

Research Mode User Manual

Revolution Plus™ Sample Prep System Research Mode Operation



Version A

For Research Use Only. Not for use in diagnostic procedures.



2000PLUS



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POWERING LIQUID BIOPSY

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Overview

This document shows some of the capabilities of the Research Mode operation of the Revolution Plus instrument.

The Revolution Plus Research Mode GUI allows the user to cycle through a set of 20 user-customizable profiles. Each profile is saved into the instrument's internal flash memory and will be reloaded when the instrument powers on with the Research Mode USB Key inserted into the USB drive. The user can cycle through these profiles using the two arrow icons at the top corners of the Research Mode GUI as shown in Figure 1.

After a parameter is modified (for example, the "Angle [deg]"), the unit needs to remain powered for at least 2 minutes, at which point the modification is automatically saved to internal memory. The user does not need to take any other action.

Note: there is no "export" feature. To transfer the tested parameters to another system, they need to be copied to an Excel spreadsheet or similar compatible application.

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 info@nrichdx.com. 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 Research Mode user manual is written for the trained operator familiar with laboratory procedures and wishing to operate the Revolution Plus instrument in Research Mode. Unlike the instrument's Kit Mode, Research Mode enables manual adjustment of several of the instrument's programmed extraction parameters.

Each Revolution Kit also comes with a separate Instructions for Use (IFU) document which describes use of the specific Revolution Kit with the Revolution Plus instrument.

Please see the Revolution Plus Sample Prep System User Manual (different from this document and provided when the instrument was purchased or from nRichDX). for information on instrument safety precautions and notices, installation, operation, and maintenance for use exclusively in the Revolution Plus's default Kit Mode. This Research Mode user manual should be used together with the Revolution Plus Sample Prep System User Manual to ensure safe operation of the instrument. Current versions of both Revolution System user manuals, as well as Revolution kit IFU's are available from nRichDX.

Instrument Overview and Activating Research Mode

The Revolution Plus System consists of the instrument, a 12-position Cartridge Rack, a Power Cord, a Drip Tray, a Magnetic Rack, and Revolution System Kit Mode USB Key. The instrument Research Mode is activated by powering the instrument off using the power switch on the back panel of the Revolution Plus instrument, inserting the Research Mode USB Key (available separately) into the instrument's USB port and powering the instrument on.



Revolution Plus Processor
(Front View)



Revolution Plus Processor
(Close-Up Back View)



Mag Capsule (x12)



Magnetic Rack

Research Mode - Graphical User Interface (GUI)

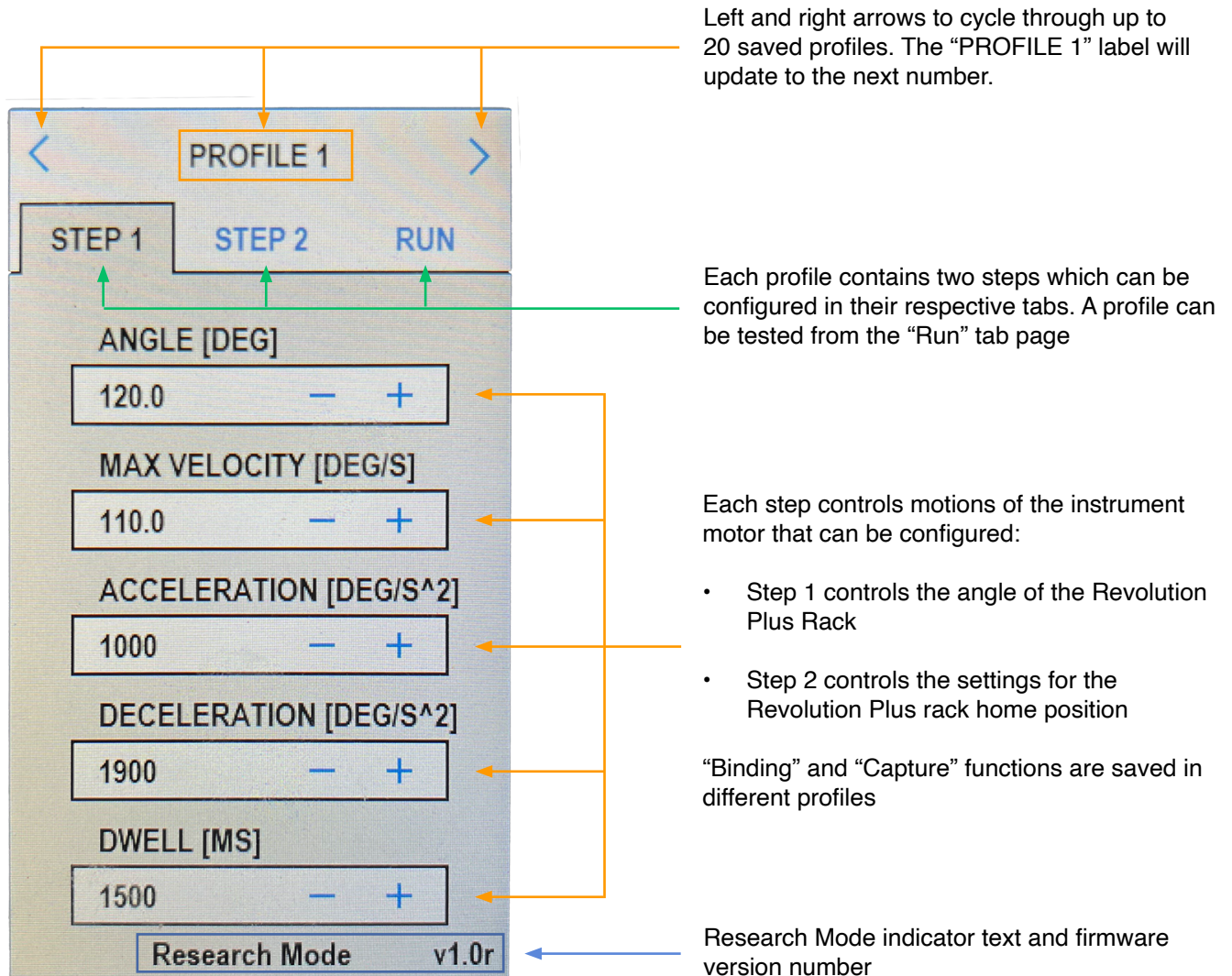


Fig. 1 - STEP 1 User Interface

Programming Example

Given the following configuration shown in the table below, two profiles would be used with two steps per profile, for a total of four steps entered.

[Continued next page]

	Binding		Capture	
PARAMETER [UNITS]	STEP 1	STEP 2	STEP 1	STEP 2
Angle [deg]	120	0	120	0
Max velocity [deg/s]	83.75	83.75	201	201
Acceleration [deg/s ²]	1900	1900	1900	1900
Deceleration [deg/s ²]	1900	1900	1900	1900
Dwell [ms]	57	57	525	225

- “PROFILE 1” Step 1 with binding raised angle (Fig. 1)
- “PROFILE 1” Step 2 with binding lowered angle (Fig. 2)
- “PROFILE 2” Step 1 with capture raised angle
- “PROFILE 2” Step 2 with capture lowered angle

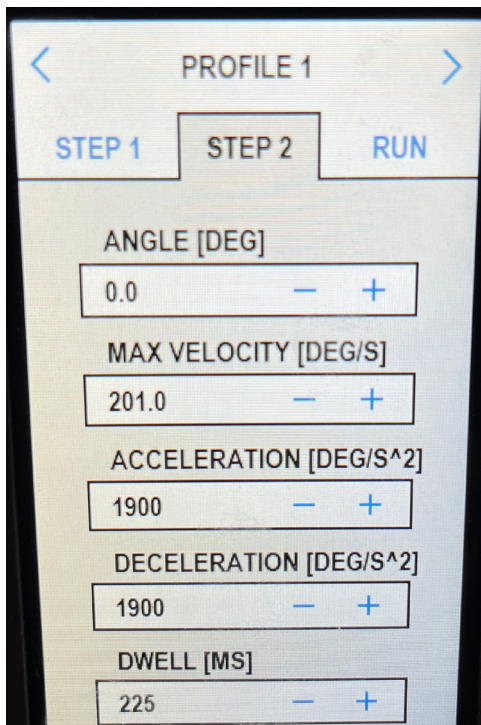


Fig. 2 - STEP 2 User Interface

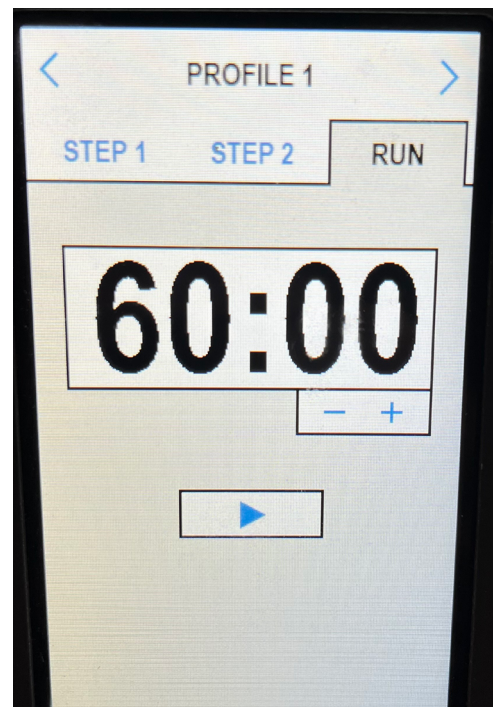


Fig. 3 - RUN User Interface (pressing the blue play icon initiates the run)

Safety and Special Notices

Please refer to the Revolution Plus Sample Prep System User Manual for safety notices and instructions for operation of the Revolution Plus instrument.

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 Max 50 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.

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