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Revision: Original
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009920200ML



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TOTALSHIELD® II SMART CHARGER

English

REF 00992020000 **TOTALSHIELD II SIX-BAY SMART CHARGER**
REF 00990020002 **TOTALSHIELD II TWO-BAY SMART CHARGER**

INTENDED USE

TotalShield II Charger is intended for use with *TotalShield II* Surgical Helmet System. The *TotalShield II* Surgical Helmet System is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.

SPECIFICATIONS

Catalogue Number	REF 00990020002	REF 00990020000
Product Description	<i>TotalShield II</i> Two-bay Smart Charger	<i>TotalShield II</i> Six-bay Smart Charger
Electrical Input	100-240VAC, 50 - 60 Hz	
Electrical Output	24VDC	
Weight	0.36kg / 12.7oz	3.3kg / 7.2lb
Dimensions	58mm x 180mm x 122mm 2.25" x 7" x 5"	127mm x 400mm x 203mm 5" x 15.75" x 8"

CONFORMANCE INFORMATION

The *TotalShield II* Smart Chargers REF 00992020000 and REF 00990020002 have been tested to, and fulfill the requirements of, the following applicable Regulations:

- EN60950:2006/A1:2010
- EN55024:1998/A1:2001 ITE/A2:2003
- EN61000-3-3:2008 (Limitation of voltage fluctuation & flicker)
- Low Voltage Directive 2006/95/EC as amended
- RoHS Directive 2002/95/EC
- ANSI/AAMI STD ES60601-1
- EN55022:2006 – ITE Class B
- IEC 60601-1-2 ed 4.0
- EN61000-3-2:2006 (Limits for harmonic current emissions)
- FCC Title 47 CFR, Part 15 Class B/ IECS-003, Issue 4
- CAN/CSA No. 60601-1

⚠ WARNINGS

- Upon initial receipt and before each use inspect each *TotalShield II* Charger for damage. Do not use the Charger if the cord and/or plug appear to be damaged, such as cuts, bent pins or contact, and/or cracks.
- Do not expose the *TotalShield II* Charger to heat, fire, or mechanical shock.
- Do not expose the Charger to heat sources or sunlight. Warm environments can cause the calibration to fail. Place the Charger in a cool spot, away from external heat sources.
- Do not cover the fan exhaust or obstruct the airflow. This will cause overheating.
- Do not use this equipment in the presence of a mixture containing a flammable anesthetic and/or air or oxygen or nitrous oxide.
- Do not sterilize, immerse, or expose the *TotalShield II* Charger or Power Supply to water, solvents, lubricants, or other chemicals to clean the Charger unless otherwise directed. Do not allow water to collect in the modules or on top of the Charger. Do not allow water to enter the power connection on the back of the Charger. Keep clean and dry.
- Do not short-circuit, crush, open, shred, incinerate, or dismantle the *TotalShield II* Charger or Power Supply case. The Charger does not have serviceable parts. Please contact Zimmer Biomet Surgical for replacement instructions.
- Do not modify or change the Charger Power Cord.
- Do not use any Charger other than those specifically provided for use with the *TotalShield II* Surgical Helmet System. Do not use a Charger accessory that is not listed in the Instructions for Use. Use of any other Charger or Charger accessory may cause fire, explosion, electric shock, or injury.
- Use only the *TotalShield II* Charger and Charger accessories in the application for which they are intended.
- Follow hospital procedure regarding electromagnetic compatibility (EMC) when using medical equipment such as the *TotalShield II* Charger.
- Do not operate the Charger at a different voltage than what is listed on the unit and in the Instructions for Use.

CHARGING INSTRUCTIONS

Reference *TotalShield II* Surgical Helmet Instructions for Use for charging instructions.

CAUTION: Only use the *TotalShield II* Rechargeable Li-Ion Batteries REF 00992010200 when using the *TotalShield II* Battery Charger REF 00990020000 and REF 00990020002.

CLEANING INSTRUCTIONS

Charger Cleaning

1. Disconnect the Charger from the power source.
2. Clean the exterior of the Charger with a cloth that has been dampened (not dripping) using a hospital disinfectant. Follow applicable hospital protocols during cleaning and dry immediately.

STORAGE AND TRANSPORTATION CONDITION

Recommended Storage and Transportation Conditions: 0°F (-18°C) to 113°F (45°C), up to 80% RH

Transport or store the Chargers in an environment that limits exposure to dust, moisture and temperature extremes.

DISPOSAL/RECYCLE

Follow the hospital and/or local regulations to recycle or dispose of electrical equipment at the end of its useful life.

TROUBLESHOOTING GUIDE

SYMPTOM	POSSIBLE CAUSES/SOLUTIONS
Battery not charging	<ul style="list-style-type: none">• Ensure Charger Power Cord is plugged in to the AC power outlet.• Ensure DC connector is plugged into the back of the Charger (for REF 00990020002, Two-bay Charger only).• Ensure Battery is properly seated in the Charger bay. Ensure arrows are aligned.• If repeated attempts to charge the Battery have failed, the Battery may be faulty. Replace the Battery.• The Charger may have a faulty Power Cord. Replace the Power Cord.
Charger LED indicator not working	<ul style="list-style-type: none">• Ensure Charger Power Cord is plugged in to the AC power outlet.• Ensure Battery is properly seated in the Charger bay. Ensure arrows are aligned.• The Charger may have a faulty Power Cord. Replace the Power Cord.
Battery LED indicator not functioning	<ul style="list-style-type: none">• Battery charge may be fully depleted. Charge the Battery pack.• Faulty Battery pack. Replace the Battery pack.
Battery does not recalibrate	<ul style="list-style-type: none">• The Battery pack may be faulty. Replace the Battery pack.• The Charger LED indicator may be faulty. Try a different Charger bay. If this is not successful, replace the Battery Charger unit.• The Charger may be faulty. Replace the Charger unit.

The *TotalShield II* Smart Charger complies with EMC criteria set forth in EN 60601-1. The user of this device should be aware that precautions should be taken in regards to EMC. The device should be installed and used according to the EMC information provided in the instructions for use. See EMC Guidance Tables included with this manual.

WARNING: Use of a mains power cord other than those specified may result in increased emissions and decreased immunity.

WARNING: The *TotalShield II* Charger System is suitable for use in Professional Healthcare Facility Environments except for near active HF SURGICAL EQUIPMENT and the RF shielded room of a ME SYSTEM for magnetic resonance imaging.

WARNING: Use of the *TotalShield II* Charger System adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the *TotalShield II* Charger System. Otherwise, degradation of the performance of this equipment could result.


**Table 1.1 Zimmer Biomet TotalShield II Smart Charger EMC Guidance and Declaration
EN 60601-1-2**

Guidance and manufacturer's declaration – electromagnetic emissions		
The <i>TotalShield II</i> Charger is intended for use in the electromagnetic environments specified below. The customer or the user of the <i>TotalShield II</i> Charger should assure that it is used in such an environment. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The <i>TotalShield II</i> Charger uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The <i>TotalShield II</i> Charger is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions EN 61000-3-3	Complies	

**Table 1.2 Zimmer Biomet TotalShield II Smart Charger EMC Guidance and Declaration
EN 60601-1-2**

Guidance and manufacturer's declaration – electromagnetic immunity			
The <i>TotalShield II</i> Charger is intended for use in the electromagnetic environments specified below. The customer or the user of the <i>TotalShield II</i> Charger should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) EN 61000-4-2	± 2, ± 4, ± 8 kV contact ± 2, ± 4, ± 15 kV air	± 2, ± 4, ± 8 kV contact ± 2, ± 4, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) 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 input lines EN 61000-4-11	100% drop, 0.5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods Voltage Interruptions (all input current)	100% drop, 0.5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods Voltage Interruptions (all input current)	Main power quality should be that of a typical commercial or hospital environment. If the user of the <i>TotalShield II</i> Charger requires continued operation during power mains interruptions, it is recommended that the <i>TotalShield II</i> Charger be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**Table 1.3 Zimmer Biomet TotalShield II Smart Charger EMC Guidance and Declaration
EN 60601-1-2**

Guidance and manufacturer's declaration – electromagnetic immunity			
The <i>TotalShield II</i> Charger is intended for use in the electromagnetic environments specified below. The customer or the user of the <i>TotalShield II</i> Charger should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF EN 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the <i>TotalShield II</i> Charger, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance levels in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	

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) telephone 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 *TotalShield II* Charger is used exceeds the application RF compliance levels above, the *TotalShield II* Charger should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *TotalShield II* Charger.
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Table 1.4 Zimmer Biomet TotalShield II Smart Charger EMC Guidance and Declaration
EN 60601-1-2**

Recommended separation distances between portable and mobile RF communication equipment and the <i>TotalShield II</i> Charger.			
The <i>TotalShield II</i> Charger is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <i>TotalShield II</i> Charger can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <i>TotalShield II</i> Charger as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.

TOTALSHIELD II ИНТЕЛИГЕНТНО ЗАРЯДНО УСТРОЙСТВО

Български

REF 00992020000 TOTALSHIELD II ИНТЕЛИГЕНТНО ЗАРЯДНО УСТРОЙСТВО
REF 00990020002 TOTALSHIELD II ИНТЕЛИГЕНТНО ЗАРЯДНО УСТРОЙСТВО

ПРЕДНАЗНАЧЕНИЕ

Зарядното устройство *TotalShield II* е предназначено за употреба с хирургичната система с шлем *TotalShield II*. Хирургичната система с шлем *TotalShield II* е предвидена да бъде носена от хирургичния персонал, за да се осигури бариера между оперативната среда и хирургичния персонал за предпазване от контаминация и/или експозиция на инфекциозни телесни течности и вредни микроорганизми.

СПЕЦИФИКАЦИИ

Каталожен номер	REF 00990020002	REF 00990020000
Описание на продукта	<i>TotalShield II</i> интелигентно зарядно устройство	<i>TotalShield II</i> интелигентно зарядно устройство
Входящ електрически ток	100-240 V AC, 50 - 60 Hz	
Изходящ електрически ток	24 V DC	
Тегло	0,36 kg / 12,7 oz	3,3 kg / 7,2 lb
Размери	58 mm x 180 mm x 122 mm 2,25" x 7" x 5"	127 mm x 400 mm x 203 mm 5" x 15,75" x 8"

ИНФОРМАЦИЯ ЗА СЪОТВЕТСТВИЕ