Testing Site Acceptance

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The following organization has been assessed and found to comply with the relevant requirements of ISO/IEC 17025 and the Intertek Global Recognized Test Laboratory Policy Manual

Recognized Test Laboratory

under the Test Data Acceptance for the ETL and is authorized to perform test work for the product types identified on the endorsement to this Testing Site Acceptance.

Intertek RTL Program

Our data acceptance testing program allows a qualified laboratory to perform product testing at their site, with the same validity as if it were conducted in an Intertek laboratory.

Organization:

Medical Equipment Compliance Associates, LLC (MECA)

5060 West Ashland Way
Franklin, WI 53132

Acceptance Number	2012-RTL-L4-19
Issue Number	00000
Issue Date	04 September 2019
Expiry Date	04 September 2020

This Testing Site Acceptance is valid until the expiry date shown above, subject to continuing compliance with the conditions specified in the endorsement of this site acceptance.

The Testing Site Acceptance is comprised of this front sheet and 1 endorsement.

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Endorsement to Acceptance No: 2012-RTL-L4-19

The details below define the conditions applicable to the Testing Site Acceptance granted to the Laboratory, and are valid only for the period stated below. The acceptance is subject to the laboratory's continuing compliance with the applicable rules according to Intertek's Recognized Test Laboratory Program.

Scope of Acceptance:

Standards :

Standard	Description	Date & Edition
IEC 60601-1:1988 Ed.2	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance	1988 Ed.2
UL 60601-1:2003 Ed.1 +R:26Apr2006	Medical Electrical Equipment - Part 1: General Requirements For Safety	R:26Apr2006
CSA C22.2#601.1:1990 Ed.1+G1;S1;A2;G2 Expires: 12Oct2017>	Medical Electrical Equipment - General Requirements For Safety	1990 Ed.1+G1;S1;A2;G2
IEC 60601-1:2005 Ed.3 +C1;C2	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety & Essential Performance	2005 Ed.3 +C1;C2
AAMI ES60601-1:2005 +C1;A2	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance	(R2012) [AAMI ES60601-1:2005 +C1;A2]
CSA C22.2#60601-1:2008 Ed.2+C2	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance	(R2013) [CSA C22.2#60601-1:2008 Ed.2+C2]
IEC 60601-1:2005 Ed.3 +C1;C2;A1	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety & Essential Performance	2005 Ed.3 +C1;C2;A1
AAMI ES60601-1:2005 +A1	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance	2005 +A1
CSA C22.2#60601-1:2014 Ed.3	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance	2014 Ed.3
IEC/CSA/EN 60601-1-1 (Ed. 2)	Medical Electrical Equipment – Part 1-1: General Requirements For Safety – Collateral Standard: Safety Requirements For Medical Electrical Systems	2000 Ed.2

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Scope of Acceptance:

Standards :

Standard	Description	Date & Edition
IEC 60601-1-6:2006 Ed.2	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	2006 Ed.2
IEC 60601-1-6:2010 Ed.3	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	2010 Ed.3
IEC 60601-1-6:2010 Ed.3+A1	Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability	2010 Ed.3+A1
IEC 60601-1-8:2003 Ed.1 +A11	Medical Electrical Equipment - Part 1-8: General Requirements For Basic Safety And Essential Performance - Collateral Standard: General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems	2003 Ed.1 +A1
IEC 60601-1-8:2006 Ed.2	Medical Electrical Equipment – Part 1-8: General Requirements For Basic Safety And Essential Performance – Collateral Standard: General Requirements Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems	2006 Ed.2
IEC 60601-1-8:2006 Ed.2 +A1	Medical Electrical Equipment – Part 1-8: General Requirements For Basic Safety And Essential Performance – Collateral Standard: General Requirements Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems	2006 Ed.2 +A1
AAMI IEC 60601-1-8:2006 +A1	Medical Electrical Equipment - Part 1-8: General Requirements For Basic Safety And Essential Performance - Collateral Standard: General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical System	2006 +A1
CSA C22.2#60601-1-8:2008 Ed.2+A1	Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral standard: Requirements for the development of physiologic closed-loop controllers	2008 Ed.2+A1
IEC 60601-1-10:2007 Ed.1	Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral standard: Requirements for the development of physiologic closed-loop controllers	2007 Ed.1

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Standards :

Standard	Description	Date & Edition
CSA C22.2#60601-1-10 Issued: 2009/11/01	Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral standard: Requirements for the development of physiologic closed-loop controllers	2009/11/01
IEC 60601-1-11:2010 Ed.1 +C1 (Excluding: Shock and Vibration)	Medical Elec. Equip.- Part 1-11: Gen. Req. For Basic Safety & Essential Perf.- Collateral Standard - Req. For Medical Elec. Equip. & Medical Elec. Systems Used In The Home Healthcare Environment; Corr. 1: 2011	2010 Ed.1 +C1
IEC 60601-1-11:2015 Ed.2 (Excluding: Shock and Vibration)	Medical Electrical Equipment Part 1-11: General Requirements For Basic Safety And Essential Performance Collateral Standard - Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment	2015 Ed.2
AAMI HA60601-1-11:2015 Ed.2 (Excluding: Shock and Vibration)	Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety & Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment & Medical Electrical Systems Used In The Home Healthcare Environment	2015 Ed.2
CSA C22.2#60601-1-11:2011 Ed.1 (Excluding: Shock and Vibration)	Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety & Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment & Medical Electrical Systems Used In The Home Healthcare Environment	2011 Ed.1
CSA C22.2#60601-1-11:2015 Ed.2 (Excluding: Shock and Vibration)	Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety & Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment & Medical Electrical Systems Used In The Home Healthcare Environment	2015 Ed.2
IEC 60601-1-12:2014 Ed.1	Medical Electrical Equipment - Part 1-12: General Requirements For Basic Safety And Essential Performance: Requirements For Medical Electrical Equipment And Medical Electrical Systems Intended For Use In The Emergency Medical Services Environment	2014 Ed.1
IEC 60601-2-2:2006 Ed.4	Medical Electrical Equipment – Part 2-2: Particular Requirements For The Safety Of High Frequency Surgical Equipment	2006 Ed.4
IEC 60601-2-2:2009 Ed.5	Medical Electrical Equipment - Part 2-2: Particular Requirements For The Safety Of High Frequency Surgical Equipment And High Frequency Surgical Accessories	2009 Ed.5

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Standards :

Standard	Description	Date & Edition
AAMI IEC 60601-2-2:2009	Medical Electrical Equipment Part 2-2: Particular Requirements For Basic Safety And Essential Performance Of High Frequency Surgery Equipment And High Frequency Surgical Accessories	2009
IEC 60601-2-2:2009 Ed.5 +C1	Medical Electrical Equipment – Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgery Equipment And High Frequency Surgical Accessories	2009 Ed.5 +C1
CAN/CSA C22.2 NO. 60601-2-2-09 (R2014)	Medical Electrical Equipment – Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgery Equipment And High Frequency Surgical Accessories	R2014
IEC 60601-2-4:2002 Ed.2 – Requires client to provide test meter (or rent) if pacing provided in defibrillator	Medical Electrical Equipment - Part 2-4: Particular Requirements For The Basic Safety And Essential Performance Of Cardiac Defibrillators	2002 Ed.2
IEC 60601-2-4:2002 Ed.2+C1 – Requires client to provide test meter (or rent) if pacing provided in defibrillator	Medical Electrical Equipment Part 2-4: Particular Requirements For The Safety Of Cardiac Defibrillators	2002 Ed.2+C1
IEC 60601-2-4:2010 Ed.3 – Requires client to provide test meter (or rent) if pacing provided in defibrillator)	Medical Electrical Equipment - Part 2-4: Particular Requirements For The Basic Safety And Essential Performance Of Cardiac Defibrillators	2010 Ed.3
AAMI IEC 60601-2-4:2010 – Requires client to provide test meter (or rent) if pacing provided in defibrillator	Medical Electrical Equipment - Part 2-4: Particular Requirements For Basic Safety And Essential Performance Of Cardiac Defibrillators	2010
CAN/CSA C22.2 NO. 60601-2-4:12 (R2016)	Medical Electrical Equipment - Part 2-4: Particular Requirements For Basic Safety And Essential Performance Of Cardiac Defibrillators	R2016
IEC 60601-2-10:1987 Ed.1 +A1;C1	Medical Electrical Equipment Part 2-10: Particular Requirements For The Safety Of Nerve And Muscle Stimulators	1987 Ed.1 +A1;C1

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Standards :

Standard	Description	Date & Edition
IEC 60601-2-10:2012 Ed.2	Medical Electrical Equipment Part 2-10: Particular Requirements For Basic Safety And Essential Performance Of Nerve And Muscle Stimulators	2012 Ed.2
IEC 60601-2-10:2012 Ed.2+A1	Medical Electrical Equipment - Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators	2012 Ed.2+A1
CSA C22.2#60601-2-10 Issued 2014/05/01 Ed: 2	Medical Electrical Equipment — Part 2-10: Particular Requirements for The Basic Safety and Essential Performance of Nerve and Muscle Stimulators	2014/05/01 Ed: 2
IEC 60601-2-18:1996 Ed.2	Medical Electrical Equipment – Part 2-18: Particular Requirements For The Basic Safety And Essential Performance Of Endoscopic Equipment	1996 Ed.2
IEC 60601-2-18:1996 Ed.2+A	Medical Electrical Equipment - Part 2-18: Particular Requirements For The Basic Safety And Essential Performance Of Endoscopic Equipment	1996 Ed.2+A1
IEC 60601-2-18:2009 Ed.3	Medical Electrical Equipment – Part 2-18: Particular Requirements For The Basic Safety And Essential Performance Of Endoscopic Equipment	2009 Ed.3
CAN/CSA C22.2 No. 60601-2-18:11 (R2016)	Medical Electrical Equipment – Part 2-18: Particular Requirements For The Basic Safety And Essential Performance Of Endoscopic Equipment	R2016
IEC 60601-2-24:1998 Ed.1 – Except shock/ vibration	Medical Electrical Equipment - Part 2-24: Particular Requirements For The Safety Of Infusion Pumps And Controllers	1998 Ed.1
IEC 60601-2-24:2012 Ed.2 – Except shock/ vibration	Medical Electrical Equipment - Part 2-24: Particular Requirements For The Basic Safety And Essential Performance Of Infusion Pumps And Controllers	2012 Ed.2
CAN/CSA C22.2 NO. 60601-2-24:15 Except shock/ vibration	Medical Electrical Equipment - Part 2-24: Particular Requirements For The Basic Safety And Essential Performance Of Infusion Pumps And Controllers	2015
IEC 60601-2-25:1993 Ed.1)	Medical Electrical Equipment - Part 2-25: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographs	1993 Ed.1]
IEC 60601-2-25:1993 Ed.1 +A1	Medical Electrical Equipment Part 2: Particular Requirements For The Safety Of Electrocardiographs	1993 Ed.1 +A1

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Standards :

Standard	Description	Date & Edition
IEC 60601-2-25:2011 Ed.2	Medical Electrical Equipment - Part 2-25: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographs	2011 Ed.2
CAN/CSA C22.2 NO. 60601-2-25:12 (R2017)	Medical Electrical Equipment - Part 2-25: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographs	R2017
IEC 60601-2-26:2002 Ed.2	Medical Electrical Equipment Part 2-26: Particular Requirements For The Safety Of Electroencephalographs	2002 Ed.2
IEC 60601-2-26:2012 Ed.3	Medical Electrical Equipment Part 2-26: Particular Requirements For The Basic Safety And Essential Performance Of Electroencephalographs	2012 Ed.3
IEC 60601-2-27: 2005 Ed.2	Medical Electrical Equipment - Part 2-27: Particular Requirements For The Safety, Including Essential Performance, Of Electrocardiographic Monitoring Equipment	2005 Ed.2
IEC 60601-2-27: 2011 Ed.3	Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment	2011 Ed.3
CAN/CSA C22.2 NO. 60601-2-27-06 (R2016)	Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment	R2016
AAMI IEC 60601-2-27:2011 +E2012	Medical Electrical Equipment - Part 2-27: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographic Monitoring Equipment	2011 +E2012
IEC 60601-2-30:1995 Ed.1	Medical Electrical Equipment - Part 2: Particular Requirements For The Safety Of Automatic Cycling Indirect Blood Pressure Monitoring Equipment	1995 Ed.1
IEC 60601-2-30:1999 Ed.2	Medical Electrical Equipment - Part 2-30: Particular Requirements For The Safety, Including Essential Performance, Of Automatic Cycling Indirect Blood Pressure Monitoring Equipment	1999 Ed.2
CAN/CSA C22.2 NO. 60601-2-30-02 (R2011)	Medical Electrical Equipment - Part 2-30: Particular Requirements For The Safety, Including Essential Performance, Of Automatic Cycling Indirect Blood Pressure Monitoring Equipment	R2011

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Standards :

Standard	Description	Date & Edition
IEC 60601-2-34:2000 Ed.2	MEDICAL ELECTRICAL EQUIPMENT - PART 2-34: PARTICULAR REQUIREMENTS FOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE OF INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT	2000 Ed.2
IEC 60601-2-34:2011 Ed.3	Medical Electrical Equipment Part 2-34: Particular Requirements for the Safety, Including Essential Performance, of Invasive Blood Pressure Monitoring Equipment	2011 Ed.3
CAN/CSA C22.2 NO. 60601-2-34:12 (R2017)	Medical Electrical Equipment Part 2-34: Particular Requirements for the Safety, Including Essential Performance, of Invasive Blood Pressure Monitoring Equipment	R2017
IEC 60601-2-36 (Ed. 1)	Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy	Ed. 1
CAN/CSA C22.2 NO. 60601-2-36:16	Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy	2016
IEC 60601-2-37:2007 Ed.2	Medical Electrical Equipment - Part 2-37: Particular Requirements For The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment	2007 Ed.2
IEC 60601-2-37:2007 Ed.2+A1	Medical Electrical Equipment - Part 2-37: Particular Requirements For The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment	2007 Ed.2+A1
IEC 60601-2-38:1996 Ed.1	Medical Electrical Equipment - Part 2-38: Particular Requirements For The Safety Of Electrically Operated Hospital Beds	1996 Ed.1 +A1
CAN/CSA C22.2 NO. 60601-2-38-03 (R2007)	Medical Electrical Equipment - Part 2-38: Particular Requirements For The Safety Of Electrically Operated Hospital Beds	R2007
IEC 60601-2-40:1998 Ed.1	Medical Electrical Equipment - Part 2-40: Particular Requirements For The Safety Of Electromyographs And Evoked Response Equipment	1998 Ed.1
IEC 60601-2-40:2016 Ed.2	Medical Electrical Equipment - Part 2-40: Particular Requirements For The Safety Of Electromyographs And Evoked Response Equipment	2016 Ed.2
CAN/CSA C22.2 NO. 60601-2-40:17	Medical Electrical Equipment - Part 2-40: Particular Requirements For The Safety Of Electromyographs And Evoked Response Equipment	2017

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Standards :

Standard	Description	Date & Edition
IEC 60601-2-46:1998 Ed.1	Medical Electrical Equipment - Part 2-46: Particular Requirements For The Safety Of Operating Tables	1998 Ed.1
IEC 60601-2-46:2010 Ed.2	Medical Electrical Equipment - Part 2-46: Particular Requirements For The Basic Safety And Essential Performance Of Operating Tables	2010 Ed.2
IEC 60601-2-46:2016)	Medical Electrical Equipment - Part 2-46: Particular Requirements For The Basic Safety And Essential Performance Of Operating Tables	2016
CAN/CSA C22.2 NO. 60601-2-46:12 (R2016)	Medical Electrical Equipment - Part 2-46: Particular Requirements For The Basic Safety And Essential Performance Of Operating Tables	R2016
IEC 60601-2-47:2001 Ed.1)	Medical Electrical Equipment - Part 2-47: Particular Requirements For The Safety, Including Essential Performance, Of Ambulatory Electrocardiographic Systems	2001 Ed.1
IEC 60601-2-47:2012 Ed.2)	Medical Electrical Equipment - Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems	2012 Ed.2
CAN/CSA C22.2 NO. 60601-2-47:14	Medical Electrical Equipment - Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems	2014
IEC 60601-2-49:2001 Ed.1	Medical Electrical Equipment - Part 2-49: Particular Requirements For The Safety Of Multifunction Patient Monitoring Equipment	2001 Ed.1
IEC 60601-2-49:2011 Ed.2	Medical Electrical Equipment - Part 2-49: Particular Requirements For The Basic Safety And Essential Performance Of Multifunction Patient Monitoring Equipment	2011 Ed.2
CAN/CSA C22.2 No. 60601-2-49:11 (R2016)	Medical Electrical Equipment - Part 2-49: Particular Requirements For The Basic Safety And Essential Performance Of Multifunction Patient Monitoring Equipment	R2016
IEC 60601-2-52:2009 Ed.1 +C1	Medical Electrical Equipment - Part 2-52: Particular Requirements For The Basic Safety And Essential Performance Of Medical Beds	2009 Ed.1 +C1
IEC 60601-2-52:2009 Ed.1+C1;A1	Medical Electrical Equipment - Part 2-52: Particular Requirements For The Basic Safety And Essential Performance Of Medical Beds	2009 Ed.1+C1;A1
CAN/CSA C22.2 No. 60601-2-52:11 (R2016)	Medical Electrical Equipment - Part 2-52: Particular Requirements For The Basic Safety And Essential Performance Of Medical Beds	R2016

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Standards :

Standard	Description	Date & Edition
IEC 80601-2-30 Ed. 1.1 b:2013	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	2013
CAN/CSA C22.2 No. 80601-2-30-10 (R2015)	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	R2015
ISO 80601-2-56:2009 Ed.1	MEDICAL ELECTRICAL EQUIPMENT - PART 2-56: PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF CLINICAL THERMOMETERS FOR BODY TEMPERATURE MEASUREMENT	2009 Ed. 1
ISO 80601-2-56:2017 Ed.2	Medical Electrical Equipment -- Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement	2017 Ed. 2
CAN/CSA C22.2 NO. 80601-2-56:12 (R2016)	Medical Electrical Equipment -- Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement	R2016
ISO 80601-2-61: (first edition, 2011-04-01	Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	first edition, 2011-04-01
CAN/CSA-C22.2 No. 80601-2-61:14	Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	2014
IEC 62304 Ed. 1.1 en:2015	Medical Device Software - Software Life Cycle Processes	2006 Ed.1 +A1
AAMI IEC 62304:2006	Medical Device Software - Software Life Cycle Processes	2006
CAN/CSA 62304:14	Medical device software - Software life cycle processes	2014
IEC 62366:2007	Medical Devices - Application Of Usability Engineering To Medical Devices	2007
AAMI IEC 62366-1:2015Ed.1+C1;A1	Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices	2015
AAMI IEC 62366-1:2015	Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices	2015

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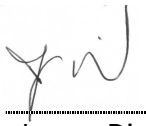
Conditions applicable to the Acceptance:
Refer to annex agreement

The Testing Site Acceptance is comprised of the front sheet and 1 endorsement.

Signature: 
Name: James Diescher
Title: Satellite Technical Lead