# **User Manual**

# Revolution Plus Sample Prep System™



# Revision B

For in vitro diagnostic use only









# **Table of Contents**

Preface	3
Important Note: Kit Mode and Research Mode Operation	3
About This User Manual	4
Safety and Special Notices	5
Symbols Glossary	7
Chapter 1: Introduction to the Revolution Plus System	11
Intended Use	11
Use Statement	11
Chapter 2: Instrument Overview	12
Initial System Set-Up	13
Graphical User Interface (GUI)	14
Chapter 3: Operating Instructions	15
Suggestions	16
Starting a Run	17
Pausing, Stopping, and Completing a Run	18
Display	19
Chapter 4: Cleaning	20
Chapter 5: Servicing, Supplies, and Replaceable Parts	21
Servicing	21
Supplies	21
Replacing Fuses	21
Chapter 6: Specifications Table	22
Technical Support, Product Orders, and Contact Information	22
Trademarks Terms and Warranty Information	23



### **Preface**

nRichDX provides this document to its customers with a product purchase to use in the product's operation. This document is copyright protected and any reproduction of the whole or any part of this document is strictly prohibited, except with the written authorization of nRichDX.

The contents of this document are subject to change without notice. All technical information in this document is for reference only. The system configurations and specifications in this document supersede all previous information received by the purchaser. nRichDX makes no representations that this document is complete, accurate or error-free and assumes no responsibility and will not be liable for any errors, omissions, damage, or loss that might result from any use of this document, even if the information in the document is followed properly.

This document is not part of any sales contract between nRichDX and a purchaser. This document shall in no way govern or modify any Terms and Conditions of Sale, which Terms and Conditions of Sale shall govern all conflicting information between the two documents.

The most current version of this document is available from nRichDX and is regularly updated at nRichDX.com.

### **IMPORTANT NOTE: Kit Mode and Research Mode Operation**

The Revolution Plus instrument is capable of operating in two modes - a **Kit Mode** and a **Research Mode**. In Kit Mode the instrument's parameters for applications for cfDNA and cfTNA extraction, or CTC isolation are fixed per the instrument's firmware. In Research Mode the application's parameters may be adjusted by the operator and saved to distinct profiles.

Research Mode operation of the instrument requires a Research Mode USB key (available from nRichDX, PN 200901) to be inserted into the USB port on your Revolution Plus instrument.

Revolution Kits for extraction of cfDNA and cfTNA are IVD-labeled when operated in Kit Mode only and only while using the most current protocol. **In Research Mode, all applications on the Revolution Plus System are Research Use Only (RUO)**, even though the Revolution



Plus instrument in Kit Mode and the specific Revolution Kit may be labeled IVD. Operation of the Revolution Plus in Research Mode is For Research Use Only. Not for use in diagnostic procedures.

To request a *Revolution Plus Research Mode USB Key* (PN 200901), please contact your nRichDX representative, or email nRichDX at <a href="mailto:info@nrichdx.com">info@nrichdx.com</a>. Instructions on how to operate the Revolution Plus instrument in Research Mode are available in a separate Revolution Plus Research Mode User Manual which is available upon request.

As a reminder, the Revolution CTC Enrichment Kit (EpCAM) is RUO-labeled only, even when operated in Kit Mode on the Revolution Plus System. For more information, please see the Instructions for Use (IFU) for the Revolution CTC Enrichment Kit (PN 407000).

### **About This User Manual**

This user manual is written for the operator (laboratory technician) and provides information on the nRichDX Revolution Plus System. It includes installation and operating instructions and addresses the following:

- Reviewing safety precautions.
- Installing the Revolution Plus System.
- Using the Revolution Plus System in routine jobs the processing step (mixing sequence).
- Performing basic cleaning and maintenance procedures.
- Troubleshooting the instrument performance.
- This user manual also describes the features, specifications of the Revolution Plus System instrument, and ordering information.
- Please read the manual in its entirety before operating the instrument.
- Print and keep the user manual for future reference. The user manual is an important part of the instrument and should be readily available during the use of the instrument.



# **Safety and Special Notices**

Make sure you follow the precautionary statements presented in this guide. The safety and other special notices appear in boxes.

Safety and special notices include the following:



**WARNING** Risk of personal injury if electronic equipment is operated near fumes or flammable gases.. Avoid this risk by never operating electronic equipment close to fumes or flammable gases.



**WARNING** Incorrect grounding can cause electric shock and damage the system. Never operate the system until the power cord is connected correctly to an electrical ground. Use a three-pronged (grounded) power cord to connect the system to a matching three-wire grounded outlet. Do not use an adapter to connect the power plug to a two-pronged outlet.



**WARNING** Use the safety features of the instrument. Do not compromise the integrity of safety interlocks and sensors. Under normal operating conditions, the instrument protects the user from exposure to moving parts. The front door is monitored by an interlock switch which will not allow operation while the door is open. Never attempt to defeat this interlock. Intentionally defeating this safety measure may cause a risk of injury from moving parts.



**WARNING** Always operate the system with the door closed to avoid injury. If the door is opened during a processing run, do not reach into the mixing chamber until the system has come to a complete stop.



**WARNING** Risk of personal injury from electrical shock. Electronic components can cause shock or injury. To prevent possible injury or shock, do not modify the instrument and do not remove any components (such as covers, doors or panels) unless otherwise instructed in this document. No user-serviceable components are inside the instrument. Contact nRichDX, Inc. if servicing is required.





**WARNING** Failure to use the provided power cords can cause risk of electric shock or fire.

#### **WARNING**

Normal operation might involve the use of solutions and test samples that are pathogenic or toxic. Such materials require that you take all necessary safety precautions.

- Handle body fluids with care because they can transmit disease. No known test offers complete assurance that they are free of microorganisms.
- Handle all infectious samples according to good laboratory procedures and methods to prevent spread of disease.
- Some of the most virulent infectious agents Hepatitis (B and C) and HIV (I-V) viruses, atypical mycobacteria, and certain systemic fungi – require extra safety precautions.
- Risk Group II materials (as identified in the World Health Organization Laboratory Biosafety Manual) require biosafe containment. Materials of a higher group require more than one level of protection.
- Dispose of all waste solutions according to correct environmental and safety guidelines



**WARNING** California Proposition 65 Warning Statement. This product can expose you to chemicals known to the State of California to cause Cancer and Reproductive Harm.



**CAUTION** Wear Personal Protective Equipment (PPE) such as gloves, eye protection, and lab coats when performing any procedure. To avoid injury, observe and follow all the warnings and cautions throughout this manual. Wash hands thoroughly after contact with sample media and all maintenance activities. Observe all laboratory policies and procedures related to the handling of biohazardous materials. Refer to the applicable sources (such as Material Safety Data Sheets) for specific hazard information.



**CAUTION** The system generates and can radiate radio frequency energy. If the system is not installed and operated correctly, this energy can cause interference with other equipment. In addition, other equipment can radiate radio frequency energy to which the system is sensitive. If you suspect interference between the system and other equipment, nRichDx recommends the following actions to correct the interference.



- This equipment complies with the emission and immunity requirements described in this part of the EN/IEC 61326 series.
- As to emission, this system has been designed and tested to CISPR 11
   Class A, so in a domestic environment, it may cause radio interference, in
   which case, you may need to take measure to mitigate interference.
- It is recommended to evaluate the electromagnetic environment prior to operations of the system.
- Do not use this system in close proximity to sources of electromagnetic radiation (for example, unshielded intentional RF sources), as they can interfere with the proper operations.
- Do not use medical equipment that can be susceptible to malfunctions caused by Electric Magnetic Field (EMF) close to the system.

**Symbols Glossary** 

<u>Oymbols alossary</u>	
Symbol	Description
	Title of Symbol: Caution  Meaning of symbol: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.  Standard Number, Title of Standard, and Symbol Reference Number: ISO 15223-1. Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied 1: General Requirements. #5 4.4



Symbol	Description
	Title of Symbol: Warning; Biological hazard
	Meaning of Symbol: To warn of biological hazard.
	Standard Number, Title of Standard, and Symbol Reference Number: <i>IEC 60878. Graphical Symbols for electrical equipment medical practices.</i> #7010-w009
	Supplemental Product-Specific Manufacturer Information
	This label indicates a caution to operate only with all covers in position to decrease risk of personal injury or biohazard.
	Wear Personal Protective Equipment (PPE) such as gloves, shields, and lab coats. Handle and dispose of biohazardous materials according to your laboratory procedures.
	Title of Symbol: Manufacturer
	Meaning of Symbol: Indicates the medical device manufacturer as defined in EU 90/385/EEC, 93/42/79/EC.
	Standard Number, Title of Standard, and Symbol Reference Number: ISO 15223-1. Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied -Part 1: General Requirements. #5.1.1



Symbol	Description
IVD	Title of Symbol: In vitro diagnostic medical device  Meaning of Symbol: Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.  Standard Number, Title of Standard, and Symbol
	Reference Number: ISO 15223-1: Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements, clause 5.5.1
REF	Title of Symbol: Graphical symbols to be used with medical device labels, labelling, and information to be supplied.
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Title of Symbol: Warning; Crushing of hands
	Meaning of Symbol: To warn of a closing motion of mechanical parts of equipment.
	Standard Number, Title of Standard, and Symbol Reference Number: ISO 7010. Graphical Symbols for electrical equipment in medical practices. #W024
	Use caution to avoid injury to hands when close to equipment with moving mechanical parts.
	Title of Symbol: cNRTLus Certification Mark
C US	Meaning of Symbol: This symbol indicates recognition by a Nationally Recognized Testing Laboratory (NRTL) that the system has met the relevant product safety standards for the United States and Canada.
	OSHA, CEC



Symbol	Description
-	Title of Symbol: Fuse Location  Meaning of Symbol: Indicates the location of a fuse.
	Title of Symbol: Protective earth; protective ground  Meaning of Symbol: to identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode. Standard Number, Title of Standard, and Symbol Reference Number: IEC 60417: Graphical symbols for use on equipment – Overview and application, #5019
SN	Title of Symbol: Serial number  Meaning of Symbol: Indicates the manufacturer's serial number so that a specific medical device can be identified.  Standard Number, Title of Standard, and Symbol Reference Number: ISO 15223-1. Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements. #5.1.7
i	Title of Symbol: Operator Instructions  ISO 7000-1641 Operator's Manual: Operating Instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.



### **Chapter 1: Introduction to the Revolution Plus System**

### **Intended Use**

The Revolution Plus Sample Prep System is designed to perform semi-automated extraction and purification of nucleic acids from biological liquid specimens intended for molecular biological applications. The instrument is intended for use by professionals such as technicians trained in molecular biological techniques and in the operation of the Revolution Plus System.

The Revolution Plus System is designed exclusively for use with nRichDX Revolution isolation reagents for the extraction of nucleic acids from human samples for in vitro diagnostic testing. The instrument is driven by an integrated microprocessor that controls the system rotational movement. The Revolution Plus System features an easy-to-use touchscreen Graphic User Interface (GUI).

### **Use Statement**

This device is intended for indoor use only. Safety protection may be impaired if the system is used in a manner not specified by nRichDX..

If you use the system in a manner not specified by nRichDX, the protection provided by the system can be impaired and incorrect results or system failure can occur.

This manual is designed to familiarize users with the Revolution Plus including its functions, specifications, operation, and routine care and maintenance. nRichDX, Inc. recommends that users read this entire manual, including all safety-related information and recommendations before operating the instrument.

[continued on next page]

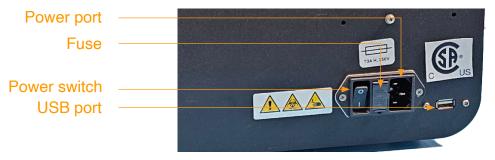


# **Chapter 2: Instrument Overview**

In addition to these instructions, the contents of the Revolution Plus System packaging includes the instrument, a 12-position Cartridge Rack, a Power Cord, a Drip Tray, a Magnetic Rack, and a Revolution Plus Kit Mode USB Key. A Revolution Plus Research Mode USB Key is available separately. USB Keys enable the Revolution Plus System to be updated with the latest firmware. To install firmware, power off the Revolution Plus Processor using the power switch on the back panel. Insert the Revolution Plus USB Key into the USB port located on the back panel and turn the Processor back on.



Revolution Plus Processor (Front View)



Revolution Plus Processor (Close-Up Back View)





Magnetic Rack



### **Initial System Set-Up**

- 1. One or two people should carefully remove/lift the instrument from packaging. Then, remove any packing material from inside the instrument while removing the 12-position Cartridge Rack, Drip Tray, Power Cord, and Magnetic Rack.
- 2. One or two people can place the instrument in its desired location by grasping under the base on both sides of the instrument and carefully setting it down on the surface of the table or laboratory bench. Carefully remove fingers from under the base as the unit is lowered into place.
- 3. Plug the female end of the power cord into the back of the instrument and the male end into a 100 240V, 50-60 Hz grounded receptacle.
- 4. Slide the Drip Tray through the slot in the bottom/front of the mixing chamber until it touches the back wall of the instrument. The Drip Tray will capture liquid that may drip during a mixing cycle.
- 5. Power the instrument on using the switch on the back of the Revolution Plus Processor. The instrument is now ready for use.

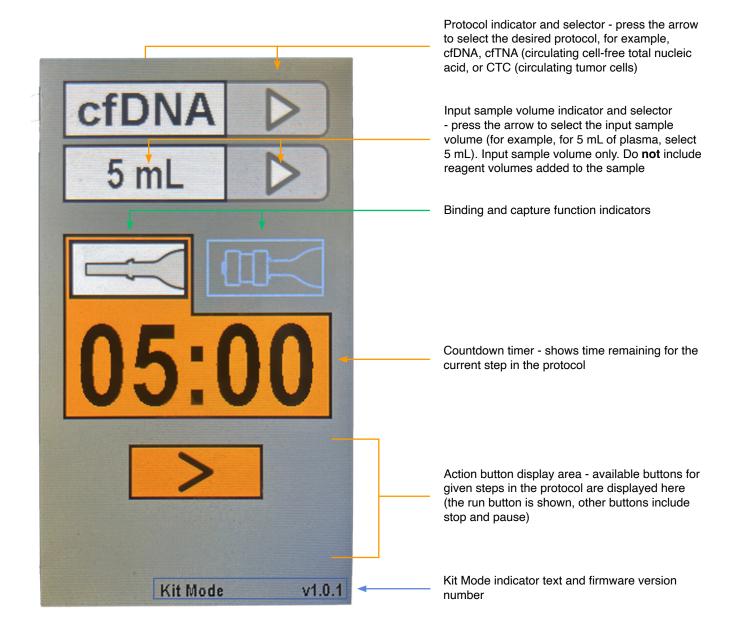
[Continued on next page]



# **Graphical User Interface (GUI)**

NOTE: Please refer to the Reagent Kit Instructions For Use when selecting operating parameters.

The Revolution Plus System has a Graphic User Interface (GUI) with a touchscreen display that will illuminate when the power is "ON". Operating commands and mixing sequences will be controlled by pressing the related button icon on the display.





Colors on the display will change relative to the two mixing steps:

- 1. When the 'Binding' function is selected, the graphic icon for the Capture Tube will be illuminated and the color on the display will be orange.
- 2. When the 'Capture' step is selected, the graphic icon for the Capture Tube with Mag Capsule will illuminate and the color on the display will be **blue**.
- NOTE 1: The background color is GRAY when the instrument is not running.

NOTE 2: The display will flash at the end of a cycle.



**Orange: Binding Function** 



**Blue: Capture Function** 

### **Chapter 3: Operating Instructions**

- 1. Turn "ON" the power switch located in the back of the instrument adjacent to the plug. After a few seconds, the Graphical User Interface (GUI) touchscreen display will illuminate indicating that the power is "ON".
- 2. Verify that the Drip Tray is in place. Otherwise, slide the Drip Tray through the slot until it touches the back wall of the chamber to ensure it is in position.



- 3. Open the mixing chamber door and verify the main shaft is in the 'home' position. The three mounting pins on the shaft should be pointed up (vertically).
- 4. Place the 12-position Revolution Plus Cartridge Rack, with samples to be processed, into the mixing chamber by lifting the rack by the two handles and positioning directly over the shaft and lowering it straight down onto the rack mounting pins. The rack will straddle the drive shaft rod. Lower it down onto the right pin first. After the right pin passes through the opening, lower it onto the left side as the two pins pass through their openings. The rack should now be fully resting on the drive shaft. Next, grip both handles and slide the entire Cartridge Rack to the left. The pin on the right will snap-fit into the spring clip. There will be an audible and tactile 'click'. Finally, lightly tug upward on the handles to ensure that the rack is secured onto the drive shaft.





# **Suggestions**

### **Loading and Unloading the Rack**

- Always make sure the pre-filled Cartridges are securely onto their respective slots on 12-Position Cartridge Rack before transferring it to the mixing chamber.
- Always use two hands (one on each handle) when loading/unloading the Cartridges into the rack mount pins on the main shaft in the mixing chamber.
- Ensure the rack is fully engaged with all three rack mount pins before starting a run.



- CAUTION! If the door is opened during a run cycle, do not reach into the mixing chamber until the Cartridge has come to a complete stop.
- When removing the Cartridge Rack, grip both handles to first release it from the rack mount pin before pulling it straight up and out of the mixing chamber. Do not manually manipulate the spring clips, manipulation of the spring clip might damage it. The spring clip will release the rack without additional manipulation as you push or pull the cartridge rack in and out of the slot.
- Turn "OFF" the instrument when not in use.

### **Graphic User Interface (GUI) Touchscreen Display**

- NOTE 1: The background turns GRAY when the instrument is on and not running.
- NOTE 2: The screen will flash at the end of a mixing cycle.

# Starting a Run

- 1. Prepare samples by following the Revolution sample kit Instructions For Use (IFU).
- 2. Once the 12-position Revolution Plus Cartridge Rack with samples is mounted in the mixing chamber, go to the touchscreen display, and select the Protocol, Mixing Function (Binding or Capture), and Sample Volume to be processed. NOTE: mixing rates and timer are automatically set relative to the test parameters.
- 3. The following is a list of selection options for each mixing cycle:

#### Extraction Protocols:

- cfDNA (cell-free DNA)
- cfTNA (cell-free TNA Total Nucleic Acid which includes cfDNA and cfRNA)
- CTC (Circulating Tumor Cells)

### Mixing Volumes:

- o 5mL
- 10mL
- 。 15mL



- 。 20mL
- 。 30mL
- 40mL
- 。 50mL

### Mixing Steps:

- Binding
- Capture

### Start (">"):

- The processing run will Start, and the timer will begin its countdown while the entire screen will illuminate orange for Binding step or blue for Capture step.
- The screen will FLASH when the cycle is completed.

### Pausing, Stopping, and Completing a Run

### 1. To PAUSE During a Run:

- a. If in **Binding step**, press the PAUSE button (=): the mixing cycle and timer will pause while the backlight turns GRAY.
- b. If in **Capture step**, press the PAUSE button (=): the mixing cycle and timer will pause while the backlight turns GRAY.
- c. After selecting PAUSE (=), two options appear:
  - START (>)
  - STOP (X)
- d. To RESUME the run from PAUSE: press the Start (>) button and the mixing cycle will resume. The display will then fully illuminate orange or blue.

### 2. Opening the Door During a Cycle:

If the operator opens the door at any time during a mixing cycle, the system will automatically stop. The timer and mixing cycle parameters will pause and be saved at the stopping point and the Cartridge Rack will return to the 'home' position. To ensure this, the Start command "(>)" disappears from the display when the door is open during a mixing cycle. Once the operator closes the door, the Start command "(>)" reappears. The operator can then tap on the "(>)" start command, and the mixing cycle will resume its countdown.

### 3. Completing a Run:

**Step 1:** At the end of a complete mixing cycle, the display will flash.



18

Step 2: Open the door.

**Step 3:** Grip the two handles on the Cartridge Rack and slide the rack to the right until the pins are released (audible and tactile click).

**Step 4:** Lift the Cartridge Rack from the mixing chamber and place the rack on a clean surface for further handling.

# **Display**

Instrument State	Screen Display
Power ON: This is the default screen at Startup.	
Protocol: cfDNA is selected. Tap on the arrow to cycle through each Protocol/Analyte option (cfDNA, cfTNA, CTC).	cfDNA >
<b>Volume selected =</b> 5mL. Tap on the arrow to cycle through all volume options.	
Mixing Step: "Binding" (Capture Tube only is illuminated).	05:00
<b>Timer:</b> Timer is automatically set for the Protocol, Volume & Binding step.	
"Start" : will begin the mixing cycle.	Kit Mode v1.0.1
<b>Protocol:</b> cfDNA is selected. Tap on the arrow to cycle through each Protocol/Analyte option (cfDNA, cfTNA, CTC).	cfDNA D
<b>Volume selected =</b> 5mL. Tap on the arrow to cycle through all volume options.	
Mixing Function: "Capture" (Mag Capsule-on-Capture Tube is illuminated).	20:00
<b>Timer:</b> Timer is automatically set for the Protocol, Volume & Capture function.	
"Start" : will begin the mixing cycle.	Kit Mode v1.0.1



Instrument State	Screen Display
Pause button : Pauses the cycle.  The screen background turns GRAY.  Then, operator can Start/Resume or Stop the cycle.	5 mL  04:54  Kit Mode v1.0.1
Door Open during a cycle: Cycle will automatically pause.  Cartridge Rack will come to a stop.  Start and Stop buttons disappear.	5 mL  05:00

# **Chapter 4: Cleaning**

Remove the Drip Tray and wash with 70% ethanol in water solution. Clean all internal instrument surfaces by wiping them down with a 70% ethanol in water solution and/or a 10% bleach in water solution. Internal surfaces include the drive shaft, rack mounts, rack pins and drip tray. Also wipe down the front panel, window, and door handle during periodic cleaning.



# Chapter 5: Servicing, Supplies, and Replaceable Parts

# **Servicing**

Units shall be returned to nRichDX for all servicing. Please contact nRichDX at <a href="mailto:info@nRichDX.com">info@nRichDX.com</a> to request a Return for Servicing Authorization (RSA).

# **Supplies**

The following supplies can be ordered by contacting nRichDX at info@nRichDX.com. Note: nRicher Cartridges are purchased as a component of the various extraction kits.

Name	Description	Part #
Revolution Plus Cartridge Rack	Rack supporting 12-position cartridges	200600
Drip Tray	Tray placed at base of mixer in case of spills	100291
Revolution Mag Capsule	Magnetic capsule used to collect beads during enrichment	200700
Fuse	Fuse, T4A 250V 5x20mm	200321

# **Replacing Fuses**

If the instrument does not seem to get power after you press the Power button, confirm that the power cord is securely connected to a functioning power outlet and to the power port on the rear of the instrument.

If the power failed while the instrument was running, verify that the power cord is not loose or disconnected and that power to the power outlet is functioning properly.

If these checks fail to remedy the loss of power, replace the fuse. There is one spare fuse in the spare fuse compartment of the fuse carrier which is part of the power outlet on the rear of the instrument. If necessary, you can obtain replacement fuses from nRichDX.



# **Chapter 6: Specifications Table**

Item	Description
Altitude	Up to 2000m (6562 ft.)
Ambient Operating Conditions	Temperature: 18°C to 28°C (64°F to 82°F) Relative humidity: 15% RH to 80% RH (non-condensing) Pollution: Degree 2
Ambient Storage Conditions	<b>Temperature:</b> 0°C to 60°C (32°F to 140°F) <b>Relative humidity:</b> 15% RH to 80% RH (non-condensing)
Dimensions	Width: 58.5 cm (23 in.) Height: 30.5 cm (12 in.) Depth: 34.5 cm (13.5 in.)
Fuse Replacement	5x20mm cartridge type, T3.0A H, 250V
Mains Disconnect	The mains disconnect is the Appliance Coupler. Ensure accessibility to the rear of the unit after installation.
Operating Environment	Indoor use only
Spacing	Allow 2" of clearance around the unit. The front side of the unit will need 12" of clearance to safely insert and remove the drip tray. This 12" is not necessary during normal operation but must be available for maintenance.
System Power	100-240V, 50/60Hz, 2A Installation Category II
Weight	7.3 kg (16 lb.)

# **Technical Support, Product Orders, and Contact Information**

For additional questions, please contact technical support services at technicalsupport@nrichdx.com

For general inquiries, please email info@nrichdx.com

For product or kit orders, please email orders@nrichdx.com

Additional information and support materials at www.nrichdx.com

In the U.S.: 1.833.nRichDX; Int'l: +1.949.341.1980 (8 AM - 5 PM, M-F Pacific Time)



### **Trademarks, Terms, and Warranty Information**

Trademarks: including the nRichDX® logo and tagline, nRicher™ Cartridge, Revolution Sample Prep System™, Revolution Plus Sample Prep System™, Revolution Pro Sample Prep System™, Revolution cfTNA Max 20 Kit™, Revolution cfTNA Max 50 Kit™, Revolution cfTNA Reagent Kit™, Revolution cfDNA Max 20 Kit™, Revolution cfDNA Reagent Kit™, Revolution CTC Enrichment Kit™, "Driving Diagnostic Excellence®," "Powering Liquid Biopsy," and "Liquid Biopsy is revolutionizing cancer treatment. nRichDX empowers that revolution.®," are trademarks of nRichDX, Inc.

nRichDX products are covered by one or more of the following patents: 10,329,554; 10,585,101; 10,927,366; D886,320; D890,362; Canada patent numbers 3,016,895; 3,042,426; 190733; Europe patent numbers 001720118; 3535058; China patent number ZL2017800688437; Japan patent number 389863; Korea patent numbers 30-1062125; 10-2239349; Australia patent numbers 201916131; 2017355635, with other patents pending internationally.

Use of this product indicates the agreement of purchaser or user of this kit to the following terms:

- 1. This product can only be used in accordance with the protocols and procedures provided in the most current versions of the Revolution Plus user manual and Instructions for Use (IFU) for the Revolution kit(s) used at the time of use. The most current versions of these documents are available from nRichDX and at www.nrichdx.com. nRichDX, Inc. grants no license under its intellectual property to employ or integrate the components of their kits with any components not included in the kit except as indicated in the protocols and procedures described herein.
- 2. Research Mode operation of the instrument may not be optimal for extraction/isolation of analytes and may deliver sub-optimal performance. Regardless of the Revolution kit labeling, the Revolution Plus System when operated in Research Mode is labeled: For Research Use Only. Not for use in diagnostic procedures.
- 3. nRichDX, Inc. does not warranty that Revolution kits or the use of Revolution kits does not infringe upon the rights of third-party entities.
- 4. Revolution kits and the components therein are only licensed for one-time use; the Revolution kits or components cannot be reused, refurbished, or resold.
- 5. nRichDX disclaims any licenses, expressed or implied, other than the licenses that are expressly stated.
- 6. The purchaser and the user of this kit agree to not act or permit anyone else to act in any way that might lead to or enable any of the prohibited acts indicated above. nRichDX may enforce the prohibitions of this Limited License Agreement in Court and shall work to recover all investigative and Court costs, including attorney fees, in any action that nRichDX takes to enforce this Limited License Agreement or any intellectual property rights that relate to this kit and/or components of the kit.

© 2025 nRichDX, Inc.



# The nRichDX Revolution Sample Prep System $^{\scriptscriptstyle\mathsf{TM}}$

Liquid Biopsy is revolutionizing cancer treatment. nRichDX empowers that revolution.®

