

nRich^{DX} Revolution™ Processor User Manual

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nRich^{DX}
DRIVING DIAGNOSTIC EXCELLENCE

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Preface

nRichDX provides this document to its customers with a product purchase to use in the product 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 purposes 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.

About This User Manual

This user manual is written for the operator (for example, laboratory technician). This manual provides information on the nRichDX Revolution™ System, including the installation and operating instructions.

This document aims to provide information for:

- Reviewing safety precautions
- Installing the Revolution System
- Using the Revolution System in routine jobs – the processing step
- Performing basic cleaning and maintenance procedures
- Troubleshooting the instrument performance

This user manual also describes the features and specifications of the Revolution System instrument as well as ordering information.

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 used 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.



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 micro-organisms.
- 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 shields, 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.



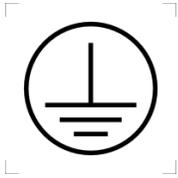
CAUTION The system generates and can radiate radio frequency energy. If the system is not installed and operated correctly, this energy can cause interference with other equipment. In addition, other equipment can radiate radio frequency energy to which the system is sensitive. If you suspect interference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

| Symbol | Description |
|---|--|
|  | <p>Title of Symbol: Caution</p> <p>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.</p> <p>Standard Number, Title of Standard, and Symbol Reference Number: <i>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</i></p> |

| | |
|---|---|
|  | <p>Title of Symbol: Warning; Biological hazard</p> <p>Meaning of Symbol: To warn of biological hazard.</p> <p>Standard Number, Title of Standard, and Symbol Reference Number: <i>IEC 60878. Graphical Symbols for electrical equipment medical practices. #7010-w009</i></p> <p>Supplemental Product-Specific Manufacturer Information</p> <p>This label indicates a caution to operate only with all covers in position to decrease risk of personal injury or biohazard.</p> <p>Wear Personal Protective Equipment (PPE) such as gloves, shields, and lab coats. Handle and dispose of biohazardous materials according to your laboratory procedures.</p> |
|  | <p>Title of Symbol: Manufacturer</p> <p>Meaning of Symbol: Indicates the medical device manufacturer as defined in EU 90/385/EEC, 93/42/79/EC.</p> <p>Standard Number, Title of Standard, and Symbol Reference Number: <i>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.</i></p> |
|  | <p>Title of Symbol: In vitro diagnostic medical device</p> <p>Meaning of Symbol: Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.</p> <p>Standard Number, Title of Standard, and Symbol Reference Number: <i>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</i></p> |

| | |
|---|--|
|  | <p>Title of Symbol: Graphical symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Indicates the manufacturer's catalogue number so that the medical device can be identified.</p> |
|  | <p>Title of Symbol: Warning; Crushing of hands</p> <p>Meaning of Symbol: To warn of a closing motion of mechanical parts of equipment</p> <p>Standard Number, Title of Standard, and Symbol Reference Number: <i>ISO 7010. Graphical Symbols for electrical equipment in medical practices. #W024</i></p> <p>Use caution to avoid injury to hands when close to equipment with moving mechanical parts.</p> |
|  | <p>Title of Symbol: cNRTLus Certification Mark</p> <p>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.</p> <p><i>OSHA, CEC</i></p> |
|  | <p>Title of Symbol: Fuse Location</p> <p>Meaning of Symbol: Indicates the location of a fuse.</p> |
|  | <p>Title of Symbol: Protective earth; protective ground</p> <p>Meaning of Symbol: to identify any terminal which is intended for connection to an external conductor for protection against electric shock in</p> |

| | |
|--|---|
| | <p>case of a fault, or the terminal of a protective earth (ground) electrode.</p> <p>Standard Number, Title of Standard, and Symbol Reference Number: <i>IEC 60417: Graphical symbols for use on equipment – Overview and application, #5019</i></p> |
| <div style="border: 1px solid black; padding: 5px; display: inline-block;"> SN </div> | <p>Title of Symbol: Serial number</p> <p>Meaning of Symbol: Indicates the manufacturer’s serial number so that a specific medical device can be identified.</p> <p>Standard Number, Title of Standard, and Symbol Reference Number: <i>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></p> |

Contacting Us

For the latest information on products and services, visit our website at: www.nrichdx.com.

For Customer Support contact us at: info@nrich.com

Chapter 1 - Introduction to the Revolution System

Intended Use

The Revolution™ Processor is designed to perform semi-automated extraction and purification of nucleic acids from biological liquid specimens intended for molecular biological applications. The processor is intended for use by professional users, such as technicians trained in molecular biological techniques and the operation of the Revolution™ Processor.

The Processor 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 rotator (measured in revolutions per minute; RPM) and the system timer. The Processor features an easy-to-use interface that allows the user to easily adjust the run time and speed.

Use Statement

This device is intended for indoor use only. Safety Protection may be impaired if 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 Processor, including its functions, specifications, operation, and routine care and maintenance. nRichDX, Inc. recommends that users read this entire manual, including all safety-related information, before operating the instrument.

Chapter 2 - Instrument Overview

In addition to these instructions, the contents of the Revolution Processor packaging include the instrument, a power cord, and a drip tray.

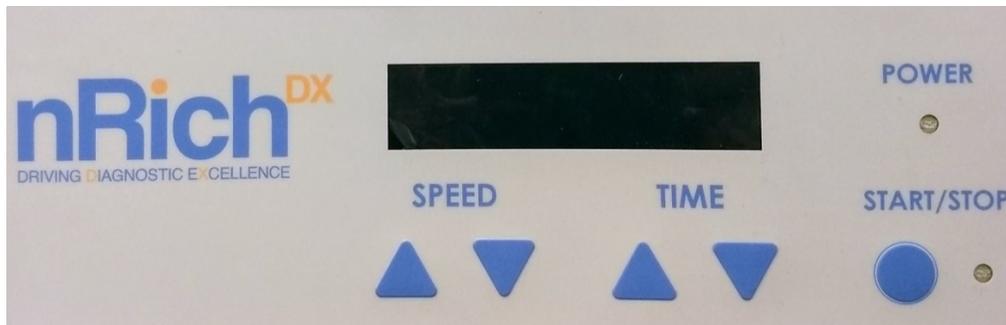
Revolution System Set-Up

1. Remove the instrument from its shipping container and ensure all packing materials have been removed from the instrument.
2. Two people should lift the instrument onto its desired location by grasping underneath the base at the sides of the instrument and then placing the rear base of the unit down first followed by the front being careful to remove fingers from underneath as the front of the unit is lowered. After setting the rear of the instrument down and at the point of lowering the front of the instrument you can grasp the metal frame adjacent to the door and lower the front onto the support feet.
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. Remove the packing materials from the drip tray.
5. Slide the drip tray through one of the openings, located on either the right or left side panels, of the mixing chamber so that the tray is resting on the bottom of the mixing chamber. The drip tray should be oriented so any liquid will be captured inside the tray.
6. The instrument is now ready for use.

User Interface

The Revolution Processor has an intuitive user interface that is comprised of the following elements:

- Digital display
- Power indicator light
- Stop/Start button and indicator light
- Time adjustment keys
- Speed adjustment keys



Chapter 3 - Operating Instructions

1. Turn on the power switch located in the back of the instrument. The POWER light on the user interface will illuminate.
2. Ensure that the instrument is in the home position. If the instrument is not in the home position, the display will read “press start to home”. Press the start key to home the instrument.
3. Open the mixing chamber door.
4. Place the Revolution Cartridge Rack containing up to 12 Revolution nRicher Cartridges into the instrument.
5. Load the Revolution Cartridge Rack onto the rack mounting pins by inserting top of cartridge rack (single hole) onto the top pin and lining up the bottom pins with the bottom slots in the rack. Slide the rack under the flange feature of the pins. Ensure that the rack is captured by all 3 pins.
6. Close the mixing chamber door. The door must be fully closed to operate the instrument.
7. Use the arrow keys to adjust the speed and time according to the appropriate Revolution Isolation Kit program located in the Revolution Isolation kit Instructions for Use. The timer range is between 1 min and 999 minutes and the speed range is between 10 RPM and 30 RPM.

Notice: The Speed and Time CANNOT be adjusted while the instrument is running.

Starting a Run

To start the run, depress the START/STOP. The START/STOP led will illuminate when the instrument is running. Once run is complete, clear the completed run by depressing any arrow key.

Stopping a Run

To stop a run at any point, depress the START/STOP key. The device will slow to a stop and the instrument will return to the home position. The run parameters will be saved at the stopping point. These parameters can be adjusted if needed. When ready to restart a run, depress the START/STOP key.

Opening the Door During a Run

Opening the door during a run will immediately turn off the motor and stop the run. If the door is opened mid-run, follow the instructions on the screen to restart the run from the stopping point:

- Depress any arrow key
- Depress the START/STOP key to home the instrument

The run parameters will be saved at the stopping point. These parameters can be adjusted if needed.

When ready to restart the run, depress the START/STOP key.

Useful Suggestions

Loading and Unloading the Rack

Always use two hands (one on each handle) to load/unload the rack onto the rack mount pins.

Ensure the rack is fully engaged with all three rack mount pins before starting a run.

Loading and Unloading the Sample Cartridges

Insert the cartridges straight down into their respective cartridge slots to load. Remove by pulling straight up out of the cartridge slot.

Always use two hands to load/unload the cartridges into the rack. One hand should hold on to the rack while loading/unloading the cartridges.

Turn Off the Instrument when not in Use

Turn off the instrument utilizing the switch at the rear of the instrument when not in use to minimize wear on the motor and the electronics.

Display Messages:

| Device State | Screen Display |
|--------------------------------------|--|
| Start Up | nRichDX Mixer VER: 1.0.0 followed by nRichDX Mixer PRESS ANY ARROW KEY TO CONTINUE |
| Un-homed | PRESS START TO HOME |
| Homing | HOMING or HOMING COMPLETE |
| Homed, Prior to Programming a Run | SPEED: 30 RPM TIME: 0:00 <i>Note: The speed and time displayed are the set points and can be adjusted.</i> |
| Running | RUNNING XX RPM <i>Note: While running, display RPM indicates actual speed.</i> TIME: XXX:XX <i>Note: Display time indicates time remaining.</i> |
| Stopping | STOPPING |
| Run Completion | RUN COMPLETE PRESS ANY ARROW KEY |
| Error | ERROR: message <i>See error messages section below.</i> |

Error Messages:

If an error occurs, follow the instructions on the screen to clear the error and restart or resume the run:

| Error Message | Sequence to Clear Error |
|---|---|
| ERROR: STALL DETECTED. CLEAR OBSTRUCTION. PRESS ANY ARROW KEY. | Clear the obstruction. Depress any arrow key. Depress START/STOP to home. |

| Error Message | Sequence to Clear Error |
|---|---|
| ERROR: DOOR OPEN. CLOSE DOOR TO CONTINUE. PRESS ANY ARROW KEY. | <i>If door is opened during a run:</i> Depress any arrow key. Depress START/STOP to home. Depress START/STOP to restart the run. <i>If door is opened prior to a run:</i> Close door. Depress START/STOP to run. |
| ERROR: HOME SWITCH NOT FOUND. PRESS ANY ARROW KEY. | Inspect device and remove any obstruction. Depress any arrow key to continue. Depress START/STOP to home. |

If the device loses power during a run and the device resets, the screen will display the start-up screen. In this case the run information will not be saved.

Chapter 4 - Cleaning

Remove the drip tray and wash with 70% ethanol in water solution. Clean all internal instrument surfaces by wiping 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 shield. Also wipe down the front panel and door handle during periodic cleaning.

Chapter 5 - User Replaceable Parts and Supplies

The following supplies can be ordered by contacting nRichDX at www.nRichDX.com

Cartridges are purchased as a component of the various extraction kits. Other instrument components and supplies that can be purchased individually include:

| Name | Description | Part # |
|---------------------------|---|--------|
| Revolution Cartridge Rack | Rack supporting 12 cartridges | 100305 |
| Drip Tray | Tray placed at base of mixer in case of spills | 100291 |
| Revolution Mag Rack | Used during bead washing and elution steps for bead capture | 10082 |
| Revolution Mag Capsule | Magnetic capsule used to collect beads during enrichment | 10080 |
| Fuse | T3.0A H, 250V 5x20mm | 100244 |

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 nor 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. See the User Replaceable Parts and Supplies section above for details on fuse specifications and part numbers.

Chapter 6 - Specifications

| Item | Description |
|------------------------------|--|
| Operating Environment | Indoor use only |
| System Power | 100-240V, 50/60Hz, 2A Installation Category II |
| Fuse Replacement | 5x20mm cartridge type, T3.0A H, 250V |
| Dimensions | Width: 35.6 cm (14 in.) Height 62.0 cm (25 in.) Depth: 62.0 cm (24.25 in.) |
| Spacing | Allow 2" of clearance around the unit. One side of unit will need 12" of clearance to safely insert and remove the drip tray. Either side can be used for this. This 12" is not necessary during normal operation but must be available for maintenance. |
| Weight | 20.55 kg (45.3lbs) |
| 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 | Temperature: 0°C to 60°C (32°F to 140°F) Relative humidity: 15% RH to 80% RH (non-condensing) |
| Altitude | Up to 2000m (6562 ft.) |
| Mains Disconnect | The mains disconnect is the Appliance Coupler. Ensure accessibility to the rear of the unit after installation. |