

Unitron Charger Combi BTE 2 user guide



A Sonova brand

unitron™ Love the
experience

Thank you

Thank you for choosing this Unitron Charger Combi BTE 2.

Unitron is a hearing solution company that believes people should feel really good about the entire hearing care experience, start to finish. Our ingenious products, technologies, services and programs offer a level of personalization you can't get anywhere else.

Get ready to **Love the experience.**™

This user guide is valid for:

Non wireless charging accessories



Unitron Charger Combi BTE 2

Optional Power Pack



Your charger combi BTE

Training is not required for handling of this device.

The Unitron Charger Combi BTE 2 is a device intended to charge rechargeable hearing aids.

A hearing care professional will help setup the hearing aids to your individual preferences.

Hearing care professional: _____

Telephone: _____

Model: _____

Serial number: _____

Warranty: _____

Date of purchase: _____

Your charger details

- ① Please also read safety information regarding handling the charger (chapter 11).
- ① The Power Pack contains a built-in and non-removable rechargeable lithium-polymer battery.

Device

Unitron Charger Combi BTE 2 includes power supply and USB cable (< 1 m)

The Unitron Charger Combi BTE 2 is a device intended to charge rechargeable hearing aids.

Please read the user guide carefully to make sure that you understand and get the best out of your charger. For more information regarding features, benefits, setup, use and maintenance or repairs – contact your hearing care professional or manufacturer representative. Additional information can be found in the datasheet of your product.

Compatible hearing aid models

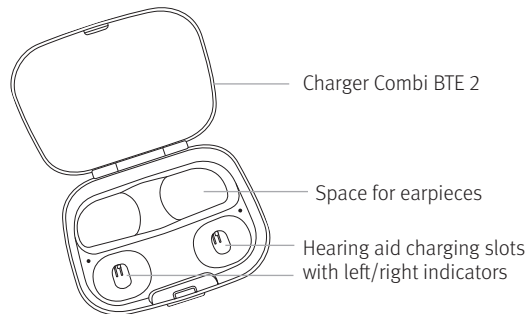
- Stride B-PR (9/7/5/3/1)
- DX Stride PR (9/7/5/3)

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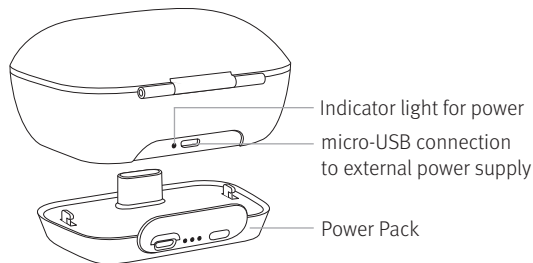
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1. Your charger at a glance

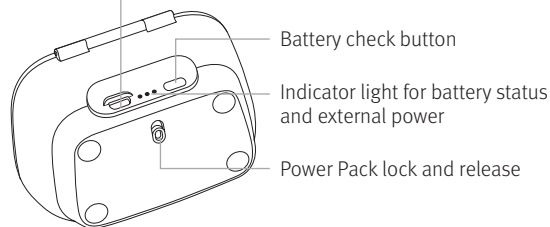
Charger



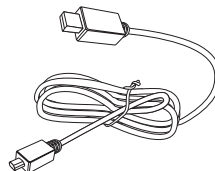
Charger Combi BTE 2 with optional Power Pack



micro-USB connection to external power supply



Accessories



USB cable (< 1 m)



Power supply

For charger, use only IEC 60950-1*, IEC 62368-1 and/or IEC 60601-1 certified equipment with an output rating of 5 VDC. Min. 500 mA.

Power supply and charger specification

Power supply output voltage: 5 VDC +/-5%, current 500 mA - 1 A

Power supply input voltage: 100-240 VAC, 50/60Hz, current 0,25 A

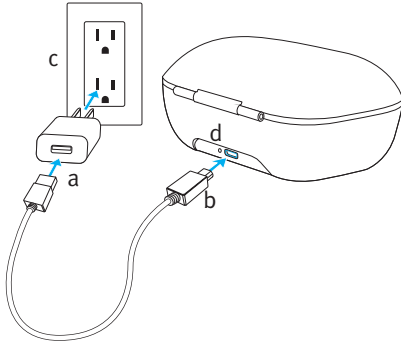
Charger input voltage: 5 VDC +/-5%, current 300 mA

USB cable specifications: 5 V min. 1 A, USB-A to micro-USB, maximum length 1 m

* Note: this standard may not be valid anymore in your country, please refer to IEC 62368-1

2. Preparing your charger

Connecting the power supply



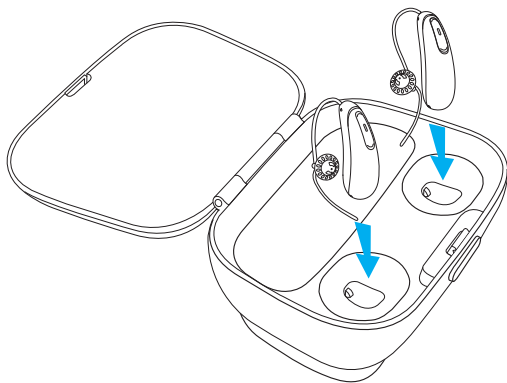
- a) Plug the larger end of the charging cable into the power supply.
- b) Plug the smaller end into the micro-USB port on the charger.
- c) Plug the power supply into a power outlet.
- d) The charger indicator light is green when the charger is connected to the power supply.

3. Charging your hearing aids

- ① Low power: You will hear two beeps when the battery is low. You will have approximately 60 minutes before you have to charge the hearing aids (this can vary, depending on the hearing aid settings).
- ① Before using your hearing aids for the first time, it is recommended to charge them for 3 hours.
- ① The hearing aids must be dry before charging, see chapter 6.
- ① Please ensure to charge and use the hearing aids within operating temperature range: +5° to +40° Celsius (41° to 104° Fahrenheit).

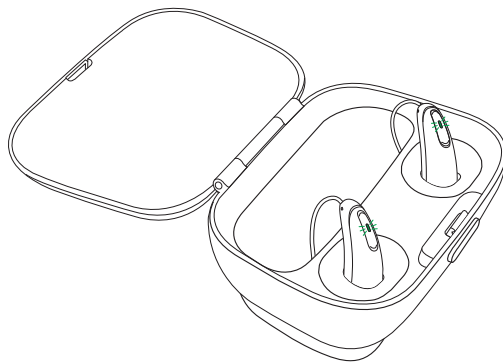
Please refer to chapter 2 for how to set up the charger.

1. Insert the hearing aids into the charging slots. The hearing aids will automatically be switched off when inserted into the charger.



- ① Make sure the left and right hearing aid markings match the left (blue), right (red) indicators next to the charging slots.

2. The indicator light on the hearing aids will show the charging state of the battery until the hearing aids are fully charged. When fully charged the indicator light will remain on, i.e. solid green light.

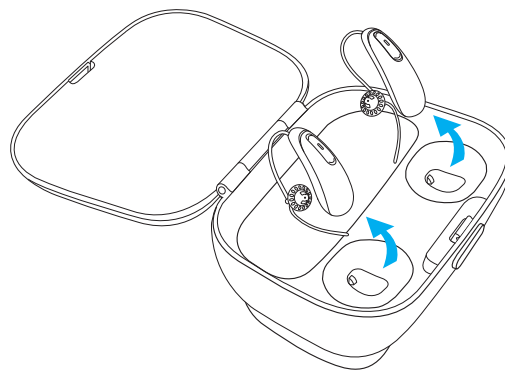


The charging process will automatically stop when the batteries are fully charged, so the hearing aids can be safely left in the charger. It can take up to 3 hours to charge the hearing aids. The charger cover can be closed while charging.

Charging times

Indicator light of the hearing aid	Charging state	Approx. charging times
● ● ●	0-10%	
● ● ●	11-80%	30 min (30%) 60 min (50%) 90 min (80%)
● ● ●	81-99%	
■	100%	3h

3. Remove the hearing aids from the charging slots by
 1. tilting the hearing aids gently towards the back and
 2. lifting them out of the charger.



- ① Do not hold the tubes to remove the hearing aids from the charger as this can damage the tubes.

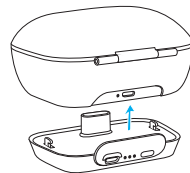
The hearing aids switch on automatically when removed from the charger. The indicator light starts blinking. The solid green light indicates the hearing aids are ready.

To switch off the charger, remove the power supply from the power outlet.

- ① Turn off your hearing aids before inserting them in the disconnected charger to store them.
- ① Always close the lid when charging you hearing aids in a humid environment.
- ① If you unplug the charger while the hearing aids are charging inside, please make sure to turn them off to prevent discharge.

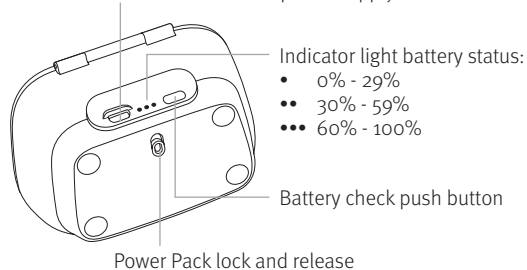
4. Using the optional Power Pack

1. Attach the Power Pack to the bottom of the charger and lock it.
 2. Plug in the micro-USB and connect to an external power supply. The Power Pack and hearing aids will be charged at the same time. While connected to an external power supply, the Power Pack indicator light will show the current battery charge status of the Power Pack.
- ① Before using Power Pack for the first time, it is recommended to charge it for 3 hours.



3. To check the remaining battery capacity of the Power Pack, press the battery check push button. The indicator lights will show the status.

micro-USB connection to external power supply



- ① Please ensure to charge the Power Pack within operating temperature range: +5° to +40° Celsius (41° to 104° Fahrenheit).
- ① If the device has been subject to storage and transportation conditions outside of the recommended use conditions, wait 15 minutes before starting the device.
- ① This charger is classified as IP22. This means that the charger is protected from vertically falling drops of water when the charger is tilted up to 15 degrees from the horizontal. IP22 is satisfied when the charger lid is closed.

5. Operation, transport and storage conditions

Please ensure to operate, transport and store the charging accessories according to the following conditions:

	Operation	Transport	Storage*
Temperature Maximum range	+5° to +40° C (41° to 104° F)	-20° to +60° C (-4° to 140° F)	-20° to +60° C (-4° to 140° F)
Humidity Maximum range	0% to 85% (non-condensing)	0% to 90% (non-condensing)	0% to 70% (non-condensing)
Atmospheric pressure	800 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa

* Power pack storage for a year or longer: to prevent damage to the battery cell, the maximum temperature range should be -20° to 25° Celsius and the battery cell should be discharged and recharged a minimum once every three months.

6. Care and Maintenance

Expected Service Life

The charger has the expected service life of five years. The device is expected to remain safe for use for this duration.

Commercial service period

Diligent and routine care of your charger contributes to outstanding performance and a long service life. To ensure a long service life, Sonova AG provides a minimum of a five year service period after phase out of the charger. Please use the following specifications as a guideline. Further information regarding product safety, see chapter 11.

General information

Please make sure that the charger is used and maintained as described in this user guide.

Daily

Make sure that charging slots are clean. Never use cleaning agents such as household detergents, soap, etc. for cleaning your charger.

Weekly

Remove dust or dirt from the charging slots.

- ① Always make sure that the hearing aids and charger are dry and clean before charging.
- ① Always make sure that the charger is disconnected from the power mains before cleaning.

7. Service and warranty

Local warranty

Please ask the hearing care professional where you purchased your charger about the terms of the local warranty.

International warranty

Sonova AG offers a one year limited international warranty, valid from the date of purchase. This limited warranty covers manufacturing and material defects in the charger. The warranty only comes into force if a proof of purchase is shown.

The international warranty does not affect any legal rights that you might have under applicable national legislation governing sale of consumer goods.

Warranty limitation

This warranty does not cover damage from improper handling or care, exposure to chemicals or undue stress. Damage caused by third parties or non-authorized service centers renders the warranty null and void. This warranty does not include any services performed by a hearing care professional in their office.

Serial number: _____

Date of purchase: _____

Authorized hearing care
professional (stamp/signature):

8. Compliance information

Declaration of conformity

Hereby Sonova AG declares that this product meets the requirements of the Medical Devices Regulation (EU) 2017/745 and the UK Medical Device Regulation 2002.

Notice 1

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

Notice 2

Changes or modifications made to this device not expressly approved by Sonova AG may void the FCC authorization to operate this device.

Notice 3

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the device into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help
- Please keep at least 20 cm (7.9 inches) separation distance between the charger and the human body during operation

Compliance with emission and immunity standards

Emission standards	EN 60601-1-2
	IEC 60601-1-2
	EN 55011
	CISPR11
	CISPR25
	EN 55025
Immunity standards	EN 60601-1-2
	IEC 60601-1-2
	IEC 60601-1-11
	EN 61000-4-2
	IEC 61000-4-2
	EN 61000-4-3
	IEC 61000-4-3
	EN 61000-4-4
	IEC 61000-4-4
	EN 61000-4-5
	IEC 61000-4-5
	EN 61000-4-6
	IEC 61000-4-6
	EN 61000-4-8
	IEC 61000-4-8
	EN 61000-4-11
	IEC 61000-4-11
	IEC 60601-1
	ISO 7637-2

9. Information and explanation of symbols



With the CE symbol, Sonova AG confirms that this product meets the requirements of the Medical Devices Regulation MDR 2017/745



Indicates the medical device manufacturer, as defined in EU Medical Devices Regulation MDR 2017/745



Indicates the Authorized representative in the European Community. The EC REP is also the importer to the European Union



This symbol indicates that it is important for the user to read and take into account the relevant information in this user guide



This symbol indicates that it is important for the user to pay attention to the relevant warning notices in this user guide



Important information for handling and product safety



Copyright symbol



This symbol confers that the electromagnetic interference from the device is under limits approved by the US Federal Communications Commission



Indicates the manufacturer's serial number so that a specific medical device can be identified

REF

Indicates the manufacturer's catalogue number so that the medical device can be identified

MD

Indicates that the device is a medical device



This symbol indicates that it is important for the user to read and take into account the relevant information in this user guide

IP22

IP Rating = Ingress Protection Rating. IP22 rating indicates that the device is protected against solid foreign objects of 12.5 mm diameter and greater and is additionally protected against vertically falling water drops when enclosure tilted up to 15°



Temperature during transportation and storage:
-20° to +60° Celsius (-4° to +140° Fahrenheit)



Humidity during transportation and storage: 0% to 70%, (non condensing)



Atmospheric pressure during transportation and storage: 500 hPa to 1060 hPa



During transportation keep dry



The symbol with the crossed-out garbage bin is to make you aware that this charger and power pack may not be thrown away as normal household waste. Please dispose of old or unused devices, at waste disposal sites intended for electronic waste, or give your device to your hearing care professional for disposal. Proper disposal protects the environment and health.



Regulatory Compliance Mark (RCM) is a trade mark for electrical safety for equipment which is compliant with the EESS



With the UK Conformity Assessed mark, Sonova AG confirms that the product has conformed to applicable Great Britain legislations.

Symbols applicable to the European power supply only



Power supply with double isolation



Device designed for indoor use only



Safety isolating transformer, short circuit proof

10. Troubleshooting guide

Cause	Possible remedy
Issue: charging does not start	
Charger not connected to power supply	Connect the charger to power supply, see “2. Preparing the charger.”
Hearing aids not inserted correctly into charger	Insert your hearing aids correctly into the charger, see “3. Charging your hearing aids.”

For any problems not listed in the guide or if problem persists, contact your hearing care professional.

11. Important safety information

Please read the relevant safety information and limitations-of-use information on the following pages before using your device.

Intended use

The charger is intended to charge the battery of the rechargeable hearing aids.

The Power Pack is intended to allow the compatible charger to recharge the battery of the rechargeable hearing aid, when no external power source is available.

Intended user

Intended for people with hearing loss using the compatible rechargeable hearing aids, their caregivers and the hearing care professional.

Intended patient population

The intended patient population is the user of the compatible hearing aids.

Indications

Indications are not derived from the charging accessories, but from the compatible hearing aids. General clinical indications for the use of hearing aids and Tinnitus feature are:

- Presence of hearing loss
- Uni- or bilateral
- Conductive, sensorineural or mixed
- Mild to profound
- Presence of a chronic tinnitus (only applicable for devices which provide the Tinnitus feature).

Contraindications

Contraindications are not derived from the charging accessories, but from the compatible hearing aids. General clinical contraindications for the use of hearing aids and Tinnitus feature are:

- Hearing loss is not in the fitting range of the hearing aid (i.e. gain, frequency response)
- Acute tinnitus

- Deformity of the ear (i.e. closed ear canal; absence of the auricle)
- Neural hearing loss (retro-cochlear pathologies such as absent/non-viable auditory nerve)

The primary criteria for the referral of a patient for a medical or other specialist opinion and / or treatment are as follows:

- Visible congenital or traumatic deformity of the ear;
- History of active drainage from the ear in the previous 90 days;
- History of sudden or rapidly progressive hearing loss in one or both ears within the previous 90 days.
- Acute or chronic dizziness;
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz and 2000 Hz;
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal;

- Pain or discomfort in the ear;
- Abnormal appearance of the eardrum and ear canal such as:
 - Inflammation of the external auditory canal,
 - Perforated eardrum;
 - Other abnormalities which the HCP believes are of medical concern

The hearing care professional may decide that a referral is not appropriate or in the best interests of the patient when the following applies:

- When there is sufficient evidence that the condition has been fully investigated by a medical specialist and any possible treatment has been provided;
- The condition has not worsened or changed significantly since the previous investigation and / or treatment.

If the patient has given their informed and competent decision not to accept advice to seek a medical opinion, it is permissible to proceed to recommend appropriate hearing aid systems subject to the following considerations:

- The recommendation will not have any adverse effects on the patients health or general well being;
- The records confirm that all necessary considerations about the patient's best interests have been made. If legally required, the patient has signed a disclaimer to confirm that the referral advice has not been accepted and that it is an informed decision.

Clinical benefits

The charging accessories themselves do not provide a direct clinical benefit. An indirect clinical benefit is provided by enabling the rechargeable hearing aids to achieve their intended purpose.

Any serious incident that has occurred in relation to the charging accessories, should be reported to the manufacturer representative and the competent authority of the state of residence. The serious incident is described as any incident that directly or indirectly led, might have led or might lead to any of the following:

- the death of a patient, user or other person
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- a serious public health threat

To report an unexpected operation or event, please contact the manufacturer or a representative.

Please note, side effects are not derived from the charger, but from the compatible hearing aids.

Hazard warnings

- ⚠ The hearing aids must be dry before charging. Otherwise the charging reliability cannot be guaranteed.
- ⚠ Both your hearing aid(s) and Power Pack contain lithium-ion batteries with a Watt hour rating <20 Wh which have been tested according to UN 38.3 of the "UN Manual of Tests and Criteria" and should be shipped in accordance with all the rules and regulations on the safe shipment of lithium-ion batteries.
- ⚠ Do not use the charging accessories in explosive areas (mines or industrial areas with danger of explosions, oxygen rich environments or areas where flammable anesthetics are handled). The device is not ATEX certified.
- ⚠ Do not cover the whole charger while charging, e.g. with a cloth etc.
- ⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- ⚠ The following is only applicable for persons with active implantable medical devices (i.e. pacemakers, defibrillators, etc.):
Keep the charging device at least 15 cm (6 inches) away from the active implant. If you experience any interference do not use the charging device and contact the manufacturer of the active implant. Please, note that the interference can also be caused by powerlines, electrostatic discharge, airport metal detectors etc.
- ⚠ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- ⚠ Do not touch the contacts of the charger when powered.
- ⚠ Cables and cords wrapped around the neck may cause strangulation. Do not leave the device and its components unattended with children, individuals with cognitive impairment or pets.

- ⚠ The USB port of the charger is to be used for the described purpose only.
- ⚠ For charger, use only IEC 60950-1*, IEC 62368-1 and/or IEC 60601-1 certified equipment with an output rating of 5 VDC. Min. 500 mA.
- ⚠ Only authorized personnel are allowed to open the charging accessory due to possible electrical hazard.
- ⚠ Only use approved chargers and Power Pack described in this user guide for charging your hearing aids, otherwise the devices may be damaged.
- ⚠ The rechargeable hearing aids and the Power Pack contain lithium-ion batteries that can be taken onto airplanes as carry-on luggage. The Power Pack cannot be placed in the checked-in baggage and can only be placed in the carry-on luggage.

*Note: this standard may not be valid anymore in your country, please refer to IEC 62368-1

Product safety

- ① Protect your charging accessories from heat and sunlight (never leave near a window or in the car). Never use a microwave or other heating devices to dry your charging accessories (due to risk of fire or explosion). Ask your hearing care professional about suitable drying methods.
- ① Do not place the charging accessories close to an induction cooking surface. Conductive structures inside the charging accessories could absorb inductive energy resulting in thermal destruction.
- ① Do not drop your charging accessories! Dropping onto a hard surface can damage your charging accessories.
- ① Charging accessories and power supply must be protected against shocks. If the charging accessories or power supply is damaged after a shock, they must not be used anymore.
- ① Do not use your charging accessories in areas where electronic equipment is prohibited.

Your feedback

Record your specific needs or concerns and bring to your first office visit after getting your hearing aids.

This will help your hearing care professional to address your needs.

UK Responsible person and UK Importer:

Sonova UK Limited
Sonova House
Lakeside Drive, Centre Park
WA1 1RX Warrington
United Kingdom



And importer for European Union :

Sonova Deutschland GmbH
Max-Eyth-Str. 20
70736 Fellbach-Oeffingen, Germany

Australian Sponsor:

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Australia

Pat. www.sonova.com/en/intellectualproperty

For a listing of Unitron group
companies, please visit
www.unitron.com

Distributor

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Attributes

<u>Attribute Type</u>	<u>Value</u>	<u>Description</u>
Affected Site	5300	Unitron Hearing
Affected Site		
Project	Combi Charger BTE RIC Product	
Project		
Project Phase	Finished Product	
Project Phase		

Reference

<u>Document No.</u>	<u>Title</u>	<u>Content Type</u>	<u>Relation</u>
PDL-18111 [1]	029-6811-02 User guide AudioNova Charger Combi BTE 2 - EN	DOCUMENT	Related
PDL-18163 [1]	029-1301-01 User Guide Unitron Charger-Combi-BTE-2 - DE	DOCUMENT	Sub Document
PDL-18165 [1]	029-1301-04 User Guide Unitron Charger-Combi-BTE-2 - FR	DOCUMENT	Sub Document
PDL-18166 [1]	029-1301-05 User Guide Unitron Charger-Combi-BTE-2 - IT	DOCUMENT	Sub Document
PDL-18167 [1]	029-1301-06 User Guide Unitron Charger-Combi-BTE-2 - ES	DOCUMENT	Sub Document
PDL-18170 [1]	029-1301-07 User Guide Unitron Charger-Combi-BTE-2 - NL	DOCUMENT	Sub Document
PDL-18193 [1]	029-1301-12 User Guide Unitron Charger-Combi-BTE-2 - PT	DOCUMENT	Sub Document
PDL-18199 [1]	029-1301-45 User Guide Unitron Charger Combi BTE 2 - CZ	DOCUMENT	Sub Document
PDL-18197 [1]	029-1301-13 User Guide Unitron Charger-Combi-BTE-2 - HU	DOCUMENT	Sub Document
PDL-18189 [1]	029-1301-44 User guide Unitron Charger Combi BTE 2 -TW	DOCUMENT	Sub Document
PDL-18201 [1]	029-1301-14 User Guide Unitron Charger-Combi-BTE-2 - SL	DOCUMENT	Sub Document
PDL-18203 [1]	029-1301-46 User Guide Unitron Charger Combi BTE 2 - SK	DOCUMENT	Sub Document
PDL-18206 [1]	029-1301-47 User Guide Unitron Charger Combi BTE 2 - UK	DOCUMENT	Sub Document
PDL-18204 [1]	029-1301-15 User Guide Unitron Charger-Combi-BTE-2 - HR	DOCUMENT	Sub Document
PDL-18207 [1]	029-1301-70 User Guide Unitron Charger Combi BTE 2 - CN	DOCUMENT	Sub Document
PDL-18209 [1]	029-1301-71 User Guide Unitron Charger Combi BTE 2 - TH	DOCUMENT	Sub Document
PDL-18211 [1]	029-1301-83 User Guide Unitron Charger Combi BTE 2 - 83	DOCUMENT	Sub Document
PDL-18210 [1]	029-1301-16 User Guide Unitron Charger-Combi-BTE-2 - PL	DOCUMENT	Sub Document
PDL-18212 [1]	029-1301-91 User Guide Unitron Charger Combi BTE 2 - LV	DOCUMENT	Sub Document
PDL-18213 [1]	029-1301-92 User Guide Unitron Charger Combi BTE 2 - LT	DOCUMENT	Sub Document
PDL-18220 [1]	029-1301-94 User Guide Unitron Charger Combi BTE 2 - EN-FR-CA	DOCUMENT	Sub Document
PDL-18221 [1]	029-1301-19 User Guide Unitron Charger-Combi-BTE-2 - KO	DOCUMENT	Sub Document
PDL-18222 [1]	029-1301-20 User Guide Unitron Charger-Combi-BTE-2 - EL	DOCUMENT	Sub Document
PDL-18223 [1]	029-1301-21 User Guide Unitron Charger-Combi-BTE-2 - AR	DOCUMENT	Sub Document
PDL-18224 [1]	029-1301-22 User Guide Unitron Charger-Combi-BTE-2 - TR	DOCUMENT	Sub Document
PDL-18225 [1]	029-1301-23 User Guide Unitron Charger-Combi-BTE-2 - SR	DOCUMENT	Sub Document
PDL-18229 [1]	029-1301-25 User Guide Unitron Charger-Combi-BTE-2 - ID	DOCUMENT	Sub Document
PDL-18262 [1]	029-1301-26 User Guide Unitron Charger-Combi-BTE-2 - RU	DOCUMENT	Sub Document

PDL-18263 [1]	029-1301-27 User Guide Unitron Charger-Combi-BTE-2 - HE	DOCUMENT	Sub Document
PDL-18264 [1]	029-1301-28 User Guide Unitron Charger-Combi-BTE-2 - RO	DOCUMENT	Sub Document
PDL-18265 [1]	029-1301-29 User Guide Unitron Charger-Combi-BTE-2 - FA	DOCUMENT	Sub Document
PDL-18266 [1]	029-1301-42 User Guide Unitron Charger-Combi-BTE-2 - ES-SA	DOCUMENT	Sub Document
PDL-18267 [1]	029-1301-43 User Guide Unitron Charger-Combi-BTE-2 - PT-BR	DOCUMENT	Sub Document
PDL-18365 [1]	029-6812-02 User guide Hansaton B Charger	DOCUMENT	Related

Approvals

<u>Level</u>	<u>Actor</u>	<u>Job Title</u>	<u>Sign-off Date</u>	<u>Sign-off By</u>
1	Bryan Hynes	Coordinator, Information Control	02-Feb-2023	53BHYNES
2	Janette Brookes	Technical Administrator, Information Control	02-Feb-2023	53JBROOKES
2	Zeljko Nadjmico	Manager, Quality Assurance and Regulatory Systems	07-Feb-2023	53HPARMAR
2	Samson Berhane	Product Manager	06-Feb-2023	53SBERHANE

Revision Notes

<u>Access Activity</u>	<u>Note</u>	<u>Accessed By</u>	<u>Accessed Date</u>
Remark	CHANGE-PLN-1100-01063 Humidity 70% Added to chapter 1.: For charger, use only IEC 60950-1*, IEC 62368-1 and/or IEC 60601-1 certified equipment with an output rating of 5 VDC. Min. 500 mA. added: add "IEC 60601-1-11" Changed "Power pack" to "charging accessory" in warning: Only authorized personnel are allowed to open the charging accessory due to possible electrical hazard.	53TMARINIC	07-Feb-2023
Remark	The User Guide was approved with discrepancies compared to the warning texts of RISK-145 and RISK-1085. Impact was assessed and recorded in NC-2023-000681, NC Deviation record. The User Guide can be released to the market in its current version.	53MWHITEMAN	28-Apr-2023