Technical Specifications

General Device Information

Applied Part Classification ..... Type BF (body floating)
Applied Parts ..... Handpiece and Lens piece
Ingress Protection Rating (IP code) ..... ME Equipment: IPX0
Monitor: IPX1
Footswitch: IPX8

Device Characteristics

Device Dimensions (WxDxH-minimum) .....
.....660 x 610 x 1372 mm (26 x 24 x 54 in)
Device Weight .... With FA (61-000300): Approximately 85 kg (188 lb) fully loaded
Without FA (61000400): Approximately 82.6 kg (182 lb) fully loaded
Display Properties ..... 21.5" IPS touchscreen HD 1920 x 1080 monitor
CPU and Storage ..... Intel® Core i7
16 GB Random Access Memory
1 TB Solid State Storage Drive

Operating System

Microsoft Windows® 10 Operating System (OS)
Software v7.0
Instrument Control Firmware v1.0

Electrical/Power Supply

Ratings ..... 100-240 V~, 50/60 Hz, 400 VA
Fuses ..... Fuses: 3AG 6.3A 250V slo-blo 5 x 20 mm
Power Consumption ..... 400 W maximum with all options
Power Cord ..... Meeting the following specifications:
Detachable hospital-grade
305 cm (10 ft) maximum length
Rated at 10A (minimum)
UL/CSA listed
REACH, RoHS compliant
Battery LI-ION (2) 14.4V
Battery Charging Module 240W
Full Battery Charge Operation (battery run time when AC supply is interrupted) ..... 10 mins
Battery Recharge Time .....
.....If completely discharged, charge a minimum of 5 hours

Environmental Conditions for Use

Operating Environmental Limits
Temperature ..... 10° – 35° C (50° – 95° F)
Relative Humidity ..... 30% – 90% noncondensing
Atmospheric Pressure ..... 70 – 106 kPa (20.7 – 31.3" Hg)
Altitude ..... -382 – 3012 m (-1255 – 9822 ft)

Storage (unboxed)
Temperature ..... -10° to 55° C (14° to 131° F)
Relative Humidity ..... 30% – 90% noncondensing
Atmospheric Pressure ..... 70 – 106 kPa (20.7 – 31.3" Hg)
Altitude ..... -382 – 3012 m (-1255 – 9822 ft)

Transport (in original shipping material)
Temperature ..... -29° – 50° C (-20° – 122° F)
Relative Humidity ..... 10% – 85% noncondensing
Atmospheric Pressure ..... 50 – 106 kPa (14.7 – 31.3" Hg)
Altitude ..... -382 – 5574 m (-1255 – 18,288 ft)

*NOTE: Specifications are subject to change without notice.

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Applicable Standards

Australia

EN ISO 15223-1:2016
Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

EN 60601-1:2006
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

EN 60601-1-6:2010
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)

IEC 60601-1-2:2014 – EMC Fourth Edition
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 62304:2006+AMD1:2015
Medical device software - Software life cycle processes

ISO 10940-2009
Ophthalmic Instruments - Fundus Cameras

Canada

CAN/CSA-C22.2 NO. 60601-1:14 (R2018)
Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition, 2005-12, including amendment 1:2012, with Canadian deviations)

CAN/CSA-C22.2 NO. 60601-1-6:11 + A1 (R2016)
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (Adopted IEC 60601-1-6:2010, third edition, 2010-01)

IEC 60529
Degrees of protection provided by enclosures (IP Code)

IEC 62304:2006+AMD1:2015
Medical device software - Software life cycle processes

IEC 62366:2014 - Ed. 1.1
Medical devices – Application of usability engineering to medical devices

EU

EN ISO 15223-1:2016
Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

EN 60601-1:2006
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

EN 60601-1-6:2010
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)

EN 60601-1-2:2015
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60529
Degrees of protection provided by enclosures (IP Code)

IEC 62133:2012
Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

EN 62304:2006
Medical device software - Software life-cycle processes

Japan

IEC 60601-1: 2005+A1:2012+Cor1:2014
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

USA

ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD)

EN ISO 15223-1:2016
Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

IEC 60601-1-6:2010+A1:2013
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 60601-1-2:2014 – EMC Fourth Edition
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 62133:2012
Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

IEC 62304:2006+AMD1:2015
Medical device software - Software life cycle processes

ISO 10940-2009
Ophthalmic Instruments - Fundus Cameras

UL2054:2011
Standard for Household and Commercial Batteries

UL1642:2009
UL Standard for Safety for Lithium Batteries

Worldwide

ANSI Z80.36-2016
For Ophthalmics - Light Hazard Protection for Ophthalmic Instruments

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes

ISO 15004-2:2007
Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection

ISO 10993-1
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ISO 14971:2019
Medical Devices – Application of Risk Management to Medical Devices

ISO 15223-1:2016, Corrected version 2017-03
Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

ISTA 2A Shipping Tests
International Safe Transit Association

ISTA 2B Shipping Tests
International Safe Transit Association

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