

Instructions for Use

Masimo Shuttle™
Part Number 4721



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- Masimo®
- Shuttle™
- iSirona™
- DCX™
- HBox®

Revision history

Date	Revision number	Description
August 27, 2019	1.0	Initial release
October 31, 2019	2.0	The operating temperature range was updated to 0 °C - 40 °C.
December 6, 2019	3.0	The serial port speed was updated to 1M baud. The operating temperature range was updated to 5 °C - 40 °C.
May 7, 2020	4.0	The company name, logo, fonts, and product image were updated to Masimo branding. The corporate contact address was removed and the manufacturer contact address was updated. The title of the manual was updated from User Manual to Instructions for Use.
June 4, 2020	5.0	The part number was updated to 4721.
September 23, 2020	6.0	Updated the required environmental humidity range to 5%-95%

Preface

Symbols

	Caution
	Manufacturer
	Authorized representative
	The CE mark indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area
	Separate collection for waste of electrical and electronic equipment
	Temperature
	Humidity
	Atmospheric pressure

Intended audience

The intended audience for this document is biomedical engineers and nursing staff authorized by Masimo to install the Masimo® Shuttle™.

Masimo® Shuttle™ cable is used to connect medical devices with RS-232 ports for the purpose of sending medical device data to either a Masimo iSirona™, Masimo HBox, or a PC node with a USB port that is running DCX™ Client software.

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Authorized representative



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2514 AP The Hague
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Contacts

Support contact information

Call Masimo Support at 1-833-274-4955, 24 hours a day, seven days a week.

You can also send an email to dcx-support@masimo.com. We monitor emails from 8:00 a.m. to 5:00 p.m. Central Time, Monday through Friday. Use email for non-emergencies only.

Manufacturer contact



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Compliance and safety information

Masimo Shuttle is currently designed to meet regulations for use in the United States, Canada, and Europe.

Federal Communications Commission (FCC)

The Masimo Shuttle cable complies with the FCC rules and regulations delineated in Title 47 CFR, Part 15, Subpart B, Class B for unintentional radiators.

Canadian ISED Compliance

Masimo Shuttle complies with Canada's Interference-Causing Equipment Standards, ICES-003 Class B for unintentional radiators.

Conformité Européenne (CE)

The Masimo Shuttle complies with the following CE directives:

- Electromagnetic Compatibility Directive 2014/30/EU
- Restriction of Hazardous Substances Directive 2011/65/EU
- Waste Electrical and Electronic Equipment Directive 2012/19/EU

Disposal



This symbol on the Masimo Shuttle indicates that this product must not be disposed of with your other unsorted waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste for recycling, please contact your local authority, or the manufacturer contact.

IP rating





Masimo Shuttle has an IP rating of IP-54.

- Protected from limited dust ingress.
- Protected from water spray from any direction.

Note *Ingress of dust or liquid is not entirely preventable.*

Cautions

	Any and all configurations that use this device must be tested for electrical isolation before being used for patient care.
	Do not modify device without authorization. Any modifications must be inspected and approved by Masimo.
	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation or degraded performance.

	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.
	The use of ITE grade USB extenders or USB hubs is not recommended. Only the RS232 interface can be extended but not more than 15m.
	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 Masimo Shuttle cable assembly or any attached RS-232 extension cables. Otherwise, a degradation in the performance of this equipment could result.
	The Masimo Shuttle should only be connected to IEC 60601-1 compliant devices.

Use the Masimo Shuttle

The Masimo Shuttle is a medical-grade USB-to-RS232 converter specially designed to connect various medical devices to the Masimo iSirona, Masimo HBox, or a PC node running Masimo's DCX™ Client software.

- It connects medical devices with RS-232 ports to a USB port on either an iSirona, HBox, or a Windows® PC running DCX Client for the purpose of reporting vitals data.
- It provides a unique identifier used by DCX that enables proprietary medical device data to be streamed to a DCX Client and DCX Server for processing before being sent to the EMR.

The Masimo Shuttle includes a 9-pin RS-232-type male connector for connection to a medical device. Opposite the RS-232 connector is a USB-A connector for connection to the iSirona, HBox, or node.



Light Emitting Diodes (LEDs) at the base of the USB connector indicate when the Masimo Shuttle is transmitting or receiving data to and from the medical device.

When flashing, the green LED indicates that the Masimo Shuttle is transmitting data from DCX to the medical device. The blue LED, when flashing, indicates that the Masimo Shuttle is receiving data from the medical device.

Features

The Masimo Shuttle is compliant with IEC 60601-1. Other features include the following:

- Adds one RS-232 serial port by connecting to USB
- Easy plug-and-play installation and RS-232 device connection
- USB 2.0 compatible device
- First-in first-out (FIFO) transmission: featuring a 128-byte transmit buffer and 256-byte receive buffer
- RS-232 data signals: TxD, RxD, RTS, CTS, DSR, DTR, GND
- Powered by the USB port. No external power adapter is required.
- Serial port speed is up to 1M baud
- Serial Communication Parameters
 - Parity: None, Even, Odd
 - Data bits: 7, 8
 - Flow control: RTS/CTS, DSR/DTR, X-ON/X-OFF, None
 - One DE-9P male connector
- LEDs indicate transmit and receive activity for monitoring port status and easy diagnostics

General handling instructions

General cleaning

The Masimo Shuttle cable is water resistant and may be wiped down or sterilized with alcohol or liquid cleaners without degrading. Clean per hospital protocol.

Note *Medical disinfectant wipes are recommended.*





Environmental requirements

Ensure the following environmental requirements are met:

- Keep the Masimo Shuttle away from sunlight.
- Keep the Masimo Shuttle dry.

The following table details the normal environmental limits within which the Masimo Shuttle will operate.

Environmental requirements

	Parameter	Range low	Range high
	Operating Temperature	5° C	40° C
	Storage Temperature	-25° C	+70° C
	Humidity	5%	95%
	Atmospheric Pressure	700 hPa	1060 hPa

Transportation and storage

Do not store or transport Masimo Shuttle in an uncontrolled environment where the storage temperature is below -25°C or above 70°C. Do not store or transport it in an uncontrolled environment where the atmospheric pressure is below 700 hPa or higher than 1060 hPa. Do not store or transport Masimo Shuttle in an uncontrolled environment where it exceeds the IP rating. Doing so may damage it.

Connect the Masimo Shuttle

To connect the Masimo Shuttle to a medical device and a Masimo iSirona, Masimo HBox, or PC node, follow these steps:

Note *If you don't need an extension cable, you can connect the Masimo Shuttle directly to the medical device.*

1. Connect an extension cable, with a vendor-specified pinout, to the serial port on the medical device.

If you don't know what extension cable to use, contact Masimo Support.

2. Insert the Masimo Shuttle RS-232 9-pin male connector into the extension cable's 9-pin female adapter.
3. Insert the USB-A connector of the Shuttle into a USB port on the iSirona, HBox, or PC node.

Troubleshoot the Masimo Shuttle

When flashing, the green LED indicates that the Masimo Shuttle is transmitting data from DCX to the medical device. The blue LED, when flashing, indicates that the Masimo Shuttle is receiving data from the medical device.

While the LEDs are not required for intended operation, if neither are flashing within the cycle period defined within DCX for the medical device, there may be an issue with connectivity and data flow.

To troubleshoot the problem, take the following steps:

1. Ensure the extension cable that you use to connect the medical device to the Masimo Shuttle is the correct cable and that it works.
2. Ensure the extension cable plugged into the medical device is connected to the correct port.
3. Make sure the RS-232 connection between Masimo Shuttle and the medical device is a solid connection.
4. Make sure the USB connection between Masimo Shuttle and the Masimo iSirona, Masimo HBox, or node is a solid connection.
5. Ensure that both the medical device and the iSirona, HBox, or node are plugged into their respective power outlets and are powered on.
6. If none of the above resolves the issue, the Masimo Shuttle itself may have a problem. Do the following:
 - a) Check the *DCX-CS* log or *DCX-Server* log to see whether the device is transmitting data despite no indication from the LEDs.
 - b) Contact Masimo Support.

Appendix

Electromagnetic emissions

Emission Standards

TVU SUD Reports: TP72151747.100 | Issue: 01, TP72151747.200 | Issue: 01

Standard	Test Description	Test Level/Limits	Results
EN 55032	Radiated Emissions	EN 55011 Class B	Pass
CISPR 11 2009/A1: 2010 EN 55016-23: 2004 + A1: 2005	Electromagnetic Radiation Disturbances	EN 55011 Class B	Pass

Immunity standards

Immunity Standards

TVU SUD Reports: TP72151747.200 | Issue: 01, TP72151747.300 | Issue: 01

Standard	Test Description	Test Level/Limits	Results
EN 55024:2010 / A1:2015	Enclosure Port - Radio-frequency electromagnetic field Amplitude modulated	80 to 1000MHz, 3 V/m	Pass
EN 55024:2010 / A1:2015	Enclosure Port - Electrostatic discharge	Air: +/-2, 4, & 8kV Direct Contact: +/-8kV Indirect Contact: 8kV	Pass
IEC 61000-4-2 2008	Immunity to Electrostatic Discharge (Enclosure Port)	Air: +/-2, 4, 8 & 15kV Direct Contact: +/-8kV Indirect Contact: 8kV	Pass
IEC 61000-4-3 2006 A2:2010	Immunity to Radiated RF Electromagnetic Fields (Enclosure Port)	80 to 2700MHz, 3 V/m	Pass
IEC 61000-4-3 2006 A2:2010	Immunity to Proximity Fields from RF Wireless Communication Equipment	385MHz - 27 V/m; 450MHz - 28 V/m; 710, 745, 780MHz - 9 V/m; 810, 870, 930MHz - 20 V/ m; 1.720, 1.845, 1.970, 2.450GHz - 28 V/m; 5.240, 5.500, 5.785GHz - 9 V/m	Pass
IEC 61000-4-6 2013	Immunity to Conducted Disturbances Induced by RF Fields (Signal Input/ Output Ports)	0.15 - 80MHz - 3V, ISM bands in this range 6V	Pass