the Protective Earth Connection, it must be proven that there is a proper and safe connection of all touchable conductive components, which could become live in the event of a fault, with the protective earth connector of the mains socket.

Step	Configuration	Criterion
Connection	Connecting Point A: Connecting Point on the bottom plate of the UBC II, marked with this symbol  Connecting Point B: PE-Pin of the mains socket of UBC II	
Measurement 1	Measurement without mains cable	The resistance of the Protective Earth Connection must be below 100 mΩ.
Alternative to Measurement 1	Measurement with connected mains cable	The total resistance of the Protective Earth Connection and mains cable must be below 200 mΩ.

3. Earth Leakage Current

By measuring the earth leakage current, it must be proven that the current through the protective conductor does not exceed the normatively specified limit value.

Step	Configuration	Criterion
Preparation	Switch the UBC II on	
Connection	Connecting point A: PE-Pin of mains socket of UBC II Connecting point B: Earth, e.g. PE terminal of the mains	
Measurement 1 (normal condition NC)	Normal polarity of P and N	The Earth Leakage Current NC must be below 5 mA AC.
Measurement 2 (normal condition NC)	Normal polarity of P and N	The Earth Leakage Current NC must be below 5 mA AC.
Measurement 3 (single fault condition SFC)	Normal polarity of P and N N interrupted	The Earth Leakage Current SFC must be below 10 mA AC.
Measurement 4 (single fault condition SFC)	Reverse polarity of P and N N interrupted	The Earth Leakage Current SFC must be below 10 mA AC.

4. Touch Current

With the measurement of the touch current it has to be proved that the current resulting from touching the device does not exceed the normatively defined limit value.

Step	Configuration	Criterion
Preparation	Switch the UBC II on	
Connection	Connecting Point A Connecting Point on the bottom plate of the UBC II, marked with this symbol  Connecting point B: Earth, e.g. PE terminal of the mains	
Measurement 1 (normal condition NC)	Normal polarity of P and N	The Touch Current NC must be below 100µA AC.
Measurement 2 (normal condition NC)	Normal polarity of P and N	The Touch Current NC must be below 100 µA AC.
Measurement 3 (single fault condition SFC)	Normal polarity of P and N PE interrupted	The Touch Current SFC must be below 500 µA AC.
Measurement 4 (single fault condition SFC)	Reverse polarity of P and N PE interrupted	The Touch Current SFC must be below 500 µA AC.

5. Isolation

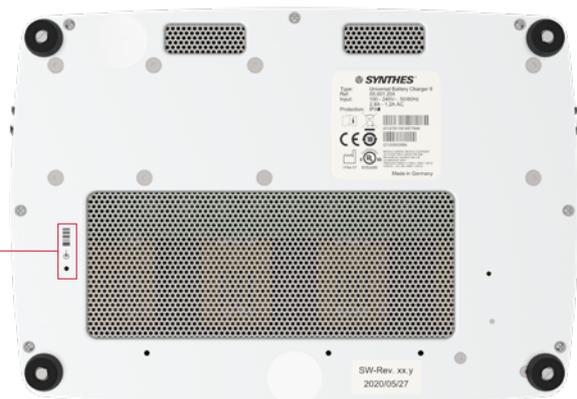
By measuring the insulation, it must be verified that the insulation of the components carrying the mains voltage is intact.

Step	Configuration	Criterion
Preparation	Switch the UBC II on	
Connection	Connecting point A: P- and N-Pin of mains socket of UBC II Connecting point B: PE-Pin of mains socket of UBC II	
Measurement 1	Test voltage of 500V DC	No breakthrough

6. Functional Check

Following the measurements, a functional test must be performed to prove that the device is functioning properly.

Connecting point for the protective earth measurement on the bottom plate of UBC II



Compatibility

Battery for Battery Power Line II

Art. 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



Battery for Colibri II/Small Battery Drive II

Art. 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



Power Module for Trauma Recon System

Art. 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



UNIUM™ Power Unit

Art. no.	05.001.602
Operating voltage (rated)	10.8 V
Battery capacity	2.0 Ah/21.6Wh
Battery	Li-Ion
Typical charging time	<60 min



Subject to technical modifications.

Explanation of Symbols Used

Symbols for Operating the Charger



Battery, Power Module and Power Unit is charged. The charger has switched to maintenance charge and checks that they remain fully charged and ready to use.



Yellow symbol: the Battery, Power Module and Power Unit is partially charged.
The charging process is not completed.
Flashing yellow symbol: the Battery, Power Module and Power Unit is too hot.



The Battery, Power Module and Power Unit is faulty and has to be replaced or the charger bay is faulty.



Button to check Battery Power Line II, Colibri II/SBD II Batteries, Power Module or Power Unit.
Button to start the 30% state of charge feature.



Symbol is yellow: the process to check Battery Power Line II, Colibri II/SBD II Batteries, Power Module and Power Unit is ongoing. Flashing yellow symbol: the inserted Trauma Recon System Power Module or UNIUM™ Power Unit should be checked.



Symbol for Battery Power Line II battery (532.630)



Symbol for Trauma Recon System Power Module (05.001.202) and UNIUM™ Adapter for UBC II (05.01.604)



Symbol for Colibri II/SBD II battery (532.103)



The symbol on the UNIUM™ Adapter for UBC II shows how the UNIUM™ Power Unit is to be inserted.

General Symbols

	Caution (Ref. 5.4.4 ISO 15223-1)		Do not immerse device in liquids
	Consult Instructions For Use (Ref. 5.4.3 ISO 15223-1)	IPX0	Water ingress protection rating according IEC 60529
	Manufacturer and Date of Manufacture (Ref. 5.1.1 ISO 15223-1)		Product is UL Classified to the requirements of both the United States and Canada
	Date of Manufacture (Ref. 5.1.3 ISO 15223-1)		Separate collection (EN 50419)
REF	Reference or Catalogue Number (Ref. 5.1.6 ISO 15223-1)		Indicates Environment-Friendly Use Period of 5 years in China (SJ/T 11364)
SN	Serial Number (Ref. 5.1.7 ISO 15223-1)		Indicates Environment-Friendly Use Period of 10 years in China (SJ/T 11364)
LOT	Lot or Batch Number (Ref. 5.1.5 ISO 15223-1)		Firmware version of UBC II
	Packaging unit, indicates the number of pieces in the package (Ref. 2794 ISO 7000)		Fuses 2x 5AT/250V, breaking rupture 1550 A/250 V
	Non-sterile (Ref. 5.2.7 ISO 15223-1)		Connecting Point for Protective Earth Measurement
MATERIAL	Materials		Temperature Limit (Ref. ISO 5.3.7 ISO 15223-1)
MD	Medical Device in the European Community/Union		Humidity Limitation (Ref. ISO 5.3.8 ISO 15223-1)
EC REP	Authorized Representative in the European Community (Ref. 5.1.2 ISO 15223-1)		Atmospheric Pressure Limitation (Ref. ISO 5.3.9 ISO 15223-1)
CE	CE marking of conformity in European Community (Regulation (EU) 2017/745)		Non-ionizing electromagnetic radiation (Ref. 5140 IEC TR 60878): Interference may occur in the vicinity of equipment marked with the following symbol (IEC 60601-1-2, clause 5.1.1)
Rx only	Caution: United States Federal law restricts this device to sale by or on the order of a physician or other licensed health-care provider (21 CFR 801.109)		
MADE IN	Made in		
Qty	Quantity, indicates the number of pieces in the package		

Ordering Information

Battery charger

05.001.204 Universal Battery Charger II

Batteries, Power Module and Power Unit

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

05.001.602 UNIUM™ Power Unit

UNIUM™ Adapter for UBC II

05.001.604 UNIUM™ Adapter for UBC II

Power cord

05.001.136 Power Cord, three-pole (Europe)

05.001.137 Power Cord, three-pole (Australia)

05.001.138 Power Cord, three-pole (Great Britain)

05.001.139 Power Cord, three-pole (Denmark)

05.001.140 Power Cord, three-pole (North America)

05.001.141 Power Cord, three-pole (Switzerland)

05.001.142 Power Cord, three-pole
(India, South Africa)

05.001.143 Power Cord, three-pole (Italy)

05.001.144 Power Cord, three-pole (China)

05.001.145 Power Cord, three-pole (Japan)

05.001.146 Power Cord, three-pole (Argentina)

05.001.147 Power Cord, three-pole (Israel)

Slot Covers Set

05.001.228 Slot Covers Set,
for Universal Battery Charger II

Some devices listed in these Instructions for Use may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your DePuy Synthes Representative for items approved for sale in Canada.
Not all products are currently available in all markets. Data available on request.
Please contact your DePuy Synthes Representative for more information.
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