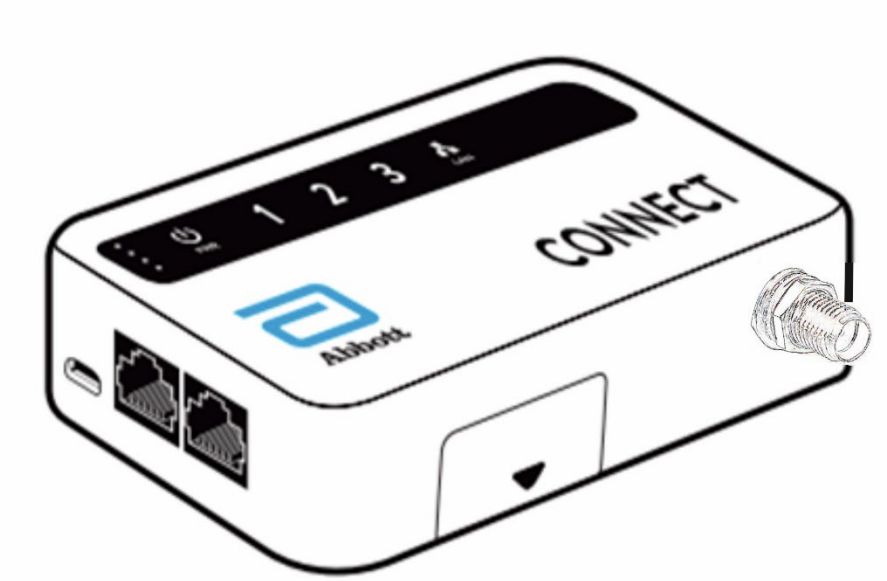
CONNECT Universal Gateway

ACR2-G-01 User Manual



AI-MNL0476 Rev 1.0

Trademarks
GL.iNet is a trademark of Shenzen Guanglianzhitong Tech Co., Ltd. All other trademarks appearing in this manual are the sole property of their respective owners.

PUBLISHED BY:.....Abbott Rapid Diagnostics Informatics, Inc.
(Abbott Rapid Diagnostics Informatics, Inc. is a registered trading division of Abbott Laboratories)

Registered Office:.....Abbott Rapid Diagnostics Informatics, Inc.
2000 Holiday Dr. Suite 500
Charlottesville
22901-3601
Virginia
United States

Manufacturing Address: .....Shenzhen Guanglianzhitong Tech Co., Ltd.
3rd floor, building 1,
No. 9 Jiejiabao Road,
Shuitian Community,
Shiyan Street,
Bao'an District,
Shenzhen,
P.R. China 518108

Table of Contents

Overview

Intended Use

The CONNECT Universal Gateway (Gateway) transfers data between point-of-care (POC) and other supported devices to supported data management systems.

Product Description

The Gateway is a digital bridge between a local decentralized network, and a wide area network. This bridge enables medical professionals and emergency personnel to collect device and health data from locations which may otherwise be unreachable.

The Gateway is installed and located close enough to the POC device to use the Ethernet cable supplied to connect the POC device to the Gateway LAN ports.

Definitions/Abbreviations

Term	Definition		Term	Definition
AC	Alternating Current		**OTA**	Over The Air
CPU	Central Processing Unit		**POC**	Point-of-Care
DDR2	Double Data Rate 2 (SDRAM memory)		**PPE**	Personal Protective Equipment
Gateway	CONNECT Universal Gateway		**RF**	Radio Frequency
ISP	Internet Service Provider		**RRC**	RALS Remote Connect
LAN	Local Area Network		**SIM**	Subscriber Identity Module
LED	Light Emitting Diode		**SDRAM**	Synchronous Dynamic Random Access Memory
MB	Megabyte		**SMA**	SubMiniature version A
Mbps	Megabits per second		**SoC**	System on a Chip
MHz	Mega Hertz (frequency)		**USB**	Universal Serial Bus
Micro SD Card	Micro Secure Digital Memory Card		**V**	Voltage
MiFi	MiFi is a brand name used to describe a wireless router that acts as a mobile Wi-Fi hotspot.		**WAN**	Wide Area Network
OS	Operating System		**Wi-Fi**	Wireless Fidelity (Network Type)

References

Document Reference	Document Title
https://globalpointofcare.eifu.abbott/en/index.html	The Abbott eLabeling site

Safety

The equipment described in this manual has the following hazards which are potentially dangerous and could cause harm to personnel if the recommended precautions are not observed:

- **MAINS VOLTAGES**
- **CHEMICAL HAZARDS**
- **BIOLOGICAL HAZARDS**

Icons and Warnings

The safety notices and warnings for the protection against loss of life or severe personal injury or for the protection against damage to equipment are highlighted in this manual, and if applicable, also by means of labels attached to the equipment close to the source of the danger.

Warning notices are provided to highlight specific hazard levels associated with a particular task or procedure and bring them to the attention of operators and service personnel; the significance for the use of a Warning, Caution or Note is defined as follows:

WARNING

Personal injury COULD RESULT unless the proper precautions are taken (the WARNING notice shall precede the relevant text).

CAUTION

Device operation or material damage may be caused unless the proper precautions are taken (the CAUTION notice shall precede the relevant text).

Note:
Contains essential information about the equipment, product, or operation, or draws attention to specific information the operator or service personnel should be aware of. (The Note is located at its point of application.)

Hazard Notices and Symbols

The following symbols highlight specific forms of hazards that may be encountered on the Gateway; they are intended to inform the user about the nature of the danger they should be alerted to:

Symbol	Indication
	Temperature limitations
	Separate waste collection for this electrical/electronic item indicated, Equipment manufactured / put on the market after 13 August 2005; Indicates compliance with Article 10(3) of Directive 2002/96/EC (WEEE) for the European Union (EU).
	Biological risks
	Direct current
	Keep dry
	Caution: Risk of electrical shock
	Poison
	Attention: See instructions for use

Packaging and General Information Notices and Symbols

On the packaging, labelling and instructions for use (IFU) of the Gateway you may encounter the following symbols described in the table below:

Symbol	Indication
	Manufacturer
	Country of Manufacture
	Serial Number
	Universal Serial Bus (USB) Port
	Consult User Manual for instructions
	The product conforms to all applicable EC Directives and Regulations
	UK Conformity Assessed marking indicates the product is in compliance for products sold within Great Britain. Refer to the Declaration of Conformity for full details.
	Signifies that the product bearing the Federal Communications Commission (FCC) logo complies with the specific requirements set forth by the FCC under Rules and Regulations, Title 47, Part 15 Subpart B, for Class A devices.
	Signifies that the product complies with the Restriction of Hazardous Substances Directive
	The product can be recycled, or it was made from recycled materials.

General Safety Rules

WARNING

Failure of the Gateway due to malfunction or operator error could result in a delay of the transfer of test results to the data manager

CAUTION

Do not operate the Gateway if the local temperature is below 0°C (32°F) or greater than 40°C (104°F).

DO NOT cover the vents on the Gateway; this will cause the Gateway to overheat.

Using the Gateway above or below the temperature limits may result in device malfunction.

CAUTION

DO NOT submerge the Gateway or use near liquids.

Prolonged contact with water or other liquids will cause the Gateway to malfunction.

Note:
Read these instructions for use and make sure you are familiar with all potential hazards and are confident in your understanding of how to operate and use the Gateway before using for the first time.

Refer to this User Manual whenever you need further clarification about a particular feature or process.

Physical Hazards

CAUTION

- DO NOT place the Gateway inside any other container when in use.
- DO NOT drop or mishandle the Gateway.
- DO NOT place objects on top of the Gateway.
- DO NOT insert any foreign objects into the Gateway's vents, power socket, aerial connectors, SIM card slots, USG 2.0 socket, Reset Buttonhole or any other apertures.
- DO NOT remove either the SIM or SD card from the device; both the SIM and SD cards have been preconfigured specifically for your device and are not considered field replaceable.

Failure to observe the above precautions may result in a malfunction of the Gateway and as a consequence a delay in the transfer of test results to the data manager

Biosafety Hazards

WARNING

If the Gateway is used in medical and health care environments there is a risk of contamination and the possibility for the transmission of potentially infectious bio-hazards and exposure to toxins present in the samples or reagents used. WHEN USED IN MEDICAL AND HEALTH CARE ENVIRONMENTS ALWAYS FOLLOW THE CLEANING AND DISINFECTING METHODS DESCRIBED IN THIS USER MANUAL.

Electrical Hazards

WARNING

- DO NOT attempt to open or dismantle the Gateway or AC Adapter to access the internal components.
- Opening and/or repairing your device could result in electric shock, device damage, fire, and personal injury risks and other potential hazards.
- Only use the AC power adapter and power cord provided with the Gateway.
- DO NOT use damaged power cords, accessories, or other malfunctioning peripherals.
- If the AC Adapter is not working, do not try to repair it; request a replacement from the contact ARDx Informatics Support.
- To prevent electrical shock hazard, disconnect the power cable from the electrical outlet before relocating the system.

Battery Safety

WARNING

- In the event of a battery leakage: wear personal protective equipment when handling the Gateway.
- Avoid contact with battery fluid. If a battery leaks, prevent the leaked fluid from contacting skin, eyes, clothes, or other susceptible surfaces.
- If battery fluid contacts your skin, eyes, or clothes, wash the affected area with water and seek immediate medical attention.

WARNING

- Only charge the Gateway with the power adapter and power cable provided with your device. Using the incorrect charging method may result in fire or explosion.
- Incorrect use of the Lithium-ion battery may result in fire or explosion.
- Do not heat, open, puncture, mutilate, or dispose of your Gateway or its battery by incineration.
- Do not leave or charge your Gateway in direct sunlight for an extended period of time; doing so may damage the battery.
- If the Gateway appears to be deformed (bulging/swelling), there may be a fault with the internal battery. DO NOT USE the Gateway and contact ARDx Informatics Support if you think such damage has occurred.
- The Gateway contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment.
- Specific disposal or recycling instructions for the Gateway must be comply with local laws or regulations that apply.

CAUTION

- The Gateway should not be stored at temperatures below -20°C (-4°F) or above +45°C (+113°F). Exceeding the recommended storage temperatures can cause damage to the Gateway internal battery.
- Dropping your device, especially on a hard surface, can result in damage to the Gateway and its battery. Contact ARDx Informatics Support if you think such damage has occurred.
- Failure to observe the above precautions may result in a malfunction of the Gateway and consequently a delay in the transfer of patient test results to the data manager.

Components (Contents of Box)

Component	Description	Quantity
Gateway device	ACR2-G-01	1
Global Power Adapter	5V/2A Power Adapter (EU, UK)	1
4G Antenna	External 4G LTE External Antenna	2
Ethernet cable	0.8m Ethernet Cable	1
USB Cable	0.8m Micro-USB to USB Cable	1
Power connector	Plug type B	1
Power connector	Plug type E	1
Power connector	Plug type G	1
Power connector	Plug type I	1

Internal Components:

DO NOT ATTEMPT TO REMOVE ORREPLACE THE SD CARD OR SIM CARD FROM THE GATEWAY DEVICE

Component	Description	Quantity
SD Card	8GB microSD card	1
SIM Card	Activated Nano SIM	1

Environmental Considerations

Placement Requirements

The Gateway has no special placement requirements, other than those specified in the safety section of this document. For the best performance, consider the following recommendations:

- Place the Gateway horizontally, as high as possible, and as centered as possible (close to the POC device).
- Position the antennas upright.
- Keep the Gateway visible and easily accessible.
- Avoid installing the Gateway in an area surrounded by heavy metal or concrete walls.
- Avoid placing the Gateway on the floor or stacked on top of other equipment.
- Keep away from sources of RF (Radio Frequency) interference, such as metal partitions, high-power electrical wiring or electrical appliances such as microwaves or refrigerators.

Electrical Requirements

The Gateway is a low voltage, low power device that can be powered with an AC power adapter or the internal Lithium-ion battery. If using an AC power adapter **only use** the adapter and power cord provided with the device.

Category	Requirement
External Power (with Power adapter)	100 – 240 VAC
Frequency	50 – 60 Hz
Power Consumption	<3.4W (with battery), <4.4W (without battery)
Power (Without Power adapter)	5V/2A (with battery), 5V/3A (without battery)

Environmental Requirements

Condition	Requirement
Operating Temperature	0 to 40°C (32 to +104° F)
Storage Temperature	-20 to 45°C (0 to +113° F)
Working Humidity	5% to 90%, non-condensing
Storage Humidity	5% to 95%, non-condensing

Dimensions and Weight

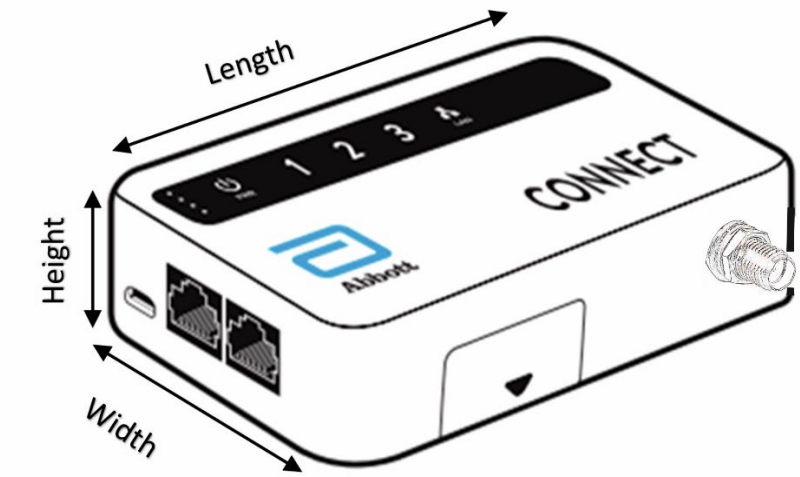


Figure 1: CONNECT Universal Gateway Dimensions

Item	Dimension
Length	120mm, 4.72 Inches
Width	74mm, 2.9 Inches
Height	28mm, 1.10 Inches
Weight	224g, 7.9 oz (with battery)
Enclosure material	ABS (Acrylonitrile butadiene styrene) plastic

Assembly and Installation

1. Unpack the contents of the box, (refer to the Components section of this manual for a list of contents contained in the Gateway box).

2. Attach the two external 4G antennas to the two female SMA (Sub Miniature A connector) ports on the Gateway.

> *Note:*
> *The antenna SMA ports are located on the opposite end of the Gateway to the USB-C power port and Ethernet ports. Refer to Figure 2: CONNECT Universal Gateway port locations.*

3. Connect the power supply.
   a. Connect the USB-A end of the power cable to the AC power adapter.
   b. Connect the USB-C end of the supplied power cord to the USB-C port labeled *Power*, on Gateway.
   c. The power LED will light when a power source is connected.

Using The Gateway

LED Status Indicators

LED	Status
Power	Illuminates when the power is applied.
Battery	Shows the status of the on-board battery, each point represents 25% charge.
Initializing 1	The Gateway is booting up. Restart if a solid LED is not seen within 2 minutes.
Connecting 2	The Gateway is attempting to connect to a cellular network and a data manager.
Connected 3	The Gateway has established a connection with the data manager.
LAN	Illuminated when connected to an external device.

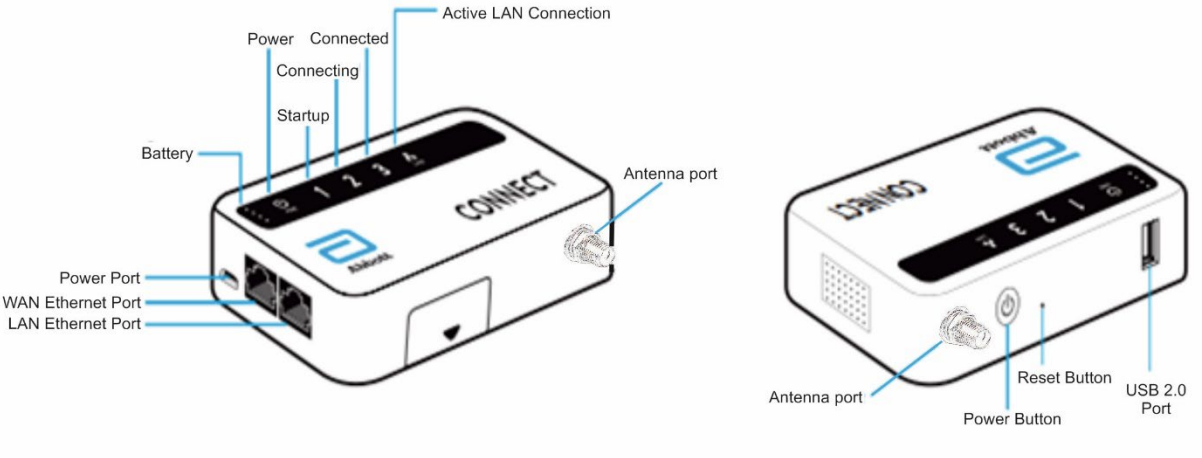


Figure 2: CONNECT Universal Gateway port locations

CAUTION

- DO NOT connect any device to the USB 2.0 Port unless instructed to do so by ARDx Informatics Support; connecting a device not approved for use with the Gateway may damage it.
- DO NOT insert anything into the Reset Buttonhole unless instructed to do so by ARDx Informatics Support; resetting the device may result in loss of data and the Gateway may cease to function.

Apply Power to the Gateway

- When power is applied to the Gateway the Power LED will illuminate.
  The Battery charge indicator will also light and display the current charge; each dot indicates 25% of charge.
- A blinking dot indicates the battery is charging.

Connect the Gateway to a Data Manager Using a Cellular Connection

The Gateway is shipped preconfigured to automatically connect to a data manager using a cellular connection.

When power is applied, the internal software is loaded.

- LED 1 will illuminate when the Gateway has booted successfully.
- After the Gateway has booted up correctly, it will connect to a cellular network and send a handshake message to the data manager, then wait for a response.
  LED 2 will illuminate when this has been completed.
- If the Gateway receives a “Connection Acknowledged” signal from the data manager, LED 3 will light.

> *Note:*
> *It is common for the Acknowledge Connection to take a few attempts,* **LED 2** *will flash intermittently as it attempts to connect. In areas with weaker cellular signals, it can take up to an hour to establish a connection.*

- LED 3 will illuminate and remain lit when a connection has been successfully established.

Connect External Device(s) to the Gateway

- To connect a single external device, attach the Ethernet cable (supplied) to the LAN Ethernet Port on the Universal Gateway and the other end to the external device.
- Additional devices, up to seven devices in total, can be connected to the Gateway using a generic network switch. The LAN interface supports 10/100 Mbps Ethernet connectivity. For best performance use a 100 Mbps capable switch.
- RS232 Serial devices can be added to the Gateways LAN interface using a Serial-to-Ethernet adapter. A Digi data port provided by ARDx Informatics is the only Serial-to-Ethernet adapter supported by ARDx Informatics. In this configuration the port labeled Network Connection on the Digi data port is connected to the LAN port on the Gateway.

> *Note:*
> *Each Gateway supports the connection of up to seven (7) external devices. Additional Gateways will be needed if you are planning to connect more than seven devices. Contact ARDx Informatics support for advice and assistance.*

Connect the Gateway to a data manager using your local network

> Note:
> *The Gateway requires additional configuration when using the WAN/LAN functionality. Please contact ARDx Informatics support for assistance if you plan to use WAN/LAN.*

The WAN/LAN feature connects the Gateway's Wide Area Network (WAN) interface to a Local Area Network (LAN) interface. This enables results to be sent from a device to an ARDx Informatics hosted RALS server, through the local Internet Service Provider (ISP). When using this connection method, the Gateway will require additional configuration by ARDx Informatics Support. Contact your ARDx Informatics Project Manager or ARDx Informatics support for assistance.

Connect the Gateway WAN port to the local network using an Ethernet cable.

CAUTION

DO NOT connect your local network to the LAN port on the Gateway. The LAN port is a DHCP server. Connecting a DHCP server to your local network can cause IP conflicts on your network.

If an ethernet cable connected to the local network has been incorrectly plugged into the port labeled LAN, instead of the port labeled WAN, the LAN port will be disabled, and the lights on the Gateway will flash in a "chasing lights" pattern.

The LAN port will remain disabled until the Gateway is rebooted.

> Note:
> *Check with your Abbott Project Manager or ARDx Informatics Support to confirm your choice of connected data manager.*

Troubleshooting

Symptom/Error	Explanation	How to Respond	Note
The Gateway will not power on	The Gateway power port is not receiving 5V/2A	Confirm the power cord is connected correctly at both ends. Confirm the USB-C end of the power cord is plugged into the power port. Check that the USB-A port is plugged in to the AC adaptor provided.	USB-C  USB-A 
		Confirm the AC power adapter is the 5V/2A adapter provided, and that it is not damaged.	
LED 1 will not illuminate	The internal boot process has not completed	Wait for at least 2 minutes before cycling the power off and then back on.	Wait at least 2 minutes again. If LED 1 fails to light after 2 attempts, contact ARDx Informatics Support.
LED 2 flashing	The Gateway is attempting to establish a connection with the data manager	Confirm that the Power LED and LED 1 are both on (not flashing). Wait for up to 1 hour for the Gateway to connect.	Reboot after 1 hour. If LED 2 fails to Illuminate within an hour contact ARDx Informatics Support.
LED 1 to LED 3 flashing in a chasing light pattern	DHCP conflict	Remove the cable connecting your local network to the Gateway LAN port and reconnect it to the Gateway WAN port. Power the Gateway off then back on.	

Note:
The Gateway's LAN IP address is 192.168.1.1 by default. If the Gateway is communicating with the RALS data manager, the Gateway LAN IP is configurable within the RALS data manager. External devices should be configured to use the Gateway LAN IP as the data manager "Host IP".

Maintenance

CAUTION

The Gateway has no parts which can be repaired or maintained by the User.

Contact ARDx Informatics Support for assistance if you believe repair or replacement is required.

Refer to the cleaning and disinfecting methods described below for details about maintaining device hygiene of the Gateway.

Cleaning and Disinfecting

The following parts of the Gateway can be cleaned and/or disinfected:

- The Gateway enclosure surfaces
- The Gateway antennas
- The AC adapter surfaces

WARNING

It is important to observe the disinfecting guidelines.

Failure to follow these procedures may result in the risk of cross-contamination of pathogens, toxins and other harmful deposits to patients and Gateway users.

Cleaning involves the physical removal of dirt or other foreign material from the Gateway outer surfaces and exposed peripheral components. The Gateway should be cleaned whenever it is visibly dirty.

Cleaning Procedure

WARNING

Do NOT attempt to put any objects or cleaning materials inside the Gateway itself and take care to avoid the LAN Ethernet ports, power port and antennas ports (if the antennas are not connected to the Gateway).

CAUTION

- Use a slightly damp cloth (NOT WET) to clean the Gateway; excess moisture could damage the Gateway.
- Do NOT spray or pour solution directly onto the Gateway.
- Always wear clean disposable gloves to clean the Gateway.

Disinfection involves the chemical removal of possible harmful microorganisms (pathogens) from the Gateway and peripheral surfaces after patient contact or anytime you believe the Gateway may have been contaminated with a patient sample or Quality Control solution.

Disinfecting Procedure

This procedure should be followed to prevent the risk of blood-borne pathogen transmission after potential contact by a patient.

- Always wear clean disposable gloves to disinfect the Gateway.
- Use medical grade antimicrobial disinfecting wipes (*for example:* TECcare® Control textured wipes or equivalent) to disinfect the Gateway.
- Allow the Gateway surface to air dry for approximately 5 minutes.
- Dispose of the disinfecting wipes eco-responsibly in accordance with local procedures.

After cleaning and disinfection, remove gloves and wash hands.

Software Updates and Cybersecurity

The Gateway software including cybersecurity measures will be updated periodically.

The user is contacted by ARDx Informatics prior to the update.

Note:
The Gateway software cybersecurity updates will be implemented by ARDx Informatics, but it is also the responsibility of the user to ensure diligent cybersecurity measures are complied with at all stages of data transfer.

Regulatory Compliance with FCC

THIS DEVICE COMPLIES WITH 47 CFR part 15 OF THE FCC RULES. OPERATION IS SUBJECT TO THE FOLLOWING TWO CONDITIONS: (1) THIS DEVICE MAY NOT CAUSE HARMFUL INTERFERENCE, AND (2) THIS DEVICE MUST ACCEPT ANY INTERFERENCE RECEIVED, INCLUDING INTERFERENCE THAT MAY CAUSE UNDESIRED OPERATION.

FCC ID: 2BAKJ-ACR2G01

FCC ID: XMR201903EG25G

The Gateway complies with 47 CFR part 15 Radio Frequency Devices.

The Gateway as a Class B digital device must operate in accordance with the following two conditions:

(1) this device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note 1: The Gateway has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy, and if not installed and used and in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If the Gateway does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the Gateway and receiver.
- Connect the Gateway into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The Gateway is confirmed to comply with the requirements set out in the European Council Directive on the Approximation of the Laws of the Member States relating to RED (2014/53/IEU). The equipment passed the test which was performed according to the following European standards:

- EN 300 328 V2.2.2; EN 301 893 V2.1.0; EN 300 440 V2.1.1, EN 301 908-2 v13.1.1, 301 908-13 v13.1.1
- EN 301 489-1 V2.2.3; EN 301 489-17 V3.2.4, EN 301 489-52 V1.1.2
- EN 55032
- EN 61000-4-2, EN 61000-4-3,
- IEC/EN 62368:1: 2014 (Second Edition)
- IEC/EN 60065: 2014 (Eighth Edition)
- EN 60950-1:2006 (Second Edition) + A1:2010 + A2:2013

Radiation Exposure Statement

This device meets the government's requirements for exposure to radio waves.

The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies.

The standards include a substantial safety margin designed to assure the safety of all persons regardless of age or health.

The SAR limit of USA(FCC) is 1.6 W/kg averaged over 1 gram of tissue.

To comply with RF exposure compliance requirements, this device must be installed in such a way to allow all persons to maintain a minimum separation distance of 20 cm from the device and its internal antenna while in operation.

ARDx Informatics Support

For technical support please contact the ARDx Informatics Support team.

https://www.rals.com/us/en/home/rals-system/support.html/ (click the "Please Use This Form to Send Us Your Question" button at the bottom of the page)

Telephone: 1-877-627-7257, Email: RALS.support@abbott.com