YRS100
Cardiac amplifier

Version 1.0

User Manual
Revision E

Date of issue: September 3rd 2019

YOURRHYTHMICS

CE 1912

Table of contents

1 Service and support

About this manual

This manual is intended for the user of the YRS100 system – referred to as 'product' throughout this manual. It contains general operating instructions, precautionary measures and information for use of the product. Read this manual carefully and familiarize yourself with the various controls and accessories before starting to use the product.

Contact information YourRhythmics

YourRhythmics Support can be reached via email (support@yourrhythmics.com) or by phone during office hours (CET). Please make sure you have read our troubleshooting section, because this may resolve your problem without the need of external assistance. Always provide as much information on your problem as possible, including serial numbers of the products. This will help us to support you in the best and most efficient way.

Warranty information

The product, except its cables and accessories, is warranted against failure of materials and workmanship for a period of 2 years from the date of delivery. Cables and accessories have a warranty period of 6 months.

Repairs can only be performed by the manufacturer. Warranty will terminate automatically when the product is opened by any person other than qualified personnel (authorized by YourRhythmics).

The warranty does not cover the following:

- failure resulting from misuse, accident, modification, unsuitable physical or operating environment
- failure caused by a product for which YourRhythmics is not responsible
- damage resulting from use of non-approved accessories

The warranty is voided by removal or alteration of identification labels on the product or its parts.

Any technical or other support provided for a product under warranty, such as assistance with "how-to" questions and those regarding device set-up and installation, is provided without warranty.

2 Safety information

This section contains general warnings, explanation of markings, limitations of use, safety measures, and precautionary measures that are important for the safe use of the product.

The following safety information applies to the YRS100.

Read all instructions before using the product.

Important instructions

1. This manual is written for clinical professionals who operate the YRS100 Cardiac Amplifier. Clinical professionals are expected to have a working knowledge of appropriate medical procedures, practices, and terminology used in treatment of patients.

2. The functioning of the YRS100 system could possibly interfere with implantable cardiac pacemakers, internal cardiac defibrillators, or any other such device. Never use the YRS100 system while programming or interrogating such device.

3. The YRS100 unit shall only be connected to the personal computer's Ethernet connection. Further, connection to the mains should be via an earth protected socket outlet, using the mains lead and plug provided by the manufacturer or one of an equivalent quality. For safety reasons, extension leads or multi-socket connections should not be used.

4. The YRS100 is only to be used with CE certified electrodes.

5. The unit shall be placed on any flat surface of at least the size of the unit. Care must be taken to ensure a free flow of air around the unit. Do not cover the unit with blankets or similar. Make sure that the power plug can be easily (un)plugged.

6. The unit should be protected from the risk of fluids entering it.

7. If service is required, the unit should be serviced by a qualified service technician appointed by YourRhythmics only.

8. The power supply is not protected against ingress of liquids. Therefore, it should be placed in a position where there is no chance of any liquid to get in contact with the power supply. Do **NOT** place the power supply on the floor.

9. To prevent the patient from exposure to an electrical shock, connect the patient-cables only to the YRS100 unit. **NEVER** connect the cables to any other device, such as a computer, a printer, etc.

10. Use only silver/silver chloride surface electrodes (Ag/AgCl) of good quality (e.g. 3M red dot).

11. Any fault-situation that compromised the safety of the patient should be reported to YourRhythmics immediately by email: support@yourrhythmics.com

12. This equipment complies with International Standard EN 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radiofrequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of interference due to close proximity or strength of a source might disrupt the device's performance. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in chapter 8 of this document.

13. This device has not been tested for immunity to magnetic disturbances.

14. Portable and mobile RF communications equipment can affect medical equipment.

15. The YRS100 system is not intended to be used in combination with High Frequency Surgical Equipment.

16. To prevent the RISK of electric shock, only connect the power adapter to a mains outlet with a protective earth connection.

Using YRS100 safely

1. Before using YRS100, make sure to read the User Manual and fully understand the safety information

2. The YRS100 unit does not contain user serviceable parts. Do not open or perform any modifications to the unit.

3. Avoid damaging the power cord. Do not bend it excessively, step on it, place heavy objects on it, etc. A damaged cord can cause an electrical shock or fire hazard.

4. Always grasp only the plug on the power cord when plugging into, or unplugging from, an outlet.

5. Never handle the power cord or its plugs with wet hands when plugging into, or unplugging from, a mains outlet.

6. Prevent cords and cables from becoming entangled.

7. Changes of the YRS100, which are executed without our written permission are not allowed and will lead to an extinction of any warranty.

8. Use only ECG cables of type YRS100 sECG and YRS100 xECG. These cables provide protection against defibrillation.

9. Use cables with shrouded pins only for connection to Unipolar and/or Bipolar inputs sockets on the YRS100 front-panel. The inputs provide protection against defibrillation (built in the YRS100).

Proper use

1. Connect the patient cables only to the front-panel of YRS100. Never try to connect a patient cable to another connector such as the PC or any other device.

2. Prevent connecting cables to the patient-electrodes while the cable is not connected to YRS100.

3. When using a defibrillator do not come into contact with the patient during defibrillation. Otherwise, serious injury or death could result. Patient signal inputs labelled with the CF symbols with paddles are protected against damage resulting from defibrillation voltages. To ensure proper defibrillator protection, use only YourRhythmics- recommended cables. Proper placement of defibrillator paddles in relation to the electrodes is required to ensure successful defibrillation.

4. The YRS100 is not intended for use as a patient monitor. For ECG monitoring purposes, a dedicated patient monitor should be used.

5. The YRS100 is not intended for direct cardiac applications.

6. The YRS100 may only be used in combination with the data acquisition software provided by YourRhythmics and is not part of this system. The data acquisition software is for research purposes only and not for diagnostic purposes.

7. Every time before use of the examination of the next patient the ECG cables should be cleaned, disinfected or sterilized. Before starting the cleaning, disinfection, or sterilization, the cables should be disconnected from the YRS100. Instructions about cleaning, disinfection, or sterilization can be found in the accompanying ECG cable manual.

Special considerations

When a signal from the YRS100 disappears, or only the baseline is shown, or only a line at maximum/minimal amplitude level, this can indicate that the amplifier has become inoperable. In this case verify the connection to the patient. In any case of doubt do not use the system anymore and contact YourRhythmics.

System combinations

The YRS100 may be connected to other devices or to parts of systems only after making certain that there is no danger to the patient, operators, or environment as a result. Standards IEC 60601 must be complied with in all cases.

Preventive inspection

Accessories such as ECG cables or other cables may degrade or deform when in use for a long time. Should this occur they should be replaced to prevent artefacts on signals or malfunction. Also for replacement use certified accessories only. The ECG cables have to be checked on a daily basis.

The YRS100 system must be tested, at least once a year, for electrical safety according to EN60601-1. Qualified personnel must carry out this inspection. In any case of doubt do not use the system anymore and contact YourRhythmics.

Disposal

Please refer to your local requirements regarding the disposal of used medical equipment and accessories. You can also return the YRS100 device to the manufacturer for disposal.

In accordance with the European Council Directive 2002/96/EC of January 27th, 2003 on waste electrical and electronic equipment (WEEE) be informed that the YRS100 device is to be treated as WEEE and therefor the following is applicable after the lifetime of the device:

- Do not dispose of WEEE as unsorted municipal waste.
- Deliver electronic devices to collection facilities for WEEE in your region or return them if possible to the manufacturer.

- Disposing of WEEE in another way then indicated above may harm the environment and human health as a result of the presence of hazardous substances in electronical and electronic equipment.

Explanation of markings

The following symbols may appear on the product, its packaging, and or its documentation.

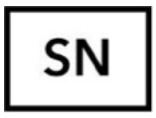
Defibrillation-proof type CF equipment

Refer to the user manual before using the system

Manual contains important safety information

Manufacturer address

Indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.



Indicates the serial number of the device

Indicates the model of the device

Maximum power concumption, input voltage

Indicates conformity with applicable European directives

3 Equipment identification

Serial number YRS100 cardiac amplifier

Item	Description
1	Serial number XXXXX in combination with Date of Manufacture YY MM
2	Product name
3	Contact details legal manufacturer

Serial number sECG leadwire
sECG leadwires are marked with the following print:

SORIMEX KT-10/i-M/10-FD14xs/L-70/110/200-10 CE ZPXXXX.YYYYYY

Item	Description
XXXX	Batch number
YYYYYYY	ID within batch

Serial number xECG leadwire
sECG leadwires are marked with the following print:

SORIMEX KT-10/i-M/10-FD14ys/L-70/110/200-10 CE ZPXXXX.YYYYYY

Item	Description
XXXX	Batch number
YYYYYYY	ID within batch

4 Product overview

The YRS100 system consists of a cardiac amplifier, a power adapter and the necessary cables and accessories. The YRS100 unit is connected to a personal computer by a standard Ethernet cable.

4.1 General information

YRS100 system

The YRS100 system is an ECG acquisition system designed for both regular and experimental studies.

The YRS100 system consists of a cardiac amplifier, a power adapter and the necessary cables and accessories.

The YRS100 is connected to a computer by a standard Ethernet cable. To view, and record signals from the YRS100, dedicated data acquisition software provided by YourRhythmics is needed which is not part of this system. The data acquisition software is for research purposes only and not for diagnostic purposes.

The YRS100 enables the acquisition of the 12-lead standard Surface ECG, 10 channels for extra surface ECG, 10 unipolar ECG channels and 8 bipolar ECG channels. The patient connections of the YRS100 unit are isolated from the PC- and the mains side.

Intended use

The YRS100 is an ECG acquisition system used to acquire, amplify and digitize ECG signals.
The YRS100 is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility

Indication / contraindication

The purpose of the YRS100 is to help with the diagnosis of patients (suspected of) suffering from arrhythmias.

The YRS100 is not a diagnostic system. Signals are only displayed, but not evaluated in order to provide diagnostic assistance.

Application specification

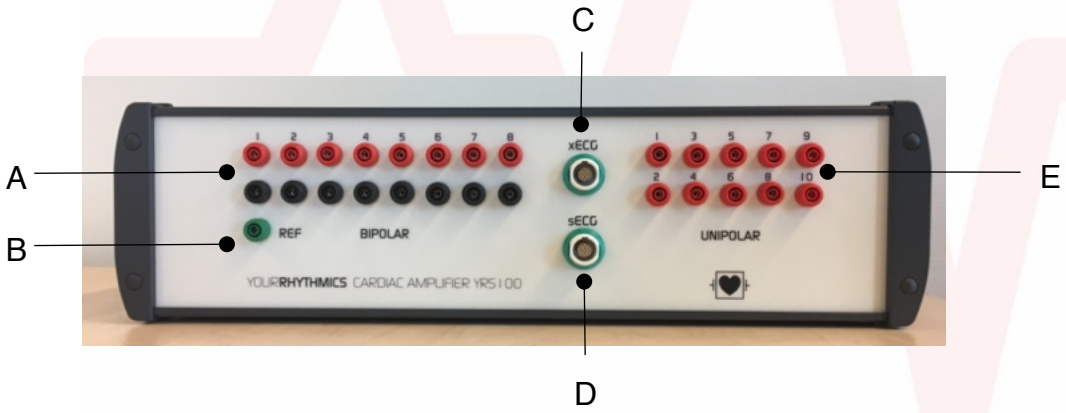
User:	Clinical Professionals e.g. electrophysiologist, cardiologist
Discipline:	Electrophysiology
Patient population:	No demographic restrictions
Contraindications:	None
Place of use:	Medical environment
User interface:	PC with YRS100 Software installed

Revision history

Revision history YRS100		
Revision	**Date**	**Comment**
A	30 October 2017	Initial release of document
B	23 November 2017	Textual updates to improve clarity manual
C	24 April 2019	Instruction positioning YRS100, additional information essential performance, update symbols and power factor.
D	21 June 2019	Add CE on frontpage and equipment identification. Update applicable standards.
E	3 September 2019	Update proper use paragraph, general information YRS100 system, maintenance and cleaning and references.

4.2 Product description

Front view cardiac amplifier



	Name	Description
A	Bipolar	These 8 inputs can be used as auxiliary input for bipolar leads.
B	REF	Output from Wilson terminal (derived from sECG), can be used as a reference for the negative input to transform the input in a unipolar input.
C	xECG	This is the input for extra surface ECG. Additional to the conventional surface ECG electrodes, 10 extra electrodes at different positions on the body can be used. From each electrode a signal will be derived.

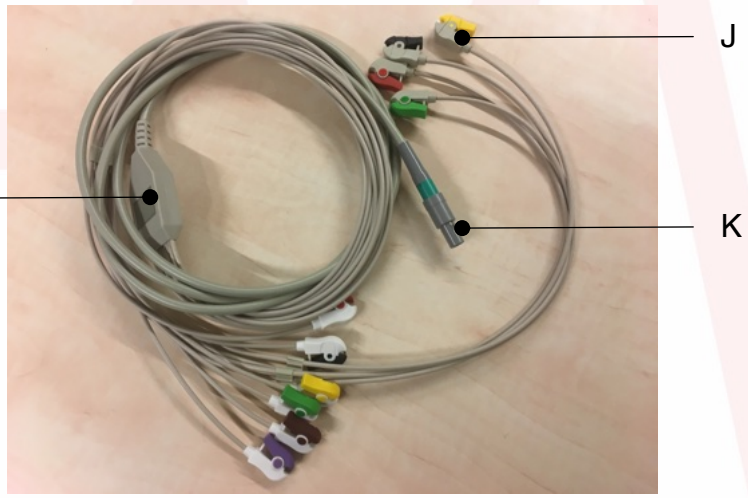
D	sECG	This is the input for the conventional surface ECG. The ECG cable is connected to the electrodes attached to the skin.
E	Unipolar	These 10 inputs can be used as auxiliary inputs for unipolar leads. Reference for these inputs is Wilson terminal.

Back view cardiac amplifier

	Name	Description
F	Communication	RJ-45 connector for connection with PC
G	Adapter	Input of the power adapter
H	Power	Power on switch

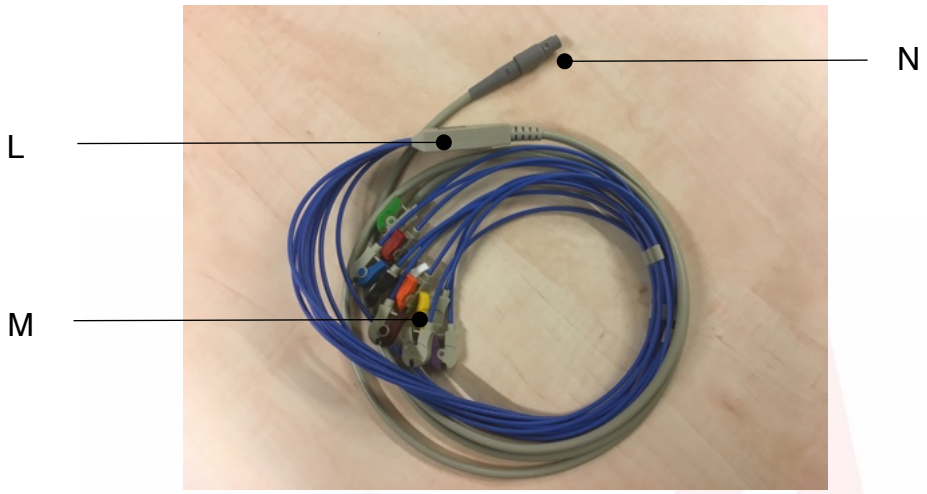
Mains adapter

sECG lead wire



	Name	Description
I	Conductor yoke	Defibrillation protection
J	Electrode grabber	Grabber to ECG monitoring electrode
K	Connector	sECG plug to front panel connector

xECG lead wire



	Name	Description
L	Conductor yoke	Defibrillation protection
M	Electrode grabber	Grabber to ECG monitoring electrode
N	Connector	xECG plug to front panel connector

UTP cable

Recommended PC Configuration

- CPU Intel Core i7 4650U, 1.7 GHz (up to 3.30 GHz) processor
- Memory 16GB DDR3L 1600/1333MHz SDRAM
- Graphics Controller: Intel HD Graphics 5000/4400
- LAN Gigabit Ethernet interface (RJ-45)
- Operating System Windows 10
- LCD monitor 24 inches
- Keyboard, mouse

4.3 Setting up the product

Setting up the YRS100 system consists of the following steps:

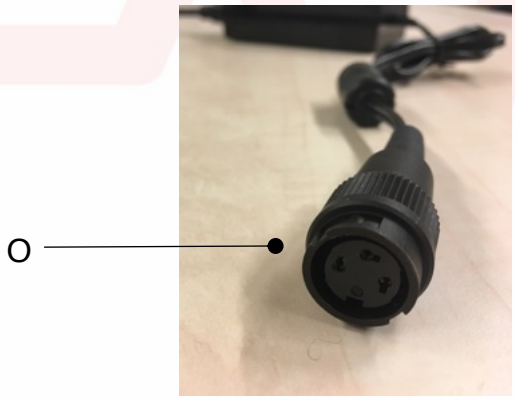
1. Connecting power adapter
2. Connecting communication port
3. Turning on the unit
4. Configuring the system

Each step is described in more detail in the following paragraphs.

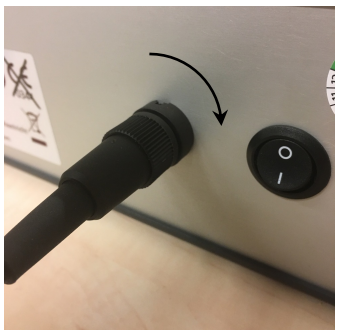
Connecting power adapter

Connect the mains cable to the power supply and the other side into a grounded power outlet. The LED on the power supply will light up green.

Connect the power supply cable into the power supply socket on the back of the device (G). Make sure the notch of the connector is at the bottom of the connection, turn the connector part to position the notch correctly.



Secure the connection by clockwise rotating the bayonet locking (O).



Connecting communication port

Connect the Ethernet cable with RJ-45 connectors between the YRS100 unit (F) and the PC communication port.

The connection between YRS100 cardiac amplifier and PC is a direct peer-to-peer connection only. The YRS100 should not be connected to local area network (LAN) or wide area network (WAN).

Using local area networking equipment such as switches or hubs will result in lack of connection. Using any non-permanent connection extenders (such as wireless adapters) is, due to the nature of the device application, strongly discouraged.

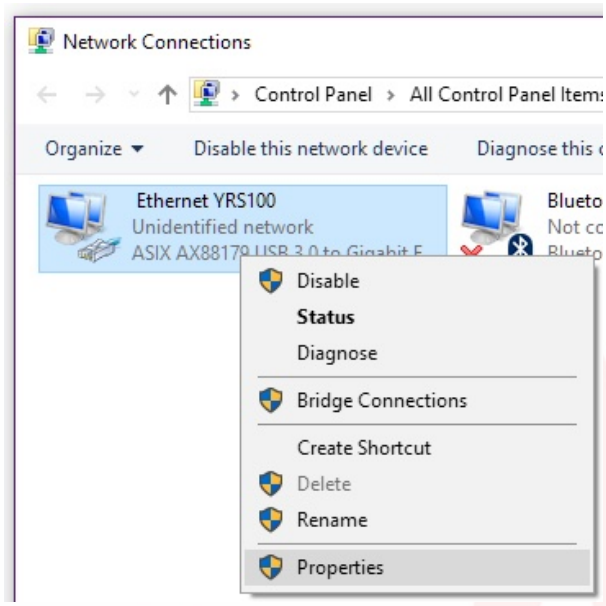
Turning on the unit

Press the power button (H) to power on the system. “O” means the power is OFF and “I” means the power is ON.

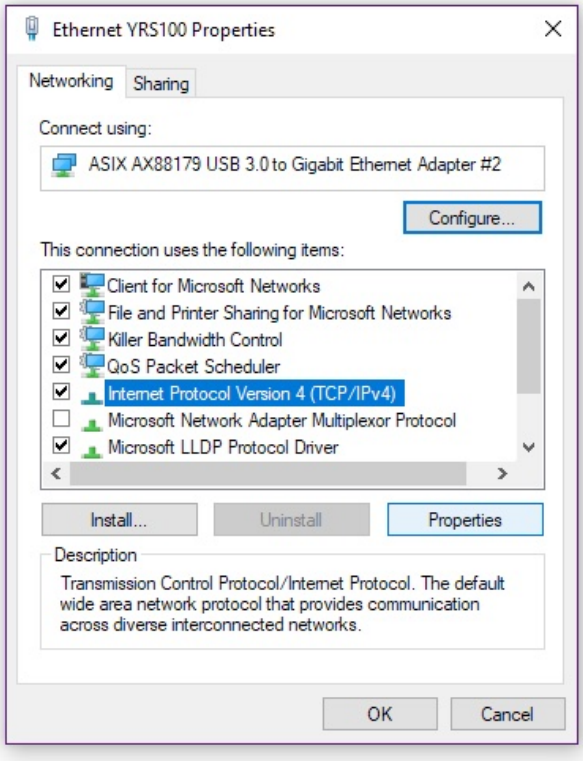
Configuring the system

This instruction is applicable to YRS100 cardiac amplifier and a suitable PC running the Windows 10 operating system. Once the connection is established by the Windows 10 operating system, it needs to be initially configured. Perform the following steps:

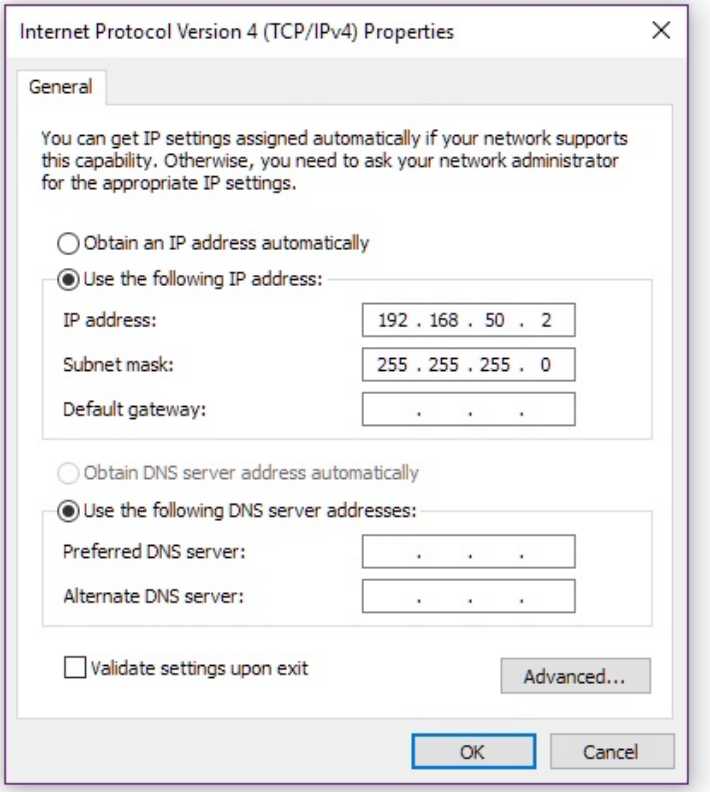
- Open the *Network and Sharing Center* in Control Panel
- Select the network connection icon representing the connection to the YRS100 and chose *Properties* from its context menu (right mouse button click), as shown on the next page:



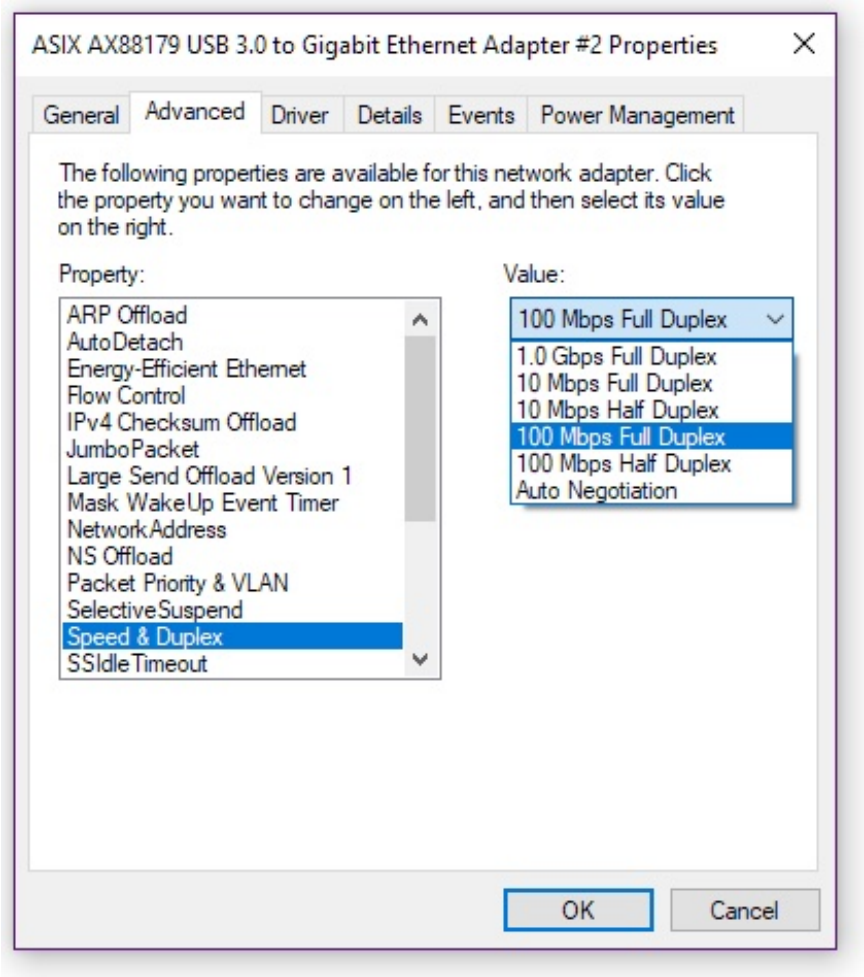
- Select the Internet Protocol Version 4 and click on the Properties button, as shown below:



- The typical setting is to use **192.168.50.2** as the IP address of the PC and **255.255.255.0** as the network mask, as shown on the next page:



- Accept the changes.
- Open the *Properties* of the network connection, as before.
- Click *Configure* button to configure additional settings.
- On the *Advanced* tab select *Speed & duplex* and chose *100 Mbps Full Duplex* (see next page)



- Accept changes.

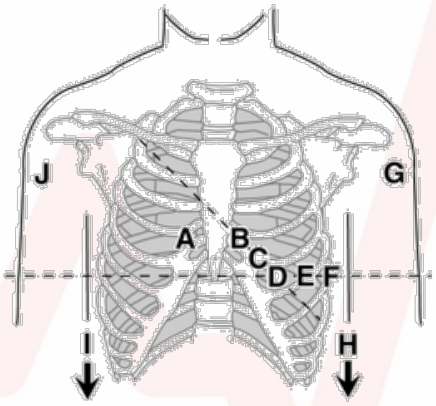
From now on it should be possible to make the connection to the YRS100 cardiac amplifier. The system firewall may request network access from the software. The access should be granted as otherwise it is not possible to connect to the device.

5 Operational principles

In general, there are four types of patient connection inputs on the device: sECG, xECG, unipolar or bipolar. All methods are described in this section.

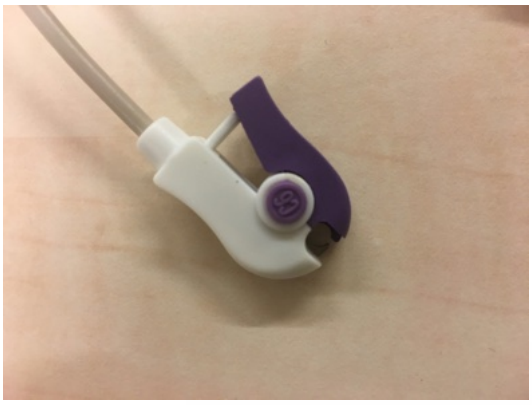
sECG input channel

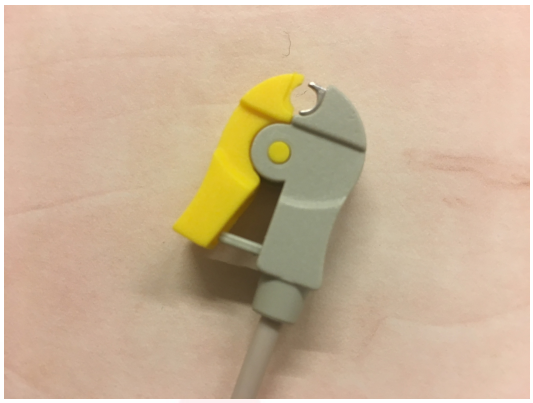
First, connect the sECG cable to the cardiac amplifier (input D). After that, connect the electrode grabbers to the monitoring electrodes. To acquire a standard 12 lead ECG, use the placement shown in the following illustration.



The electrode grabbers of the sECG cable mentions the electrode identifier and has the colour code according the table below.

	Electrode identifier	Colour code
A	C1	White / red
B	C2	White / yellow
C	C3	White / green
D	C4	White / brown
E	C5	White / black
F	C6	White / violet
G	L	Yellow
H	F	Green
I	N	Black
J	R	Red





Ensure that conductive parts of the electrodes or lead wires do not come in contact with other conductive parts, including earth.

xECG input channel

The xECG input can be used to monitor 10 extra ECG electrodes on the patient's body. It is important to mention that xECG always has to be used in combination with the standard 12 lead ECG (sECG) since the Wilson terminal is derived from sECG.

First, connect the xECG cable to the cardiac amplifier (input C). Next, connect the electrode grabbers to the monitoring electrodes.

The electrode grabbers of the xECG cable have the colour code according the table below.

Identifier	Colour code
1	White
2	Yellow
3	Orange
4	Red
5	Green
6	Blue
7	Brown
8	Violet
9	Black
10	Grey

Ensure that conductive parts of the electrodes or lead wires do not come in contact with other conductive parts, including earth.

Unipolar input channels

These 10 inputs can be used as auxiliary inputs for unipolar leads. It is important to mention that the unipolar channels always have to be used in combination with the standard 12 lead ECG (sECG) since the Wilson terminal is derived from sECG.

Only 2mm shrouded sockets may be used.

Bipolar input channels

These 8 inputs can be used as auxiliary input for bipolar leads. Red input is signal and black input is reference.

When using the bipolar inputs as unipolar using REF (Wilson terminal) output, sECG has to be connected and used since the Wilson terminal is derived from sECG.

Only 2mm shrouded sockets may be used.

6 Quality of signals, interference and defibrillation

Quality and interference of signals

The best quality of signals is obtained in a lab with a minimum of electronic and electrical devices and with grounding of all fixed (and mobile) installations including the patient-table and the cart of the YRS100.

The preparation of the patient and the fixation of the electrodes for the ECG are essential. If the skin of the patient is cleaned before the electrodes are fixed then the electrode-skin impedance will be lower resulting in a better quality ECG. Only when the ECG is of good quality the procedure should be continued. When good ECG cannot be obtained the procedure should not continue and a qualified technician should be consulted.

When the registration of the YRS100 shows interference the user should try to discover the source of interference. The source can be anything. It can be a not grounded electronic device connected to the patient e.g. a non-invasive oximeter. But it can also be a not grounded and not connected device e.g. light fixture. If the YRS100 is installed on a cart the cart should also be grounded.

50Hz interference (or 60Hz)

The best way to investigate the source of interference is by disconnecting and switching off all other devices first. Then the YRS100 should show signals without interference. If not then the power supply of the room, the grounding of the patient table, the grounding of the YRS100 configuration and the grounding of the cart of the YRS100 should be checked.

If the signals are good the other devices should be connected and powered one at a time and the quality of the signals should be checked after every step.

Defibrillation and the time of re-appearance of the signals

In case of defibrillation the charge of the defibrillator is passed to the patient. This results in a high voltage on the patient. As a result, the YRS100 signals may temporarily disappear from the screen.

7 Maintenance and Cleaning

Cleaning, Sterilizing and Disinfecting.
The YRS100 unit should be installed in such a way that the user is able to carry out the necessary cleaning and disinfection. Follow the national requirements for disinfecting methods and measures for protection against hazards of ignition of flammable anaesthetic mixtures.

Instructions about cleaning, disinfection, or sterilization the ECG cables can be found in the accompanying ECG cable manual.

Cleaning the YRS100 Unit.
The YRS100 unit does not require being sterilized or disinfected. For everyday cleaning wipe the unit with a soft, dry cloth or one that has been slightly dampened with water. To remove dirt, use a mild, non-abrasive detergent. Afterwards, be sure to wipe the unit thoroughly with a soft, dry cloth.

Maintenance and Service.
The YRS100 has no serviceable parts inside. Nor does it have adjustable parts. The only precaution can be the cleaning of the connectors to prevent oxidation. Special cleaning agents for connectors can be used.

8 Technical specifications

sECG channels

Electrode connections	R L F N C1 C2 C3 C4 C5 C6
Connector	ODU G51M03-P14QC00-A050
Leads	I II III aVR aVL aVF V1 V2 V3 V4 V5 V6
Maximal differential input-voltage	+/-5 mV
Max. common mode DC offset	+/-300 mV
(All channels against RL)	
Max. differential DC offset	+/-300 mV
Common mode rejection ratio	110 dB
(All leads to protective earth at mains frequency)	
Max. common mode voltage	20 Vrms
Noise	< 1.2 µVpp (bandwidth DC..150 Hz)
Channel separation	> 45 dB

xECG channels

Electrode connections	1 2 3 4 5 6 7 8 9 10
Connector	ODU G51M03-P14QC00-A050
Leads	1 2 3 4 5 6 7 8 9 10
Maximal differential input-voltage	+/-5 mV
Max. common mode DC offset	+/-300 mV
(All channels against RL)	
Max. differential DC offset	+/-300 mV
Common mode rejection ratio	110 dB
(All leads to protective earth at mains frequency)	
Max. common mode voltage	20 Vrms
Noise	< 1.2 µVpp (bandwidth DC..150 Hz)
Channel separation	> 45 dB

Analog to Digital conversion

Number of channels	40
Resolution	24 bit
Bit weight	1,25 µV/LSB
Sample rate	2000 samples/ sec per channel

Electrical safety

Type of equipment	Class I-CF
Patient auxiliary current	< 0.1 µA any lead except neutral lead
(normal condition)	< 1 µA neutral lead
Patient leakage current	< 50 µA (mains on applied part)
Recovery time after defibrillation	< 10 sec
Dielectric strength	1400 VAC 1 min
Protection against defibrillation	5kV

Technical Details

Electrical characteristics	100-240V~, 1,5A-0,8A, 47-63 Hz Max.: 60 VA
Dimensions	280 x 60 x 270 mm (W x H x D)
Weight	2,2 kg

Packaging

Packaging material	Classification: Waste for salvage Packing material should be disposed according to the relevant national regulations.

Environmental conditions

The equipment has been designed for use under normal laboratory conditions, with temperatures between 20 and 30 degrees Celsius (68-86°F). No special conditions are required for the YRS100.

If the equipment has been stored in a cold environment and then moved to the laboratory (with higher temperature and humidity) it can become wet due to condensing. Then the equipment should be given the time to adapt to the temperature of the laboratory before it is switched on.

Operating temperature and humidity	10 to 30°C 20 to 80% relative humidity (Non-condensing)
Storage/shipping temperature and humidity	-29 to 66°C 95% relative humidity (Non-condensing)

Atmospheric pressure	680 hPa - 1075 hPa
Recommended service life	The estimated useful life of YRS100 is 7 years.

Applied standards

The YRS100 is tested and assessed against the requirements of the following standards.

Standard(s) & Amendments	Description
EN-IEC 60601-1:2006 + AC:2010 + A1:2013 + A12:2014	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements
EN-IEC 60601-1-6:2010 + A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN-IEC 62366:2008+ A1:2014	Medical devices - Application of usability engineering to medical devices
EN-ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN-IEC 60601-2-25:2015	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
EN-IEC 60601-1-2 2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
EN-IEC 61000-3-2 (2014)	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
EN-IEC 61000-3-3 (2013)	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection.
EN-IEC 60601-2-47 (2015) (part 202 “Electromagnetic compatibility – Requirements and tests” only)	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
EN-IEC 62304 + AC:2008 + A1:2015	Medical device software - Software life-cycle processes

Essential performance

The essential performance of the YRS100 is assessed against the requirements of the standard 60601-2-25.

Essential performance item	Conclusion
Within 5 s after exposure to the defibrillation voltage, the YRS100 shall resume normal operation in the previous operating mode, without loss of any operator settings or stored data, and shall continue to perform its intended function as specified in the manual.	Note: operator setting and data storage are only in the software separated from the device. The essential performance test during defibrillation is to continue with all signals.
Automated measurement (not available) Amplitude measurement (not available) Interval measurement (not available)	It can be concluded that the essential performance are the display of the signals itself.
Filters; Operator adjustments are not possible	Not applicable
YRS100 may show temporary degradation during discharges. Within 10 s the YRS100 shall resume normal operation in the previous operating mode, without loss of any operator settings or stored data, and shall continue to perform its intended function and maintain essential performance	Note: operator setting and data storage are only in the Software separated from the device. Test conducted for the device to continue all signals
When exposed to electrical fast transients and bursts, via the power supply cord, the YRS100 shall continue to perform its intended function as described in this particular standard. Testing of patient cables and interconnecting cables specified to be more than 3 m in length may show temporary degradation during exposure to fast transients and bursts. Within 10 s the YRS100 shall resume normal operation in the previous operating mode, without loss of any operator settings or stored data, and shall continue to perform its intended function as described in the manual.	Note: operator setting and data storage are only in the Software separated from the device. The essential performance test during electrical fast transients and bursts is to continue with all signals.
When exposed to a conducted radio frequency voltage, via the power supply	No measurements done Test performed on signals

cord, the YRS100 shall continue to perform its intended function as described in the manual	
Electrosurgery interference	The device is not to be used in and electro surgery environment. Not Applicable

Power supply for the YRS100

The power adapter is not protected against ingress of liquids. Therefore, it should be placed in a position where there is no chance of any liquid to get in contact with the power supply. Do NOT place the power supply on the floor.

Transport

In case of a system placed on a cart, care must be taken when moving the system. Do not roll the wheels over the power cord since that might damage the cord which in turn can lead to an electrical unsafe situation.

When moving the cart for example in an elevator, be careful not to damage parts on the cart. In case of doubt, consult a qualified technician.

9 Electromagnetic compatibility

The YRS100 system complies with International Standard EN 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. For this compliance the system is only to be used in combination with cables and accessories either supplied by YourRhythmics or approved by YourRhythmics in writing.

In the following tables the compliance level of the systems is expressed.

Table 201 - Guidance and manufacturer's declaration – electromagnetic emissions for all EQUIPMENT and SYSTEMS (see 6.8.3.201 a) 3)

The YRS100 system is intended for use in the electromagnetic environment specified below. The customer or the user of the YRS100 system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment.- guidance**
RF emissions CISPR 11	Group 1	The YRS100 system 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 B	The YRS100 system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 202 – Guidance and manufacturer's declaration – electromagnetic immunity for all EQUIPMENT and SYSTEMS (see 6.8.3.201 a) 6)

Guidance and manufacturer's declaration – electromagnetic immunity			
The YRS100 system is intended for use in the electromagnetic environment specified below. The customer or the user of the YRS100 system should assure that it is used In such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV ± 2 kV	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 IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	< 11,5 V 92 V 161 V < 11,5V	Mains power quality should be that of a typical commercial or hospital environment. If the user of the YRS100 system requires continued operation during power mains interruptions, it is recommended that the YRS100 system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note : U_T is the a.c. mains voltage prior to application of the test level.			

Table 204 – Guidance and manufacturer's declaration – electromagnetic immunity for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING (see 6.8.3.201 b))

Guidance and manufacturer's declaration – electromagnetic immunity			
The YRS100 system is intended for use in the electromagnetic environment specified below. The customer or the user of the YRS100 system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the YRS100 system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

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 strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones 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 YRS100 system is used exceeds the applicable RF compliance level above, the YRS100 system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the YRS100 system.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V*/m.*

Table 206 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING (see 6.8.3.201 b))

Recommended separation distances between portable and mobile RF communications equipment and the YRS100 system			
The YRS100 system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the YRS100 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the YRS100 system 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 of transmitter m**		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1{,}2\sqrt{P}$	$d = 1{,}2\sqrt{P}$	$d = 2{,}3\sqrt{P}$
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.			

10 Troubleshooting

The following general troubleshooting tips can be used to help diagnose problems not specifically discussed elsewhere in this chapter.

General troubleshooting tips

Thoroughly inspect the equipment.
Disconnected or loose cables, missing hardware, and damaged equipment can cause what may appear to be unrelated symptoms or equipment failure.

Verify the equipment has not been modified.
Unauthorized modifications to the equipment may cause unexpected results, poor performance, or system failure. If the equipment has had unauthorized modifications, contact YourRhythmics Technical Support.

Verify whether there have been changes in the equipment's location or environment that could cause the failure.
For example, equipment that emits radio waves could cause interference during acquisition. If the environment or location has changed, try using the equipment in the original location to determine whether the problem persists.

Verify the problem was not caused by operator error.
Repeat the scenario and compare that to the operation as described in the manual. If the operator deviated from the manual, repeat the task using the instructions as written. If these steps do not resolve the problem, contact YourRhythmics Technical Support.

System Will Not Power Up

If the system will not power up, do the following:
Verify the unit is turned on. If it is not, turn the unit on.

Verify the unit is connected to an AC power outlet.

Verify the equipment is receiving power from the outlet.
If the unit is receiving power, the power LED of power adapter will be lit.

If these steps do not resolve the problem, contact YourRhythmics Technical Support.

ECG Data Contains Noise

If the acquired ECG data displays unacceptable noise levels, do the following:

Check the patient's position.
The patient should remain motionless during the acquisition of a resting ECG.

Verify the electrodes are placed properly.

Verify the electrodes have been applied correctly.
Perspiration, excessive hair, lotions, and dead skin cells must be removed from the electrode site.

Check for defective electrodes.
Replace the electrodes if there are any questions about their effectiveness.

Check for defective, broken or disconnected lead wires.
Replace the lead wires if there are any questions about their effectiveness.

If these steps do not resolve the problem, contact YourRhythmics Technical Support.