RAMP® 200
User Manual

RESPONSE BIOMEDICAL

RAMP® 200 USER MANUAL

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EDITION NOTICE

This manual is for users of the RAMP® 200 instrument firmware versions 1.2 and higher.

Every effort is made to ensure that all the information contained in this manual is correct at the time of printing. However, Response Biomedical Corp. reserves the right to make any changes necessary without notice as part of ongoing product development.

Any customer modification to the instrument will render the warranty or service agreement null and void.

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CORPORATE INFORMATION

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Table of Contents

INTRODUCTION **A**

Scope and Audience

Thank you for selecting the RAMP® 200 Platform, the rapid immunochromatographic system for performing *in vitro* diagnostic analyses.

This manual is intended for operators of the RAMP® 200 and describes procedures available to users with access rights up to supervisor level. Information specific to service procedures is not contained in this publication.

How to Use This Manual

This manual is divided into the following parts:

- **Part A – Introduction**: Contains an overview of the user manual and describes basic features and functions of the RAMP® 200.
- **Part B – Warnings & Precautions**: Contains important information about safe operation of the RAMP® 200.
- **Part C – Unpacking and Setup**: Contains information about the RAMP®200 delivery, packaging and setup.
- **Part D – RAMP® 200 Basics**: Contains information about the RAMP® 200 modules and startup procedures.
- **Part E – Performing a RAMP® Test**: Contains information about running an assay on the RAMP® 200.
- **Part F – Quality Control:** Contains information about the RAMP® 200 QC procedures.
- **Part G – Working with Results:** Contains information about the assay result handling on the RAMP® 200.
- **Part H – Managing Settings**: Contains general information about instrument, connectivity and user administration settings for the RAMP® 200.
- **Part I – Editing Settings:** Contains detailed information about instrument, connectivity and user administration settings for the RAMP® 200.
- **Part J – Maintenance:** Contains all necessary information concerning instrument maintenance and cleaning.
- **Part K – Troubleshooting:** Contains helpful information about troubleshooting.
- **Part L – Specifications:** Contains information about technical data of the RAMP® 200.
- **Part M – Index:** Contains an index to find information in the manual by keyword search.

Customer Information

Customer Training

Contact your local sales representative for any questions or information regarding RAMP® 200 training.

Customer Service

Contact your local sales representative for further information regarding the RAMP® 200 warranty.

Ordering Information

Replacement parts and consumable materials should be ordered from Response Biomedical Corp. When ordering, please use the Response Biomedical catalog number and reference name for each item. For more information, contact Response Customer Service at: 1.866.525.7267.

Conventions Used in This Manual

Visual cues are used to help locate and interpret information in this manual quickly. This section explains formatting conventions used in this manual.

Symbols

▶	Procedural step	⧖	Use-by/Expiry date
●	List item	⚠	**Caution, consult accompanying documents.** Indicates a situation which, if not avoided, could damage device.
⁙	Cross reference, consult manual	⚡	Electrical Hazard
⚱	Fragile, handle with care	⚠	**Warning!** Indicates a hazard which, if not avoided, could result in death or injury (i.e. fire, electrical shock or explosion).
☂	Keep away from rain	📖ℹ	Consult Instructions for Use
②	Do not re-use	**IVD**	In vitro diagnostic device
⊘	Do not use if package is damaged	∑	Contains sufficient for <n> Tests
🌡	Temperature limitation	♲	**Waste electrical and electronic equipment (WEEE)** Do not dispose of this product in municipal waste. Contact Response Technical Support for disposal or recycling information.
REF	Reference/Catalogue number	⌂	Manufacturer
LOT	Lot/Batch code	**EC** **REP**	Authorized Representative in the European Community
CONTENT	Contents of Kit	CE	**Conformité Européenne** CE Mark. Product meets the safety requirements of the European Union

Abbreviations

Abbreviation	Description
CFR	Code of Federal Regulations
CM	Control Module
CSA	Canadian Standards Association
DHCP	Dynamic Host Configuration Protocol
FCC	Federal Communications Commission
FTP	File Transfer Protocol
FTPS	File Transfer Protocol Over Secure Socket Layer
HID	Human Interface Device
HRB	High Running Background
HTTP	Hypertext Transfer Protocol
HTTPS	Hypertext Transfer Protocol Over Secure Socket Layer
IEC	International Electrical Commission
IFU	Instructions for Use
IP	Internet Protocol
IQC	Internal Quality Control
LED	Light Emitting Diode
LQC	Liquid Quality Control
MAC	Machine Address Control
NTP	Network Time Protocol
RCU	Reader Configuration Utility
RoHS	Restriction of Hazardous Substances
SN	Serial Number
SSL	Secure Socket Layer
TCP/IP	Transmission Control Protocol/Internet Protocol
TM	Test Module
UL	Underwriters Laboratories Inc.
USB	Universal Serial Bus
VGA	Video Graphics Array
WEEE	Waste Electrical and Electronic Equipment

Overview

The RAMP® 200 is a system comprised of two primary components:
- A Test Module (TM) that analyzes sample tests.
- A Control Module (CM) that manages the sample test results that it receives from the TM.

Calibration and expiration information for Test Cartridges are uploaded to the CM through Lot Cards that are included with the Test Kits.

To perform a Test, add a sample into the well of a Test Cartridge and then insert the Test Cartridge into the TM. Once the Test Cartridge has been inserted, no further intervention is required. A barcode on the bottom of the Test Cartridge is then read by the RAMP® 200 to determine the lot number. Information loaded with the Lot Card identifies lot-specific parameters and expiration date. This ensures that an expired cartridge cannot be used.

Analysis time is analyte-specific and typically takes approximately 15 minutes per sample. Analysis results may be viewed on the RAMP® 200 display screen and/or output to a USB flash drive, computer or network server, or printer.

The RAMP® 200 can be operated in either local (manual transfer) or network (auto transfer) mode. Interaction with the RAMP® 200 is through its touchscreen display and user input is accepted from either the touchscreen keyboard or an optional barcode scanner. Stored data, including results, can be transferred via USB flash drive, sent to a printer or uploaded to a computer network.

Immunoassay Measurement Principle

The measurement process is based on the use of antibodies, biologically-derived binding agents that can be used to specifically identify and bind to target analytes (e.g., analyte indicative of cardiac damage). The RAMP® 200 Platform consists of two components: a disposable Test Cartridge that houses an analyte specific immunochromatographic strip and a portable fluorescence analyzer. A "sandwich" immunoassay format is followed. Target-specific antibodies are used to tag fluorescently labeled latex particles. In addition, target-specific antibodies are immobilized at the detection zone of the immunochromatographic strip. The RAMP® 200 also incorporates a quantitative Internal Standard that is run and measured concurrently in every test. In a typical test, the operator adds sample, and antigen-bound fluorescent particles are captured at the detection zone (i.e., the antigen is "sandwiched" between the detection zone antibodies and the antibodies on the latex particle) and a portion of excess particles that are not bound to antigen and do not bind at the detection zone are captured at the control zone. The instrument measures fluorescence emitted by the complexes captured in the detection and control zones and calculates a ratio between these measurements. The more analyte present in the sample, the greater the number of antibody-binding sites that will be occupied, and correspondingly, a greater number of fluorescently-labeled latex particles will be captured at the detection zone.

Result Interpretation

Refer to the individual RAMP® Test Instructions for Use (IFU) for a detailed description of result interpretation. Depending on the test used, the result interpretation may vary due to specific Assay properties.

RAMP® 200 – components

Full operation of the RAMP® System requires the use of RAMP® Test Kits and components. Optional accessories include a printer and barcode scanner.

RAMP® 200 is comprised of the following components:

RAMP® 200 Control Module (CM)

User interface and connectors for all peripherals. Stores and displays Test results (view, print, transfer, search, and filter/sort).

RAMP® 200 Test Module (TM)

Features two testing ports for performing simultaneous RAMP® 200 Assays. A maximum of three TMs can connect to a CM.

Power Supply and Interconnect Cable

Power supply cord and interconnect cable to connect CM and TM.

USB Flash Drive

Pre-configured with:
- The following four file folders: *patient*, *lqc*, *iqc* and *log*. For use in bi-directional information transfer in a non-networked environment. Also contains a version of *File Converter (Excel)*.

    ❊ Refer to *Exporting or Printing Test Result or Event Log Data* section.
    ❊ Refer to *Manually Transferring/Printing Results* section.

- The Reader Configuration Utility (RCU) software executable file. Allows customized settings for the RAMP® 200.
- Electronic version of this User Manual.

WARNINGS & PRECAUTIONS B

User/Operator Qualification

Operation should be conducted by personnel who have undergone training. Prior to operating the Platform, operators are required to have knowledge of relevant guidelines and norms as well as the information and procedures contained in the User Manual and supplied USB.

Carefully follow the procedures specified in the User Manual for the operation and maintenance of the RAMP® 200. Maintenance not described in the User Manual should be left to trained Response Biomedical Technical Support personnel.

Summary of Warnings and Precautions

The RAMP® 200 and its related devices and accessories are designed to provide safe and reliable service when used according to the instructions provided in this Operator Manual.

The following warnings and precautions should be followed in order to avoid unsafe actions with the RAMP® 200 that could potentially result in personal injury or device damage.

NOTE
For U.S. customers, the RAMP® 200 must be operated in a laboratory setting when used with the RAMP® Cardiovascular Tests.

⚠️WARNING
To reduce the risk associated with potentially infectious patient samples: • Do not spill specimen or sample fluids or any of the RAMP® 200 components or on the outside of the Test Cartridge. • If a spill occurs, disinfect external surfaces only using a soft cloth containing a solution of 0.5% bleach or 70% ethanol. **To reduce the risk associated with hazardous voltage:** • Unplug the RAMP® 200 before cleaning. • Do not immerse any of the RAMP® 200 components in water. • Do not use the RAMP® 200 if there is apparent damage to a power cord or power supply.

⚠️CAUTION
To reduce the risk associated with environmental contamination: • Dispose of instrument and accessories in accordance with federal, state, and local requirements. **Do not open any RAMP® 200 device enclosures, this will void warranty.** **To reduce the risk associated with incorrect test results:** • RAMP® 200 should only be used by trained professionals and operated in accordance with facility policies and procedures.

UNPACKING & SETUP C

Unpacking and Setup

Inspect all components carefully. If any damage is visible, notify the carrier and your distributor or notify Response Biomedical Corp. to arrange for repair or replacement.

Shipping container contents

Item	Description	
RAMP® 200 Control Module (CM)	RAMP® 200 Control Module RAMP® 200 User Manual Power Supply* USB Flash Drive**	
RAMP® 200 Test Module (TM)	RAMP® 200 Test Module Interconnect cable	

*   Use only the approved power cord provided with the RAMP® 200. A power cord approved for the North American market is provided with each CM.

**   Use the manufacturer-supplied USB flash drive. If a USB flash drive is supplied by the User/Operator, ensure that the drive folders match those folders listed in *Exporting or printing Assay result or event log data* <u>OR</u> *Manually Transferring/Printing Test Results* section.

Additional accessories supported by the RAMP® 200 include an optional printer and a barcode scanner. Only use the approved USB cables that are supplied with the components.

NOTE
Only one of each type of device can be connected to a CM at any given time.

Optional Components

Item	Description
Printer	Barcode printer for self-adhesive roll labels, 2 - 2.5-inches wide. Connects to the CM via USB. Zebra® Technologies TLP 2824™ or TLP 2824 Plus™. ***NOTE:** TLP 2824 Plus™ is compatible with CM V1.3 or later software only. Consumables: Requires 2.25" W x 3" L Z-Select 4000T labels from Zebra® Technologies (p/n: 800222-305). Requires 57mm x 74m wax/resin ribbon from Zebra® Technologies (part number: 800132-102). Additional information available at www.zebra.com or phone 1.866.230.9494.
Printer (*Chinese printing capability)	Barcode printer for self-adhesive roll labels, 2 - 2.5-inches wide. Connects to the CM via USB. Zebra® Technologies 888-TT™. Consumables: Requires 2.25" W x 3" L Z-Select 4000T labels from Zebra® Technologies (p/n: 800222-305). Requires 64mm x 74m wax/resin ribbon from Zebra® Technologies (part number: 03200GS06407). Additional information available at www.zebra.com or phone 1.866.230.9494. **NOTE: This printer is only compatible with CM software version 1.3 or later. This printer supports printing in Chinese.**
Barcode Scanner (with cradle)	Omni-directional, hands-free barcode scanner for entering operator and patient/sample ID. The barcode scanner is shipped in the correct configuration and is ready for use after connecting to the CM via USB. Symbol Technologies Inc. model LS9208. Additional information available at www.motorolasolutions.com, 1.800.653.5350

Setup

▶   **To set up the RAMP® 200 for use**

1   Place RAMP® 200 components on a stable work surface within reach of an electrical outlet (and network connection, if available). Access to the back of each module is required to connect components.

❈   Refer to *Figure 2* for connector locations.

2   Remove the dust protection stickers from TM ports.
3   Connect the TM and any optional devices to the CM using the supplied interconnect cable(s).
4   Connect the supplied power cord to the CM. Plug the other end into a wall socket.

NOTE
• Up to three TMs can be connected to each CM. • TMs can be stacked vertically or horizontally (one on top of another). • CM can be placed on top of the TM.

Figure 1:   RAMP® 200 - front view

RAMP® 200 Control Module

Touchscreen display

Lot card
insertion slot

Test cartridge ports

RAMP® 200 Test Module
(a maximum of three TMs
can be connected to the CM)

Port LEDs
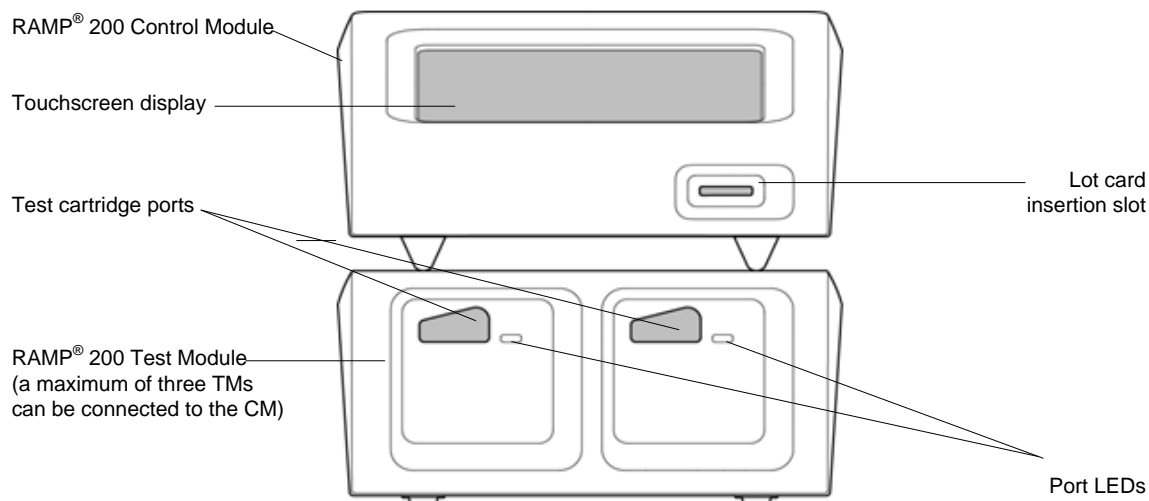
Figure 2:   RAMP® 200 - rear view

RAMP® 200 Control Module

Power on/off

Power cord connector

Ethernet connector

USB connectors for optional printer, barcode scanner and flash drive

RAMP® 200 Control Module to RAMP® 200 Test Module connectors

RAMP® 200 Test Module
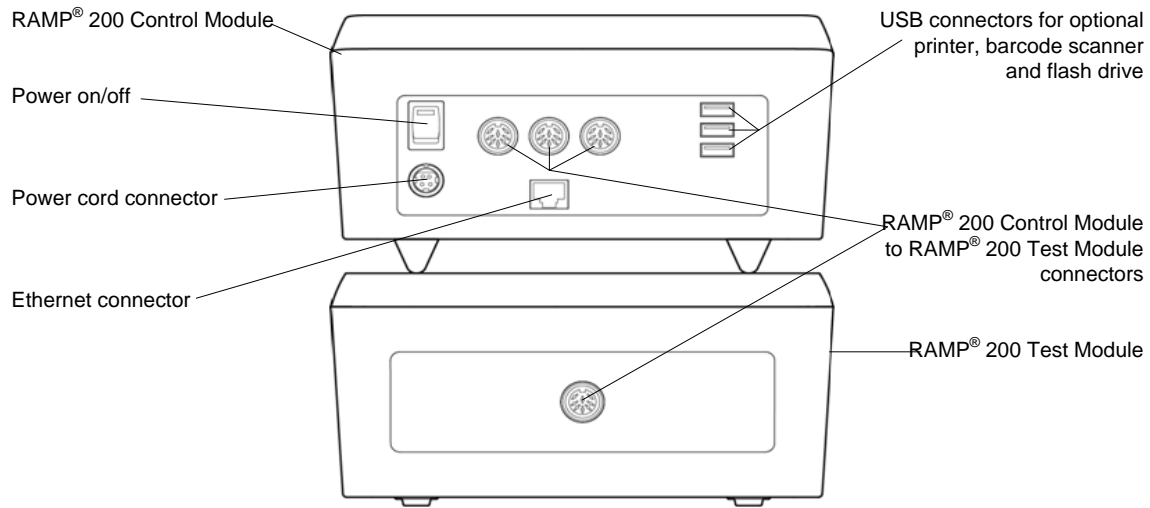
⚠ CAUTION

- Do not stack a CM on top of a TM unless all four feet of the CM rest on the TM housing.
- Do not place anything on top of the CM.

Figure 3:   RAMP® 200 Control Module - rear panel label

Power On   Power Off   TM ports   USB ports (x3)

Response Biomedical Corporation
Vancouver, BC V6P 6P2

Control Module

SN
Model
Rev

Input: 12V ⎓ 120W

R0010 r2.0

Electrical Rating   Ethernet   Safety and standards labels. For descriptions, see the Symbols section.
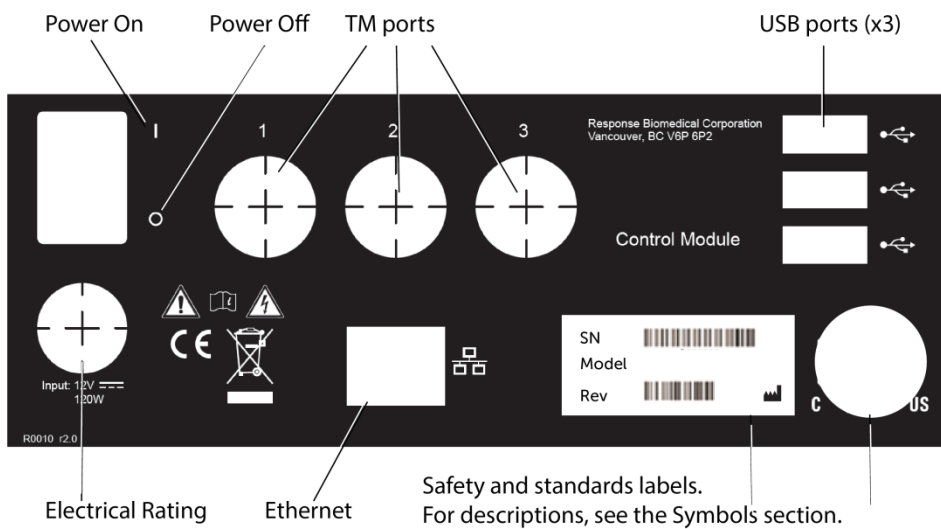
Figure 4:   RAMP® 200 Test Module - rear panel label
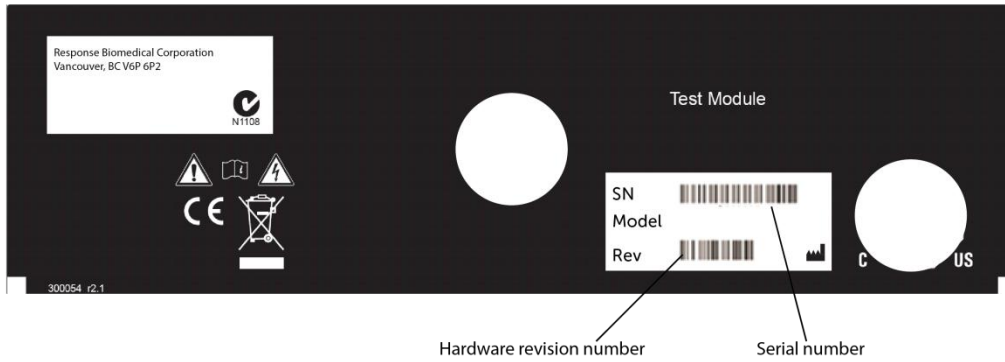
RAMP® 200 BASICS D

RAMP® 200 Basics

The RAMP® 200 is pre-programmed with default settings so you can use the instrument immediately.

Some settings can be edited manually through the Settings menu on the CM touchscreen. However, you will find that you can edit most settings using the Reader Configuration Utility (RCU) found on the USB flash drive supplied with the CM.

> ❋   Refer to *Editing Settings Using the RCU* section.

Powering On/Off

The power On/Off switch is located on the rear panel of the CM (*Figure 2*).

To turn the instrument on, press the power switch up. When the power is switched on, the LEDs on the front of the TM illuminate blue and the RAMP® 200 performs a series of internal quality control (IQC) self-tests in order to ensure that the system is operating within specifications.

> ❋   Refer to *Running IQC Tests* section.

When the power-on sequence is complete, the Home screen is displayed (*Figure 5*). The power-on sequence takes approximately 1 minute to complete.

To turn the RAMP® 200 off, press the power switch down.
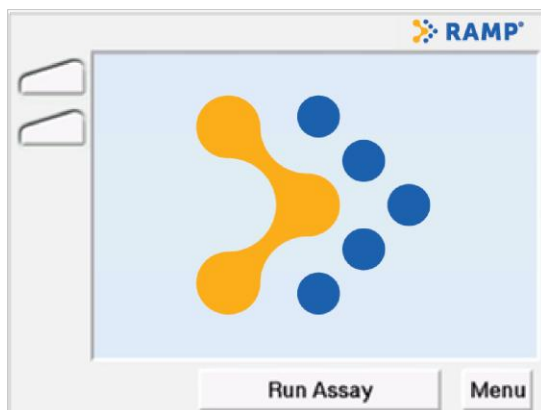
Figure 5   Home Screen

Touchscreen

The Control Module is controlled using the interactive touchscreen. Once the Home screen is displayed, selections can be made by touching the appropriate prompt on the display (i.e., **Run Assay** to initiate a RAMP® Test, or **Menu** to go to the Main Menu) (*Figure 6*).

The display is pressure/touch sensitive and can accept input from a bare/gloved finger or a blunt stylus. To complete a task, select the appropriate button, icon, or command by touching it.

In this manual, 'select' and 'touch' may be used interchangeably.

⚠️CAUTION
Pens or other sharp instruments will damage the touchscreen.

NOTE
The Reader Configuration Utility (RCU) can now be used to configure hospital/clinic preferences. ⠿　　Refer to *Editing Settings Using the RCU* section.

Display Icons

The left-hand column of the screen displays an icon for each available testing port. Selecting these icons leads to a full screen display of the status information of that test port.
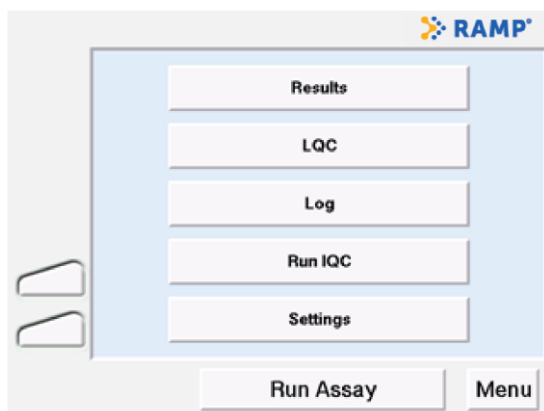
Figure 6   Main Menu Screen

The lower left corner of the display screen, below the port icons, displays LQC, printer and communication warning icons. The description of the displayed icons are as follows:

Icon	Description
	Port Idle
	Port Busy
00:09	Assay Timer
	Sample Processing and Cartridge Movement
HRB	Error Message (HRB is shown for example only) 　≫　For other error messages, refer to *Test Run Messages* in the *Troubleshooting* section
	Aborting Assay - cartridge ejecting, error message to follow
LQC (Non-selectable)	Liquid Quality Control – Warning 　≫　Refer to *Running Quality Control* section
⚠LQC (Non-selectable)	Liquid Quality Control – Expired Warning 　≫　Refer to *Running Quality Control* section
⚠🖨 (Non-selectable)	Printer Error 　≫　Refer to *Printer Errors* in the *Troubleshooting* section
⚠⇄ (Non-selectable)	Data Transfer Error 　≫　Refer to *Printer Errors* in the *Troubleshooting* section

Test Port Identification

Test ports on the RAMP® 200 are identified by a multi-character label. The first set of characters is the serial number of the TM; the second character is a location letter (A or B) referring to the left (A) or right (B) port for a particular TM. This is displayed when a port icon is selected.

PERFORMING A RAMP® TEST E

NOTE
For U.S. customers, the RAMP® 200 must be operated in a laboratory setting when used with the RAMP® Cardiovascular Tests.

⚠️ CAUTION
When entering data via the CM touchscreen (e.g., Sample/Patient/User ID), enter characters one at a time. Failure to do so may result in erroneous data entry.

⚠️ CAUTION
Be familiar with all information in the RAMP® Test Kit Instructions for Use (IFU), including Warnings & Precautions prior to running a Test.

⚠️ WARNING
Operator Hazard. Observe local protocols and appropriate precautions in the collection, handling, and disposal of specimens.

Using Lot Cards

Prior to performing any Assay, the Lot Card for that RAMP® Test Kit lot must be read by the RAMP® 200 through insertion into the Lot Card slot (*Figure 1*). The Lot Card provides lot-specific information and the expiration date for each Test Kit and is only required to be read once for each Test Kit lot. The CM can store information from 50 different lots. If the maximum is exceeded, the oldest entry is overwritten.

NOTE
The RAMP® 200 can only accept a Test Cartridge that is designed and specified for use with a RAMP® Test Kit.

⚠️ CAUTION
Do not touch the contact pads on the Lot Card. Store the Lot Card in the anti-static pouch that is provided with the RAMP® Test Kit.

▶ **To use the Lot Card**

1 Hold the card so that the arrow is on the top side and pointing away from the user.

2 Insert the Lot Card – contact end first – into the slot located on the front of the CM.

3 The display provides the following status messages:

> **Reading Lot Card**
> **Complete**
> **Lot ID: M0*XXXX***
> **Remove Lot Card**

Note: The Lot ID displayed is the lot number of the RAMP® Test Kit.

4 Remove the Lot Card and store in its original pouch.

> ❋ If the screen displays an error message, or if there is no response to the Lot Card insertion, refer to the *Troubleshooting* section.

5 Keep the Lot Card for the life of the Test Kit.

Starting an Assay

NOTE
The default setting of the RAMP® 200 does not require an Operator ID or Password. These requirements can be edited via **Edit Operator** in the Settings menu or the RCU. If using the RAMP® 200 with default settings, *Figure 7* will not appear.

If the following Liquid Quality Control warnings **LQC** or ⚠**LQC** appear:

> ❋ Refer to *LQC icons* in *Quality Control* section for instruction on how to proceed.

NOTE
If a Test Cartridge is inserted and the Lot Card data is not stored in the CM, the **Lot # XXXX Not Found**, **Insert Lot Card or Cancel** message will be displayed. The Lot Card must be inserted within 40 seconds or the Assay is aborted. Select **OK** to return to the Home screen.

▶ **To run an Assay**

1 From the **Main Menu** screen (*Figure 6*) select **Run Assay**. If prompted, enter Operator ID and/or Password (*Figure 7*) using either the touchscreen or the barcode scanner. To accept the displayed information, touch **Accept**.
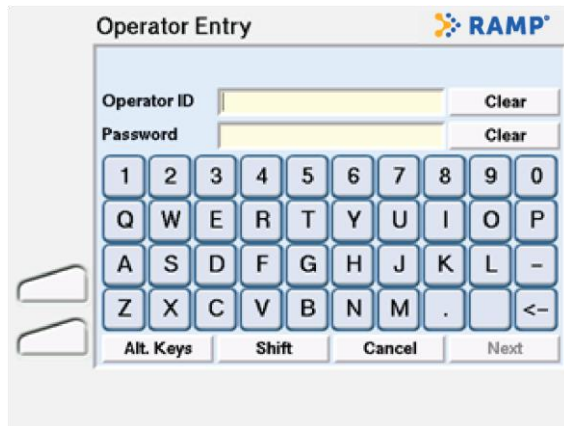
Figure 7   Operator Entry Screen

NOTE
• The Operator ID and Password entries are case sensitive.   • The CM supports Pinyin character entries only. If the CM is set to Chinese language, ensure that the Operator ID and Password are set up using the English alphabet (primary keyboard) and the English character set (select **Shift**).

2   When prompted, enter the Patient ID/Sample ID using either the touchscreen or barcode scanner (*Figure 8*). The maximum number of alpha or numeric characters for the Sample ID is 18 characters. To accept the displayed information touch **Accept**.
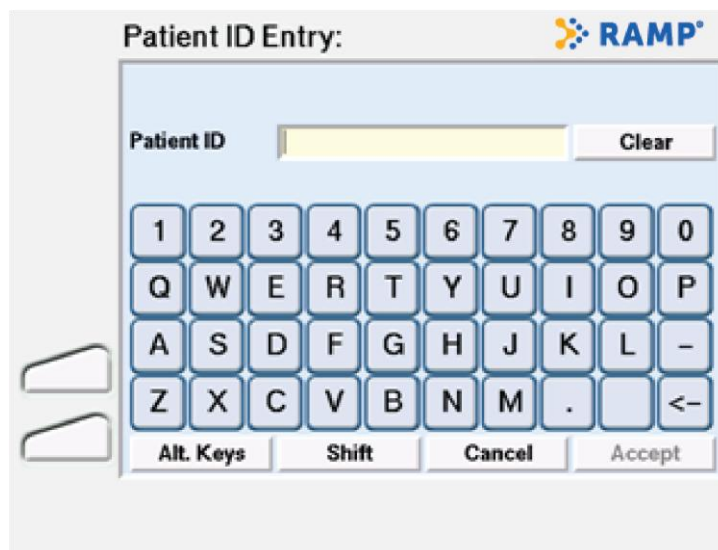
Figure 8   Patient/Sample ID Entry Screen

> **NOTE**
>
> For detailed instructions on how to handle samples, refer to the RAMP® Test Kit IFU.

3 When the display prompt to **Add Sample & Insert** appears, the LED on a free port of the TM will flash blue and the corresponding icon ![icon] on the display will illuminate blue.

4 Prepare the sample and Test Cartridge as specified in the Test Kit IFU and firmly insert the cartridge into the flashing port.

Do not use excessive force when inserting the Test Cartridge. Once inserted, the TM will automatically guide the cartridge into position for analysis.

> **NOTE**
>
> - The Test Cartridge must be inserted into the TM within approximately 30 seconds of sample application; otherwise **FAIL** will be displayed in the port icon and the system will abort the Assay.

If the Test Cartridge is not inserted within five minutes of the **Add Sample & Insert** display prompt, the instrument will time out and return to the **Main Menu**. Touch **OK** to return to the Main Menu.

5 Once the **Cartridge Inserted** message clears, the display returns to the previous screen and the active port icon ![icon 00:09] shows a timer that counts up until sample flow is detected by the RAMP® 200. The timer then counts down until the RAMP® Test is complete.

> **NOTE**
>
> Another Assay can be started once **Assay Initialization** is complete, and screen returns to **Main Menu**, by selecting **Run Assay**.

6 While the Assay is in progress, touching the port icon will show details of the Assay progression status and an **Abort Assay** option.

Selecting **Abort Assay** will eject the Test Cartridge and the RAMP® 200 will record the Test as a Failed Assay in the system **Events Log**.

To return to the previous screen, touch **Exit**.

7 When the Assay is complete, the Test Cartridge is automatically ejected and the corresponding port icon will display ![Done icon] . To view the Test details, touch the icon for that port prior to physically removing the Test Cartridge.

> **NOTE**
>
> Before removing the Test Cartridge fully from the TM, a predefined note can be added to the result from the drop-down menu in the **Result Details** screen (*Figure 9*). Once the Test Cartridge has been removed, a note can no longer be added or changed.
>
> You can add up to 10 predefined notes using the RCU.
>
> Refer to *Editing Settings Using the RCU* section
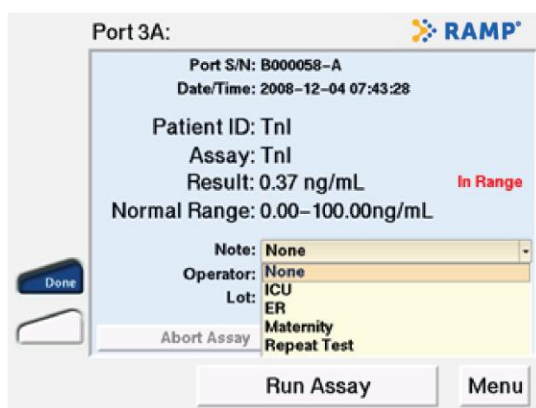
Figure 9   Results Detail Screen Prior to Cartridge Removal

8 Remove the Test Cartridge from the TM test port.

QUALITY CONTROL **F**

Two types of quality control Tests can be run and stored by the RAMP® 200:
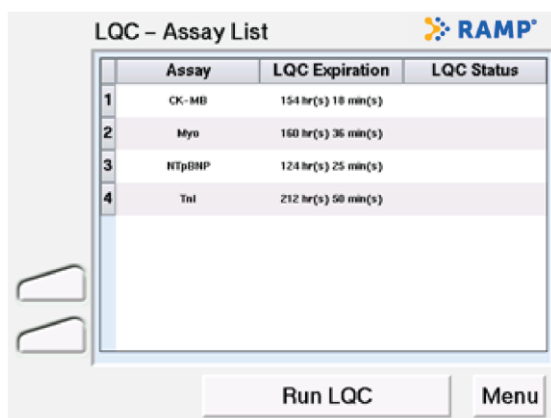
> ❖ LQC (liquid quality control): external surrogate samples used for routine QC testing.

> ❖ IQC (internal quality control): self-diagnostic test that include a check of the power supply voltage, system memory, cartridge transport system, cartridge barcode sensor, optical function, and incubator function for heated Assays.

<div style="border:1px solid">

NOTE

LQC is disabled in the default settings of the RAMP® 200. It must be enabled and configured through the RCU.

</div>

Running LQC

▶ To run an LQC Test

1 From the **Main Menu** screen (*Figure 6*) select **LQC**. The **LQC – Assay List** screen is displayed (*Figure 10*).

Figure 10   LQC – Assay List

This screen will display the entire Assay list sorted in alphabetical order. If LQC is due, the LQC Expiration column will display '**Run *x* of *y* levels**', where *x* is the number of levels required and *y* is the number of LQC levels that have been defined for that Assay in the RCU.

The LQC Status column displays the requirements for any LQC levels that have failed. If any LQC fails, that specific control level must run successfully prior to proceeding with a patient Test.

If the maximum number of failures (as defined for the Assay in the RCU) is reached; an '**Assay Lockout**' and '**LQC Lockout**' message is displayed.

<div style="border:1px solid">

NOTE

The Assay List is defined in the RCU. Any new Assays set up in the RCU will default to LQC disabled and the timers will be listed as N/A in the LQC Expiration column.

</div>

⁂   Refer to the *RCU Help Manual* for more information.

2   Select the Assay for which LQC will be performed. Touch **Run LQC**, located at the bottom of the screen. If prompted, enter the Operator ID and Password (*Figure 7*), if required, using either the touchscreen keyboard or the barcode scanner. To accept the displayed information, touch **Accept**.

> ### NOTE
> The Operator ID and the Password are case sensitive.

3   If prompted, select the appropriate Control ID using the drop-down menu (*Figure 11*). Touch **Accept**.
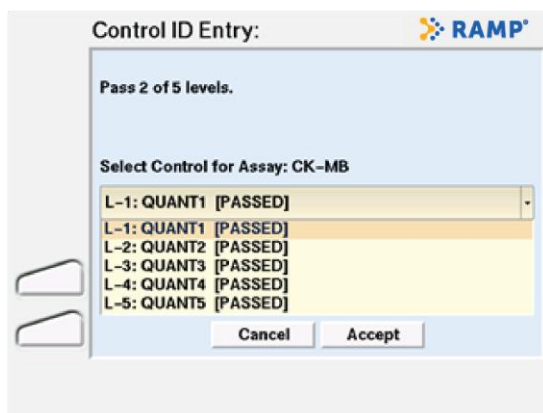
Figure 11   Control ID Entry Screen

> ### NOTE
> • If LQC has failed for the selected Assay, the maximum number of LQC attempts before Assay lockout is displayed.
>
> • If an Assay is locked due to failed LQC attempts, then the LQC timer must be reset through the RCU.

4   When prompted to **Add Control & Insert** the Test Cartridge on the display screen, the LED on a free TM port flashes blue and the corresponding icon on the display will illuminate blue.

⁂   Refer to the RAMP® Test Kit and quality control IFUs for more information.

5   Prepare the sample and Test Cartridge as specified in the Test Kit IFU and firmly insert the cartridge into the flashing port.

Do not use excessive force when inserting the Test Cartridge. Once inserted, the TM will automatically guide the cartridge into position for analysis.

> **NOTE**
>
> - The Test Cartridge must be inserted into the TM within approximately 30 seconds of sample application; otherwise **FAIL** will be displayed in the port icon and the system will abort the Assay.

If the Test Cartridge is not inserted within five minutes of the **Add Sample & Insert** display prompt, the instrument will time out. Touch **OK** to return to the **Main Menu**.

6   Once the **Cartridge Inserted** message clears, the display returns to the previous screen and

the active port icon shows a timer that counts up until sample flow is detected by the RAMP® 200. The timer then counts down until the RAMP® Test is complete.

7   While the Assay is in progress, touching the port icon will show details of the Assay progression status and an **Abort Assay** option.

Selecting **Abort Assay** will eject the Test Cartridge and the RAMP® 200 will record the Test as a Failed Assay in the system **Events Log**.

To return to the previous screen, touch **Exit**.

> **NOTE**
>
> Selecting **Run Assay** or **Run LQC** will start another Assay/LQC and the Test sequence will begin again using a different available port. The Assay progress can be checked by touching the port icon. Touch **Exit** to return to the previous screen.

8   When the Assay is complete, the Test Cartridge is automatically ejected and the

corresponding port icon will display .

To view the Test details, touch the icon for that port prior to physically removing the Test Cartridge.

9   Remove the Test Cartridge from the TM test port.

LQC Icons

Icon	Description
LQC	Indicates that LQC is due shortly. Appears when the LQC timer for an Assay has less than the user defined % of time remaining until Assay lockout.
⚠**LQC**	Indicates that the LQC has expired for one or more Assays. If icon is displayed, the **Assay Status Warnings** screen (*Figure 12*) will display upon touching **Run Assay**. Select the desired Assay and touch **Continue**. A limited number of overrides can be configured via the RCU (*Figure 13*). If overrides are available, select **Continue** to override the lockout (i.e., perform a patient Test after LQC is due). The decision to use an override must be confirmed by touching **Yes** when prompted. Once all overrides have been used, LQC must be performed prior to any further patient testing. If an Assay with no remaining overrides is inserted into the TM, the status message **LQC Required, Assay Aborted. Ejecting.** is displayed, the Assay is aborted and the Test cartridge is ejected.
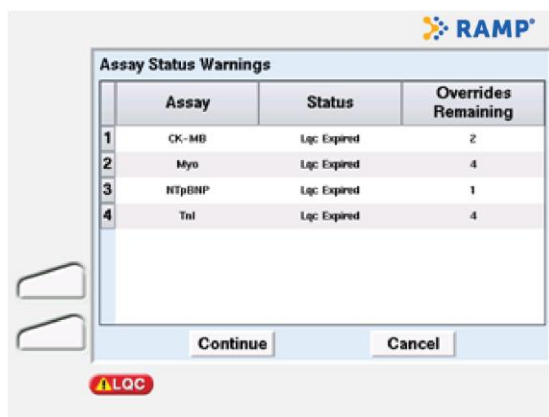
Figure 12   Assay Status Warnings Screen
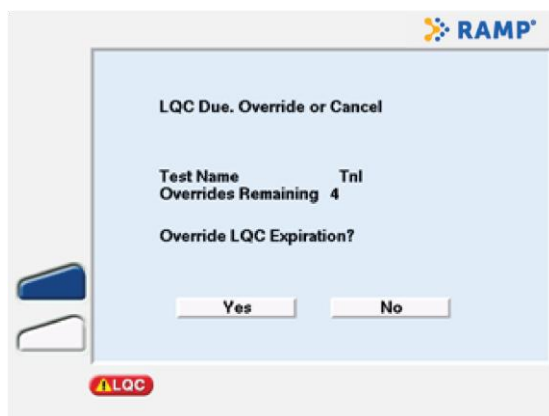
Figure 13   Override Confirmation Screen

> **NOTE**
>
> If there is more than 1 level of LQC defined for an Assay, and LQC has expired for this Assay, the LQC timer is reset to the time at which the earliest LQC level passes in the set (e.g., if 2 levels of LQC are required and Level 2 passes LQC but Level 1 fails, Level 1 must be repeated and pass). The 'Time to Expiry' column in the LQC menu will display the count down from the time when Level 2 passed.

Running IQC

An IQC Test runs automatically every time the RAMP® 200 is powered on. IQC can also be initiated manually or configured to run automatically at predefined intervals using the CM

> ✱ See *Edit Settings* or see *Editing Settings Using the RCU* sections.

▶ **To run an IQC Test manually**

1 From the **Main Menu** screen (*Figure 6*), select **Run IQC**. The **IQC Status** screen is displayed (*Figure 14*).

IQC is started on all idle ports and will automatically start on other ports as they become free.
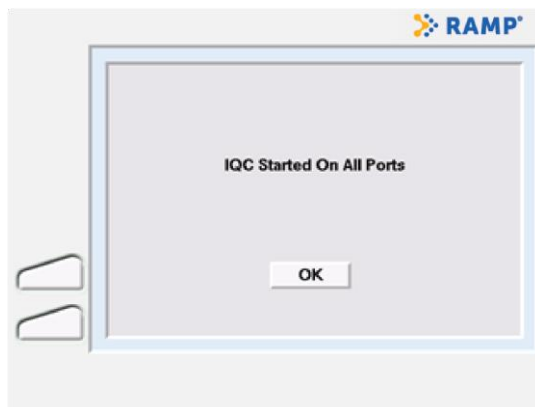
Figure 14   IQC Status Screen

2 Touch **OK** to return to the Main Menu. If IQC fails, the TM port LED illuminates red, the port icon turns red [Error 3B] and access to the failed port is prevented.

> **NOTE**
>
> To schedule IQC Tests to run at predefined intervals, the Test times must be configured using the CM.
>
> > ✱ Refer to Timer Tab section in *View Screen Tab* settings.

WORKING WITH RESULTS G

Data Management Guidelines

The RAMP® 200 can store up to 900 results:

- 300 patient results, maximum
- 300 LQC results, maximum
- 300 IQC results, maximum

When the CM database is full, the oldest result is overwritten. Dual analyte Assay results are stored as two separate records. IQC results are stored separately for each individual Test port.

In manual transfer mode only (i.e., when the instrument is not connected to a network), the warning '**Database Almost Full, Backup Data**' is displayed when there are less than 20 LQC or patient result spaces left in the database. This message will continue to be displayed until the database has cleared.

When the instrument is in auto transfer mode, only new results that have not previously been uploaded are transferred during the upload. Data is not deleted from the CM upon transfer.

NOTE
Prior to deleting results, transfer and store all data in accordance with applicable local, state and/or federal guidelines or accreditation requirement and each facility's protocol.

Viewing Saved Assay Results

▶   To view saved Assay results

1   From the **Main Menu** screen (*Figure 6*), select **Results**. A list of all **Assay Results** is displayed (*Figure 15*) in reverse chronological order, with the most recent results at the top.

Figure 15   Assay Results Screen

> **NOTE**
>
> For each Assay result, the Patient ID or Sample ID, Assay name, result value and date/time is displayed.

2 To view a list of LQC or IQC results, touch the circle next to the words **LQC Results** or **IQC Results** (in the display header) to specify the type of results to be viewed. The list of results will be displayed.

3 To view the details of a particular result, select the result and then touch **View** (*Figure 15*). The **Results Detail** screen is displayed (*Figure 16*).
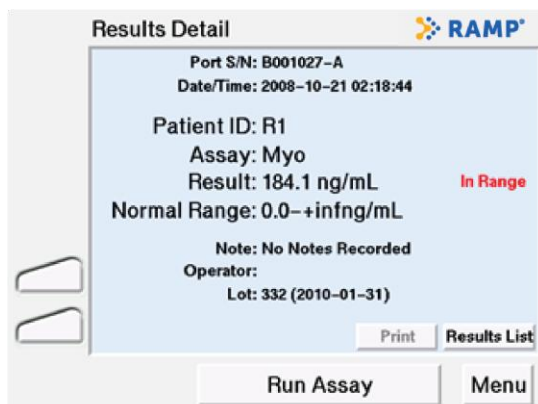
Figure 16 Results Detail Screen

4 To print the result details, touch **Print**. Touch **OK** to return to the result details. To return to the result list, touch **Results List**.

Viewing Event Logs

▶ To view event logs

1 From the **Main Menu** screen (*Figure 6*), select **Log**. A list of all recorded **Events** will be displayed (*Figure 17*), with the most recent event listed first.

> **NOTE**
>
> For each event, the screen displays the date/time. Events include system power up, upload/download of data and Assay and LQC failures.

Figure 17   All Events Log

2   To view a list of failed Assays or LQCs, touch the circle next to the words **Failed Assays** or **Failed LQCs** (in the display header) to specify the type of results/events to be viewed. The list of events will then be displayed.

3   To view the details of a particular event, select the event and then touch **View**.

4   To return to the event list, touch **Events List**.

Searching for Assay Results

The following table describes the available search option combinations you can use.

Result type	Search option	Search option	Search option
Assay	Operator Name	Sample/Patient ID	Assay Name
LQC	Operator Name	Control ID	Assay Name
IQC	Operator Name	Port	

▶   **To search for Assay results:**

1   From the **Assay** (or **IQC** or **LQC**) **Results** screen, touch **Search** to open the **Search Assay Results** screen (*Figure 18*).

Figure 18   Search Assay Results Screen

2   To change the search parameter, use the drop-down arrow ▼ on the **Operator Name:** and select the new parameter.

3   Use the touchscreen keyboard or barcode scanner to enter/scan the desired value to search. Touch **Alt. Keys** or **Shift** to display an extended character set.

> ### NOTE
> Enter the first few characters of the name or ID you are searching for.

4   To filter the results, touch the circle beside either **All Results** or **Date Range**. **All Results** is the default setting. When **Date Range** is touched, the **From/To Y M D** fields become active. Enter the desired dates in the format: **YYYY MM DD**.

5   To generate a list of results based on the search criteria entered, touch **Search**. Touch **Cancel** to clear the search criteria and return to the main **Results** screen.

   If nothing matches your search, the screen displays the message **Empty Search**.

6   To return to the complete results list, touch **View All**.

Searching for Events

Follow the directions below for searching the Assay results.

Event type	Search options		
All events	Operator Name	Event Text (enter any part of field, not case-sensitive)	
Failed Assays	Operator Name	Sample/Patient ID	Assay Name
Failed LQC	Operator Name	Control ID	Assay Name

Manually Transferring / Printing Results or Logs

Analysis results can be viewed on the RAMP® 200 display screen, exported/transferred to a USB flash drive, computer or network server, or printed out from the CM. Event logs other than failed Assay and LQC cannot be printed from the CM, however they can exported to a USB flash drive, computer or network server.

It is important to note that the user should manually delete the results from the instrument after manual transfer or they will be transferred again, unless a specific range of results is selected when the next manual transfer is performed.

NOTE
A USB flash drive can be used to transfer results and logs from multiple instruments as the Result and Log file names start with their respective CM serial numbers.

⚠️ CAUTION
The USB flash drive should **not** be removed from the CM while data is being transferred.

NOTE
The USB flash drive must be pre-configured with four (4) file folders named: *patient*, *lqc, iqc* and *log* for this use. Verify that the USB flash drive included with the RAMP® 200 includes these folders, or should a personal USB flash drive is used, the folders are added prior to transferring results and logs.

▶   **To manually transfer/export or print result or event log data**

1   From the **Assay Results** screen (*Figure 15*) or the **All Events** screen (*Figure 17*), select the desired records to be exported. Touch **Transfer** to open the **Results: Transfer** (*Figure 19*) or **Events: Transfer** screen.

2   Touch **Print**, **USB** or **Network** depending on the data output option desired. Only the options for which the connections are available will be functional.

3   Confirm the transfer by touching **Confirm**. Touch **Cancel** to abort the transfer (*Figure 20*).

4   When the transfer is complete, touch **OK** and the prior screen will be displayed. If the transfer fails the ⚠️ warning icon and a failure message are displayed.

5   Touch **OK** to return to the **Assay Results** or **All Events** screen.

> **NOTE**
>
> If the CM is set to Chinese, the 888-TT printer must be used for printing results in order to print the Chinese characters correctly.
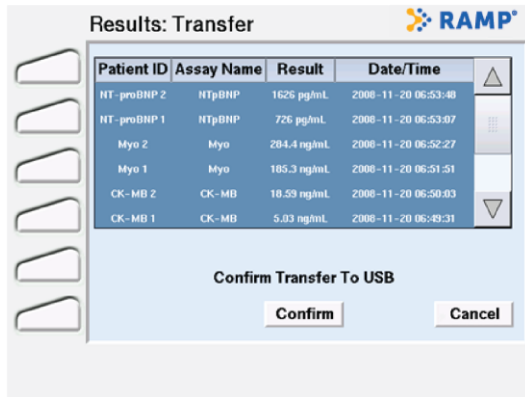
Figure 19   Results Transfer Screen
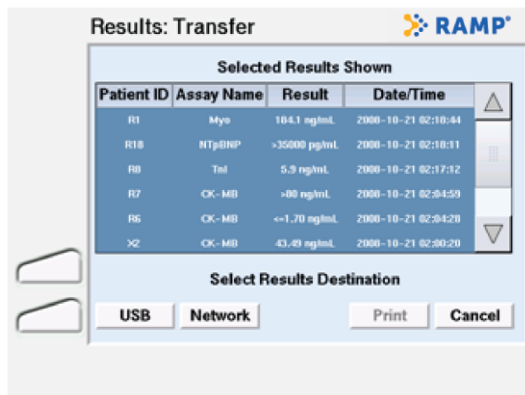
Figure 20   Results Transfer Confirmation Screen

Converting Exported Data to Excel Format

Once results have been exported, the File Converter Utility on the supplied USB Flash Drive may be used to convert the data files to Excel format.

▶   **To convert the data files to Excel format:**

1   Insert the supplied USB Flash Drive into a computer. Located and open the *"File Converter.xls"* version 1.1 or greater.

2   In Excel, enable macros and follow the directions on the screen.

3   Excel will prompt the user to save the file in an Excel format.

MANAGING SETTINGS H

Many features of the RAMP® 200 are not available until a user with Supervisor privileges has configured them on the CM, or until a Full Access user has configured them with the RCU.

> ❖ See *Edit Settings*

> ❖ See *Editing Settings Using the RCU*

Customizable features include operator IDs and passwords, data transfer options, print options, display language (only on the CM), network settings, LQC timers and ranges.

A few of these settings may be edited using the RAMP® 200 touchscreen. Most settings can be edited using the RCU.

Feature (detailed descriptions to follow)	Full Access User (edit on the RCU)	Supervisor (edit on the CM)
Assay defaults	√	
LQC	√	
Update / upload features	√	
Printer settings	√	
Login requirements	√	√ (limited)
File settings	√	√
Menu idle / timeout		√
Date / time (without network time protocol – NTP)	NTP only	√
Language		√
Auto IQC interval	√	√
Network transfer timers		√
Sound		√
IP address		√

Accessing the Settings Menu

From the **Main Menu** (*Figure 6*) touch **Settings** to display the **Settings** menu (*Figure 21*). The **Settings** menu requires an Operator ID with Supervisor access privileges.

The default login for access to the **Settings** menu is:
> Operator ID: **SUPERVISOR**
> Password: **PASSWORD**

Both entries are case-sensitive. It is highly recommended this login be changed after the RAMP® 200 has been installed.
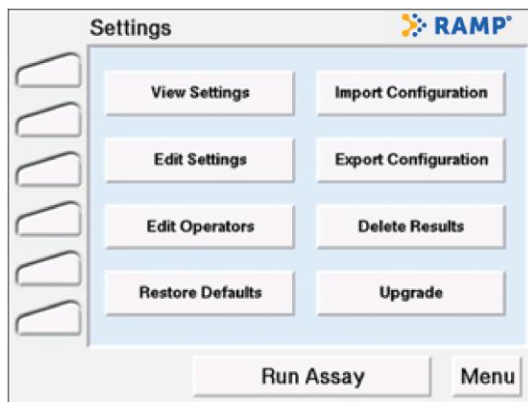
Figure 21   Settings Menu

View Settings

To view the configured settings for the RAMP® 200, touch **View Settings** from the **Settings** menu (*Figure 21*) and the **Settings: View** screen (*Figure 22*) will open. The **Settings: View** screen features a series of tabs that display the current instrument settings. Select a tab to view the settings.
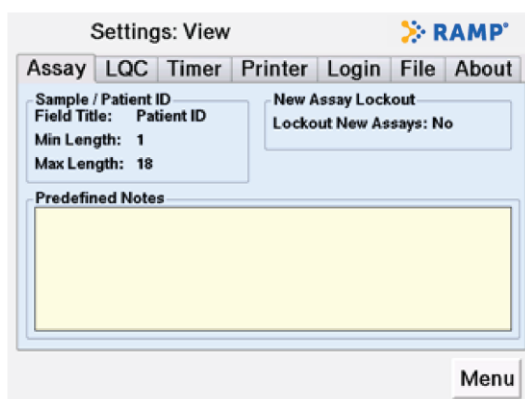
Figure 22   Settings: View Menu – Assay Tab

> ❖   For complete information on individual tabs, see *Settings: View Screen Tabs* section.

Edit Settings

To edit the configured settings for the RAMP® 200, touch **Edit Settings** from the **Settings** menu (*Figure 21*), login as described in *Accessing Settings Menu* section and the **Settings: Edit** screen (*Figure 23*) will open.

The **Settings: Edit** screen features a series of tabs that include editable instrument setting fields. Use the tabs to select those settings to be changed. Select the appropriate tab, use the touchscreen keyboard to enter or change field values, then touch **Save**.

NOTE
When in the default settings configuration only a Supervisor can access the **Settings** menu.

Figure 23   Settings: Edit Menu – Timer Tab

On all **Settings: Edit** dialogs:

● Use the touchscreen or dropdown lists to enter/select the desired settings.

● Touch **Save** to save your settings.

● Touch **Cancel** to return to the previous screen without saving your changes.

● Touch **Reset** to undo entry and return to the default setting.

● Touch Alt. Keys or Shift to display extended characters (available characters will vary depending on language setting).

❯❯ For complete information on individual tabs, see *Settings: Edit Screen Tabs* section.

Restoring Defaults

Restoring device settings to factory defaults erases all stored settings, Assay results and operator information.

> **NOTE:** Back up all device databases before you restore the system settings to the default values.

To restore the system defaults:

1   Select **Menu** > **Settings** > **Restore Defaults**. The **Settings: Restore Defaults** screen appears.
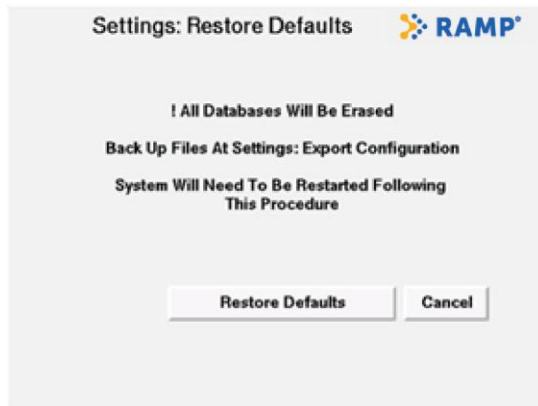
Select **Restore Defaults** and then select **Confirm**.

At the prompt, turn the RAMP® 200 off and on. The system completes the restoration of the defaults.

Managing Operators

If an operator ID or password is required, only individuals with operator IDs stored on the RAMP® 200 can perform Assays. The operator login requirements can be set on the CM and RCU.

Accessing the operator management fields

To manage operators:

1   Select **Menu** > **Settings** and enter the operator ID and password. The default login for access to the **Settings** menu is:

Operator ID: SUPERVISOR

Password: PASSWORD

> **NOTE:** Both entries are case-sensitive.

From the **Settings Menu** (**Menu** > **Settings**), select **Edit Operators**.
       The **Settings: Operators** screen appears.
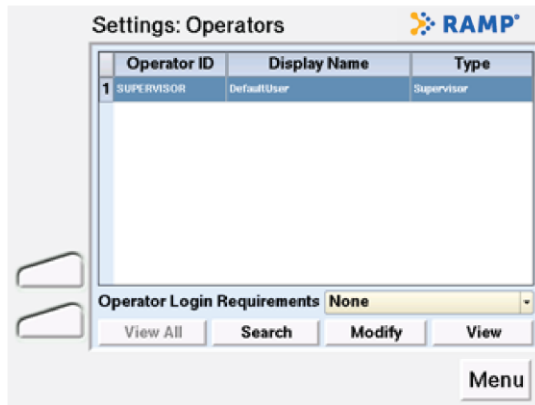
A complete list of all operators authorized to use the device with **Display Name** and **Operator Type** appears.

Operator and supervisor access privileges can be defined using the RCU only.

Defaults: Operators = Run Assays, Supervisors = Run Assays and change settings (see *Managing operators* on page 46).

To view detailed information for an operator, select the operator's entry and select **View**.
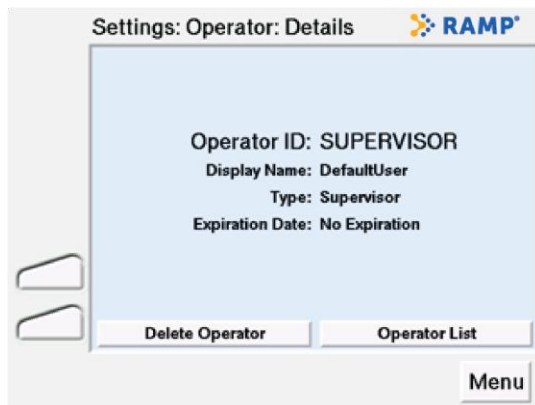
To modify an existing operator, select the operator's entry and select **Modify** (the **Add** button changes to **Modify**).

To add a new operator, select **Add** when no operator entry is highlighted.

To search for a specific operator, select **Search** (see *Searching for an individual operator* on page 48).

To delete an operator, select **Delete Operator** while you are viewing an operator's details.

Adding or modifying an operator

To add or modify an operator:

1   If you are adding a new operator, complete all desired fields in the **Settings: Operators**: **Add** screen (select **Menu** > **Settings** > **Edit Operators**).

> **NOTE:** The RAMP® 200 can store a maximum of 600 operators.

If modifying an existing operator, the screen title is **Settings: Operators: Modify** and the fields are populated.

Operator ID: Characters entered to access the RAMP® 200 (maximum length 18 characters).

Display Name: Characters displayed with results for this operator ID (maximum length 50 characters).

> **NOTE:** Although 50 characters may be entered in the **Display Name** field, it is truncated on the CM display and result print out. The full 50 characters will only be visible in the **Edit Operators** screen in the **Settings** menu or through the RCU.

Password: Maximum length 18 characters.

Verify: Re-enter the password.

Expire: Date that the operator's permission to use the RAMP® 200 expires. Operator is locked out after that date. To disable the expiration feature, leave the field blank.

Use the ▼ drop-down arrow to select the desired **Operator Type**: **Supervisor** or **Operator**.

Select **Accept**, and then select **Confirm**.

Searching for an individual operator

Use the **Settings: Operator: Search** screen to select operators by the following attributes:

Operator name
Operator ID
Expiry date

To search for a specific operator:

❖   Define who you want to search for:

In the **Operator Name** drop-down select the desired name or ID you want to search. To disable expiry date fields for searching, select **All Operators**.

To search for operators whose permission to use the system expires in a given date range, select **Expiry Date** and then enter the date range. The default value is the current date + 10 years.

Select **Search**.

(Optional) To return to the main list of operators, select **View All**.

Importing Files

Device settings, including operator lists from the RCU or another RAMP® 200, can be imported using the USB flash drive.

To import files:

❖   Click **Menu** > **Settings** > **Import Configuration**. The **Settings: Import Configuration** screen appears.

Select the files you want to import and then select **Transfer**. Transfer is indicated by blue circles across the bottom of the screen.

Select **OK** when the transfer is finished.

> **NOTE:** If the import fails, the warning icon appears. For troubleshooting tips, see *Troubleshooting*, starting on page 63.

Exporting Files

Exporting files allows back-up of critical RAMP® 200 information including configuration files, operator lists and result files. Whenever you relocate the system, use the export feature to back up your data.

To export files:

❈ Click **Menu** > **Settings** > **Export Configuration.** The **Settings: Export Configuration** screen appears.

Select **Export to USB Flash Drive**.

⚠ **CAUTION!** The flash drive must be pre-configured with four subdirectories (folders). These must be named: *patient, lqc, iqc* and *log* (case sensitive).

Transfer is indicated by blue circles across the bottom of the screen. Eleven files are transferred.

A **Transfer Complete** notification appears when transfer is finished. Select **OK** to return to the **Settings** menu.

> **NOTE:** If the import fails, the ⚠ warning icon appears. For troubleshooting tips, see *Troubleshooting* on page 63.

Deleting Assay Results

> **NOTE:** Prior to deleting results, transfer and store all data in accordance with applicable local, state and/or federal guidelines or accreditation requirements and each facility's protocol.

To delete Assay results:

❖ Click **Menu** > **Settings** > **Delete Results.** The **Settings: Delete Results** screen appears.

Select **Delete All Results** or **Delete Results Prior to Date.**

Select the Assay results you want to delete:

To delete all of the Assay results, select **Delete All Results** and then click **Confirm**.

To delete the results prior to a specific date, select **Delete Results Prior to Date.** The **Delete Results Prior to Date** screen appears.

Use the touchscreen keypad, enter the desired date in the **Year, Month** and **Day** fields, and then select **Confirm**. The confirmation screen appears.

Click **OK** to return to the **Settings** menu.

EDITING SETTINGS I

Editing Settings Using the Reader Configuration Utility (RCU)

The RCU is a Windows (2000/XP/Vista) application you can use to manage a range of RAMP® 200 features.

Installing the RCU

You must have the necessary login privileges to install software on your computer.

To install the RCU:

1   Insert the RCU USB key into an available USB slot.

2   Open the USB drive.

3   Click **InstallRCU.bat** located in the root folder of the USB drive.

4   Follow the on-screen prompts to complete the installation.

How the RCU works

The Reader Configuration Utility (RCU) allows you to set up Readers according to the needs of your institution. The RCU stores this setup information in a set of Reader configuration files. Each group of one or more Readers has its own directory containing a set of configuration files that define how the Readers in that group operate. These files include Assay lists and settings, LQC lists and settings and operator lists and settings.

> **NOTE:** More than one group can share the same Assay list, control list and/or operator list. You can set the list locations to the same directory for each group or save a list in multiple directories.

In a network environment, you can configure Readers to check their assigned group directory periodically for configuration changes. In addition, you can configure Readers to send new results and log information to a network directory.

In non-networked environments, you can use a portable USB flash drive (supplied) to download the configuration files to the Reader and gather result and log files from the Reader. In order to ensure safe archive/restore functionality, it is recommended that you use a separate USB flash drive for configuring each Reader group.

Complete instructions on the use of the RCU are in the RCU program under HELP, or from the **START** menu click **All Programs** > **Reader Configuration** > **Reader Configuration Manual**.

Getting Started with the RCU

To run an RCU session:

1   Open the RCU from the START menu: Click **START** > **All Programs** > **Reader Configuration** > **Reader Configuration Program**.

Login to the system. When the RCU is initially installed, the case sensitive default login is:

User ID: Supervisor

Password: password

Changing the Default Login

To ensure that only authorized users access the RCU, you can and should change at least the password as soon as you install the application.

To change the default login:

1   Select the **Settings** menu. The **Reader Configuration: System** Settings screen appears.

In the **Reader Configuration Utility Accounts** section change the values for the **Operator ID, Account Name** and **Password** fields and then click **File** > **Save**.

You can also add new RCU user accounts from this screen. User accounts can be set to **Limited Access** or set to **Full Access**.

Limited Access: users can only access the Controls Editor feature

Full Access: users can access all features in the application

See the RCU Help for information on adding / editing and deleting users.

Resetting the Password in an Emergency

If you forget your password, you can temporarily reset it to allow access to the encoded password list.

To reset the password in an emergency:

1 In the **User ID** field of the **RCU Login** screen type **override** and then click **Login**. A message box appears and prompts you to contact Technical Support with a five-digit number (Permit #).

Contact your Technical Support Representative to receive an override number.

Enter the override number into the **Password** field and then click **Login** (if you enter it incorrectly, you can re-enter it and try to login again). The RCU gives you temporary access to the **Settings** screen, where you can view the user list and passwords.

Restoring the Supervisor Operator ID/Password

By default, only a supervisor with a correct ID and password can access the **Settings** menu. If the password is lost and login fails, the user can override and access the **Settings** menu.

To restore the supervisor operator ID/password:

1 From the **Operator ID Entry** screen (**Menu**>**Setting**>), in the **Operator ID** field, type **OVERRIDE** and then select **Next**.

The **Password Override** screen appears and prompts you to contact Technical Support with the displayed permit number.

When you contact Technical Support, they will provide you with an override code.

In the **Override Code** field, use the touchscreen keypad to enter the code and then select **Accept**. The CM verifies the code and restores the factory default: Operator ID = SUPERVISOR, Password = PASSWORD.

Select **OK**. The screen returns to the **Settings** menu.

Select **Edit Operators**. The **Operators** screen appears**.**

In the operator list, select **Default user** with operator ID: SUPERVISOR.

Select **Modify** to change the following fields if necessary: **Operator ID, Display Name, Password** and **Expiration Date**.

Accessing Configuration Files

A group is defined as a common configuration shared by multiple Readers. As many groups as necessary can be defined. Each group must have its own directory. A directory contains a set of configuration files that define how the Readers in that group operate. For example, one group may be defined for Readers in an emergency department environment with files saved in a directory **ED**, while a separate set of configuration files, for use in an intensive care setting, would be defined in the group ICU and saved in a directory **ICU**.

A default group directory (C:\Program Files\Reader Configuration\) is set up during software installation. If only one group is needed, the initial files can be modified and saved in this directory.

If more than one group is needed, copy the default folder and re-name or use the **Save As** command to save all files to a new directory. Each new folder must contain the following files: *Assays.dtv, controls.dtv, grp_settings.dtv,* and *userlist.opl*.

If you export files by USB, you must copy all files in the group directory to the root directory of the USB.

⚠️ CAUTION. Do not change the file names.

To open all files for a group:

1   Click **File** > **Open Group**.

Select the folder that contains the files you want to use.

Click **OK**. If you only use one group, the default location is C:\Program Files\Reader Configuration\. This opens the following files: *Assays.dtv, controls.dtv, grp_settings.dtv,* and *userlist.opl*.

To open an individual configuration file:

If you only need to modify one configuration (for example, when you update operator lists), you do not need to open all of the group files. You can open just the file to be changed (in this example, userlist.opl). To open the file:

1   Click **File** > **Open**.

Select **Defaults...**, **Network...** or **USB Device...**. The **File Open** screen appears. Use this to navigate to the drive that contains the files you want.

To select different types of files to load:

1   Select the **Files of type:** drop-down list. When you select one of the file types, the system lists all the matching files in the selected directory.

Select the file you want and then click **Open**.

Setting up Communications Between RCU and Readers

To set up communications between RCU and Readers, open the default **Group Settings** file in the RCU.

Files Tab

This page sets the file locations where the Reader(s) looks for specific configuration information. The Reader supports the following file transfer protocols: HTTP, HTTPS, FTP, FTPS and CIFS. Directories are specified in URL notation. Consult your IT administrator for guidance on how to use these settings in the local network environment. If Readers use the USB flash drive for configuration information, you should set all file location fields to: **file:///** as in the default settings (except for time server, which should be blank).

The system supports the following configurations:

USB Flash drive:	file:///
Web Server:	http://medsvr/RAMP200/
Network drive:	ftp://fileserver/RAMP200_share/
CIFS Share:	cifs://fileserver/RAMP_200_share

> **NOTE:** When using CIFS, each directory named must be an explicitly shared CIFS directory and the URL must not contain a trailing slash.

When using Static IP mode, in order to designate servers by name, you must define a DNS server and use fully qualified domain names (format server.domain.tld, for example, myserver.mydomain.local).

Files Tab Fields

Field	Description
Group Directory	Identifies where the Reader(s) looks for all group specific information.
Assay List	Identifies where the Reader(s) looks for its list of supported Assays.
LQC Controls List	Identifies where the Reader(s) looks for its list of LQC controls.
Operator Accounts List	Identifies where the Reader(s) looks for its operator list.
Results Directory	Identifies where the Reader(s) places exported result files. In a networked environment, one or more groups can share the same destination directory.
Device Directory	Identifies where the Reader(s) should read and write device specific information. This is typically set to the same directory as the Group Directory.
Time Server Location	Allows the Reader group to access an NTP (Network Time Protocol) server to keep the Reader's internal clocks set to the correct time. This field should be left blank in non-networked environments or networked environments that lack access to an NTP server.

Identifying Readers Through the RCU

The RCU uses Reader information files to identify the Readers installed within an institution. Once a Reader has been identified, you can use the RCU to change Reader-specific settings.

A USB flash drive is used to transfer Reader settings between the Reader and the RCU.

1   To change Reader-specific settings in a non-networked environment: Insert a USB flash drive into an available USB port on the CM. Ensure that the USB drive contains four folders named: *lqc, patient, iqc,* and *log*.

Navigate to the Settings menu (**Menu** > **Settings**) and select **Export Configuration**.

Select **Export to USB Flash Drive**. All settings files and result logs are exported.

(Optional) Export the configurations for additional Readers.

Insert the USB flash drive into the RCU computer's USB drive.

From the RCU, click **File** > **Open** and select **USB Device** (navigate to the correct location of the USB device if this function does not work automatically).

Select **Files of Type: Readers**, select the desired Reader serial number and then click **Open**. On the **Reader Settings** menu, you can now define changes to settings for the selected Reader.

To change Reader-specific settings in a networked environment:

Each Reader must be placed into network mode and must be assigned a device information directory prior to successful bi-directional communications.

1   Using the Reader touchscreen, select **Menu** > **Settings** > **Edit Settings** > **File** tab. The **File** tab appears.

Enter the **Device** and **Group Directory** settings for the Reader as defined in the RCU.

Select the **Misc** tab and enable the **Auto Transfer Mode** option.

From the RCU, select **File** > **Open** and then select **Network**.

Select **Files of Type: Readers**, browse to the device directory for the Reader of interest, select the desired Reader serial number and then click **Open**. On the **Reader Settings** menu, you can now define changes to settings for the selected Reader.

MAINTENANCE J

Maintenance

⚠️ **WARNING!** Do not disassemble the RAMP® 200 or any of its related components and accessories. The instrument contains no operator-serviceable components.

Possible electrical shock
Unplug RAMP® 200 devices before you clean the system.

Maintenance Guidelines

The RAMP® 200 does not contain any operator-serviceable components.

Beyond gentle exterior cleaning, the RAMP® 200 does not require regular maintenance or calibration. Any liquids on the external surface of a Test Cartridge must be cleaned before inserting into the ports of the TM.

Upgrading Device Software

Software upgrades are installed by a USB flash drive that contains the latest software.

To install a software upgrade:

1   Select **Menu** > **Settings** > **Upgrade**. The **Settings: Upgrade** screen appears.

> **NOTE:** The first of the three upgrade options is always the upgrade for the CM software. However, in CM software V1.2 and in earlier CM versions, this option is labeled **Upgrade All Software** (not Upgrade CM Software).

Select the appropriate upgrade option:

> **Upgrade CM Software** upgrades the CM software only
>
> **Upgrade Port Software** upgrades the TM only
>
> **Upgrade Languages Only** upgrades the language software

Select **Confirm** to start the upgrade. Please wait until the Upgrade has completed, the system will then prompt you to restart the system to complete the upgrade.

Power off the RAMP® 200, wait approximately 30 seconds, and then power the system back on.

> **NOTE:** To prevent an Assay Error, Port Failure message and to avoid any unexpected printing of labels, ensure that your connected printer is turned off during the upgrade.

Exterior Cleaning

⚠️ **CAUTION. Possible device damage**
Do not immerse the RAMP® 200 or related devices in any liquid. Avoid spilling liquids on the RAMP® 200 and related accessory devices.

The external surfaces of the TM and CM can only be disinfected using a solution of 0.5% bleach or 70% ethanol applied to a soft cloth. DO NOT USE STRONG BLEACH (>0.5% solution) OR ACETONE! Oxidants and solvents could damage the RAMP® 200 casing and touchscreen. Clean external surfaces only.

If RAMP® 200 requires repair or replacement, it must be disinfected prior to repackaging and shipping.

⚠️ **CAUTION. Risk of permanent equipment damage**
Do not expose the RAMP® 200 to temperatures above 60°C (140°F). Do not disinfect or sterilize the RAMP® 200 using devices such as autoclaves, ultrasonic cleaners, or pasteurizers. Use of such methods to disinfect/sterilize the RAMP® 200 causes permanent device damage and voids the warranty.

Waste Electrical and Electronic Equipment (WEEE)

Do not dispose of this product in municipal waste. Contact Response Biomedical Technical Support to arrange disposal and recycling.

TROUBLESHOOTING K

Troubleshooting

This section explains problems and provides solutions for general operating issues and for error messages that appear on the CM screen. If you need additional assistance, use the following information to contact Response Biomedical.

24-Hour Response Biomedical Technical Support

Toll free: 1 (866) 525-7267 (North America only)

Tel: 1 (604) 219-6119 (International)

E-mail: techsupport@responsebio.com

General

Problem	Solution
CM touchscreen is hard to read (very dim), or colors are not visible.	Contact Technical Support to report the problem.
CM does not turn on or light up.	Check if any cable connections are loose. Check system power; ensure power supply is connected. If problem persists, contact Technical Support to report the problem.
TM is not recognized by CM.	Check if connections are loose. Switch the CM off and then on. If the problem persists, contact Technical Support to report the problem.

Power-on Self Test Message / IQC Messages

Message	Cause(s)	Solution
No Available Ports. IQC Failed To Start.	Ports are disabled.	Switch the CM off and then on. If the problem persists, contact Technical Support to report the problem.
"Cartridge in Port" "Fail"	An IQC/POST critical failure may lead subsequent IQC Tests to display as FAIL. The "Cartridge in Port" error might also display on the IQC result printout when there is no cartridge in the TM port.	Failed port is disabled. Switch the CM off and then on. If the problem persists, contact Technical Support to report the problem.
"Incorrect Firmware On One or More Ports Ports Disabled Until Upgraded"	This generally occurs when the CM software is upgraded to a newer version and becomes incompatible with the TM firmware.	Upgrade the TM firmware. Select **Menu** > **Settings** > **Upgrade** and select **Upgrade Port Software**. For more information, see *Upgrading device software* on page 61.

Test Run Messages

Test run messages are indicated by a red port icon:

Do not remove the cartridge. Select the icon to display detailed information about the failure. If the cartridge is removed, you can access this information by viewing the error log from the main menu.

Port display	Message	Cause(s)	Solution
CTG	Cartridge Error	Possible defect in Test Cartridge.	The Test Cartridge is ejected. Remove and dispose of appropriately. Repeat the Assay with a fresh set of components. If the problem persists, contact Technical Support to report the problem.
HRB	High Background	Possible interfering substances in the sample causing high running background.	
LOW	Low Signal	Insufficient sample transferred to the Test Cartridge. Insufficient mixing of the sample with the supplied Assay tip. Substances in the sample are interfering.	
Fail	Sample Error 1	Sample flow occurred before the Test Cartridge was inserted into the port. Delay of more than 30 seconds between sample addition and Test Cartridge insertion. Insertion of a used Test Cartridge.	
Fail	Sample Error 2	Sample flow has not been detected. The sample injected into the Test Cartridge is insufficient. Clogged sample pad. Failure to use supplied Assay tip. Insufficient mixing of sample. Substances in the sample are interfering. Analyte levels are significantly higher than the upper reportable range.	
Fail	Temperature Error	TM is not at the proper temperature to complete the requested Assay.	Contact Technical Support to report the problem.
Error XX *e.g.*, Error 2B	Port Disabled	The identified port is disabled due to an IQC failure or a transport carriage failure. LED remains illuminated red.	Contact Technical Support to report the problem.

Message / problem	Cause(s)	Solution
Insertion Error Remove & Reinsert	The Test Cartridge was not inserted properly into the RAMP® 200 or the operator did not wait until prompted.	Cancel the Assay or reinsert the Test Cartridge. Fully insert Test Cartridge until you feel firm resistance. Do not use excessive force. The TM automatically pulls the Test Cartridge into the port.
Followed by: Timed Out	User has not performed the action required within the maximum allowed time.	**NOTE:** You must reinsert the Test Cartridge into the TM port within approximately 30 seconds. If you do not, the system aborts the Assay and displays an error message. Repeat Assay using a fresh set of components.
Barcode Error Aborting Assay	The RAMP® 200 was unable to read the barcode on the Test Cartridge.	Repeat Assay using a fresh set of components.
No Ports Available, Assays in Progress	All ports are in use by other Assays.	Select **OK**, to return to the main menu and wait until an Assay is complete before you attempt to run another test.
No Ports Available, Remove Cartridge(s) Try Again	Cartridges occupying all ports.	Remove the Test Cartridge(s) of completed Assay(s).

Lot Card

Message / symptom	Cause(s)	Solution
No response to insertion of a Lot Card	The Lot Card assembly is not functioning.	Contact Technical Support to report the problem.
Lot Card Error, Reinsert	The system did not read the Lot Card correctly. The Lot Card may have been removed too quickly, or may not have been fully inserted into the Lot Card slot.	Select **OK**, and then reinsert the Lot Card. If the problem persists, use a Lot Card from another box of Tests with the same lot number. If another Lot Card is not available or alternate Lot Card fails, contact Technical Support.
Lot # XXXX Not Found, Insert Lot Card or Cancel	The RAMP® 200 does not contain the data required to run Test Cartridges with that lot #. The Lot Card may not have been read before running the Assay.	Insert the Lot Card for the specified lot or cancel Assay. **NOTE:** If you do not insert the Lot Card within approximately 30 seconds, the system aborts the Assay. Use a fresh set of components and repeat Assay.
Lot Card Expired	The inserted Lot Card has expired. **NOTE:** Expiry falls on the last day of the month.	Check the RAMP® 200 date/time settings. Use components that have not expired.

Settings Messages

Message	Cause(s)	Solution
Access denied. Try again.	The user does not have the login permissions necessary to access selected function.	Confirm correct login details and try again.
Assay List Size Exceeded.	The list of Assays permitted is full. No further additions can be made. **NOTE:** The maximum number of Assay entries allowed is 200.	Delete existing Assays from the Assay List. For complete instructions, start the RCU, press **F1** and refer to the online help.
Assay Locked, Aborting.	The Assay is not permitted or has been locked. May occur if LQC has failed or if the Assay is not in the Assay list.	For more information, contact the Supervisor or a full access RCU user.
Database Almost Full, Backup Data.	Displayed when RAMP® 200 is not connected to a network and either the patient or LQC result databases have less than 20 spaces left. This message continues to appear until the database is cleared.	Export data to a USB data storage device and then delete the database.
Default Restore Failed.	The action to restore defaults has failed.	Try this process again. If the problem persists, contact Technical Support.
ERROR: Invalid Code. Try Again.	The override code entered is invalid.	Contact Technical Support, and then enter the override code provided.
ERROR: Numbers Only.	Only numbers are permitted in the override code field.	Enter the code number provided by Technical Support.
Invalid Password, Try Again.	The password was incorrectly entered.	Retype the password and try again.
Invalid User, Try Again.	The user is not recognized or has been entered incorrectly.	Retype user details and try again.
Locked, Contact Supervisor.	The RAMP® 200 has been locked by the RCU.	Contact a full access RCU user to unlock using the Reader Settings screen.
Empty Search.	The RAMP® 200 cannot find the requested record. It may have been deleted or its details may have been entered incorrectly.	Re-enter the search data and try again.
User Expired, Try Again.	User certification has expired or the details were entered incorrectly.	Re-enter the operator ID or contact the Supervisor.

LQC Related Messages

Message	Cause(s)	Solution
LQC Lockout. Ejecting.	LQC is overdue for this Assay and no overrides are available.	LQC must be run and passed, or a full access user can reset the LQC timer and/or override for this Assay in Reader Settings on the RCU.
Invalid Assay or Control, Aborting LQC.	An incorrect Assay has been selected to run LQC.	Repeat LQC with the correct Assay or contact the Supervisor.
LQC required. Assay Aborted. Ejecting.	LQC has expired and all available overrides have been used. Tests cannot be run until the required LQC has been run and passed.	Run the required LQC.

Warnings and Confirmation Requests

Message	Cause(s)	Solution
! All Databases Will Be Erased Back up files at Settings: Export Configuration System will restart following this procedure	Request was made to upgrade software or reset system to default settings.	Cancel if not intended. Before performing this operation, all databases should be backed up using Export Configuration.
! All Results Will Be Deleted	Request was made to delete all results.	
ERROR - Missing Firmware Version File	The file required to complete the upgrade is missing.	Contact Technical Support
ERROR - Upgrade Failed Restart to Try again	Upgrade failed.	Restart the RAMP® 200 and re-try upgrade. If the problem persists, contact Technical Support.

Printer Errors

Message / problem	Cause(s)	Solution
Printer Error.	The RAMP® 200 is not able to communicate with the printer. The printer may be offline.	Reconnect the printer, switch it on and try again. If the printer is not being used, turn off Auto Print via the RCU. For complete instructions, start the RCU, press F1 and refer to the online help.
Poor print quality.	The printer could be using the wrong print labels or print ribbon.	Refer to the printer manual. Consumables required for TLP 2824^{TM} or TLP 2824 Plus^{TM} printer: **Labels:** 2.25" W x 3" L Z-Select 4000T labels from Zebra® Technologies (part number: 800222-305); **Ribbon:** 57mm x 74m Wax/Resin Ribbon from Zebra® Technologies (part number: 800132-102)
Failure to print.	Poor cable connection or jammed printer.	Check if any cable connections are loose. Check if the printer is jammed; refer to the printer manual for instructions. If the persists, contact Technical Support to report the problem.
Printer light does not turn on.	Printer is not receiving power.	Refer to the printer manual. Check system power; ensure the power supply is connected. Ensure that the switch on the bottom right-hand side of the printer is in the On position. If the problem persists, contact Technical Support to report the problem.

Communications Errors

Message	Cause(s)	Solution
Transfer Error Transfer Failed	Network communications error or an error writing to the USB flash drive.	Check all cable connections and try again. If the problem persists, contact the Supervisor or Technical Support.
IP settings disabled while network transfers are set to auto	Attempt to set IP address while Transfer Mode is Auto.	Set Transfer Mode to Manual, enter the IP address information, and set the Transfer Mode to Auto.

USB Device Errors

Message	Cause(s)	Solution
Multiple Printers Attached, Remove Device	Two USB printers are connected. Only one printer is permitted.	Remove the additional printer.
Multiple USB Drives attached, Remove Device	More than one USB device of the same type is connected.	Remove the additional USB device. Leave one connected.
Unrecognized Scanner or Keyboard, Remove Device	Device attached is not supported by the RAMP® 200.	Remove the device. **NOTE**: The barcode scanner must be configured for HID keyboard emulation (Refer to the Scanner Quick Start Guide). If the problem persists, contact Technical Support.
USB Not Visible, Reinsert & Try Again	The USB device is not detected by RAMP® 200.	Re-connect the USB device and try again.
Unrecognized USB Drive attached, Remove device	A USB drive without a valid partition table is inserted into the CM.	Use the USB drive that is supplied with the RAMP® 200.

SPECIFICATIONS L

Specifications

⚠️ **CAUTION. Possible device damage and warranty invalidation.**
Changes or modifications to this equipment, not expressly approved by the manufacturer, could void the warranty.

TM Specifications

Specification	Description
Model Name	RAMP® 200 TM
Dimensions	185mm D x 195mm W x 96mm H
Weight	1.5kg
External connections	(1) RS485 - TM to CM

CM Specifications

Specification	Description
Model Name	RAMP® 200 CM
Dimensions	177mm D x 195mm W x 105mm H
Weight	1kg
Input Power Requirements	12 V DC, 120 W
Power Supply	100 - 240 VAC, 50-60 Hz
Power Cord Length	4 ft (1.22 m) min from power supply to CM
Power Supply Input Connector	IEC 320 C14 compatible
Power Supply Standards	Certified for CE, CSA, UL, C-Tick, according to intended regions. Conforms to WEEE and RoHS requirements for non-medical electronic devices.
External Connections	USB 2.0 and 1.1 (3 available), RJ-45 Ethernet, Serial RS-485 (3 available),
Ethernet Connectivity	TCP/IP, DHCP dynamic IP addressing, SSL over TCP, HTTP, HTTPS, FTP, FTPS
Controls	On/Off toggle switch. O = off / I = on. Touchscreen: VGA LCD alpha-numeric display, accepts input from bare finger, latex or nitrile gloved finger, or stylus. Touchscreen buttons: Main Menu, Run Assay, Run LQC, IQC, Results, Settings, Operator List, Cartridge status area (6).
Supported USB Devices	Label printer: Zebra® TLP 2824, Zebra® TLP 2824 Plus, Zebra® 888-TT Generic USB flash drive Barcode scanner: Symbol Technologies LS9208.
Display	640 x 480 pixels, 5.7~6.5 " diag (14.48~16.51 cm diag).

TM / CM Specifications

Specification	Description
Operating Temperature	15 - 30º C (59 - 86º F)
Storage Temperature	-10 - 50º C (14 - 122º F)
Operating Humidity	20 – 90% relative humidity, non-condensing.
Operating/Storage Elevation	0 – 2000m
Pollution Degree	2
Installation Category	II
Complies with the following EMC Specifications:	FCC 47 CFR Part 15 IEC 61326-1 – Electrical equipment for measurement, control and laboratory use – EMC requirements
Complies with the following IEC Standards:	UL/IEC 61010-1 - Safety requirements for electrical equipment for measurement, control, and laboratory use. UL/IEC 61010-2-101 - Particular requirements for in vitro diagnostic laboratory (IVD) equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user is required to correct the interference at his own expense.

⚠ Caution: Changes or modifications to this equipment not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Settings: View Screen Tabs

This section describes the individual tabs in the **Settings: View** screen. For overview information on viewing system settings, see *Viewing system settings* on page 44.

To access these tabs, select **Menu** > **Settings** > **View Settings**. The **Settings: View** screen appears.

Assay Tab
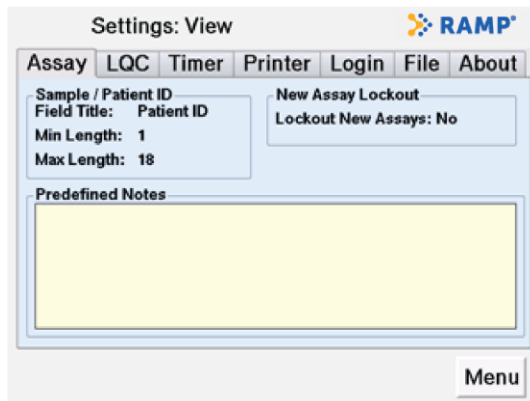
You can only edit the Assay tab settings through the RCU.

Sample/Patient ID

Defines the field name. Default is Patient ID. Alternate is Sample ID. String length can be set from 1 to 18. Default: Min Length = 1, Max Length = 18.

New Assay Lockout

Defines the ability of operators to perform Assays that are not in the Assay list. Set as Yes or No.

Yes: End users cannot run any Assays that are not on the RCU defined Assay list. The defined Assay list appears on the **LQC – Assay List** screen (select **Menu** > **LQC**).

No: End users can run any RAMP® 200 Assay. Default: No.

Predefined Notes

All notes predefined through the RCU are displayed. You can add one of these notes to each patient test result prior to removing the Test Cartridge from the TM. Once appended, the note becomes part of the result.

> **NOTE:** The predefined note can be up to 20 characters in length. For CM software V1.2, initial setup of the notes feature requires use of the default *grp_settings* file that is installed with the RCU (see the *Editing settings using the Reader Configuration Utility (RCU)*, starting on page 53). For CM software V1.3, initial setup of the notes feature can now be completed using the *grp_settings* file exported from the CM.

LQC Tab

Settings: View RAMP®

Assay | **LQC** | Timer | Printer | Login | File | About

LQC
Hide Numeric LQC Results:　　　　　No
LQC Timeout Warning (% remaining): 10
Max Failures Before Lockout:　　　　5

Control ID
Min Length:　1
Max Length:　18

Menu
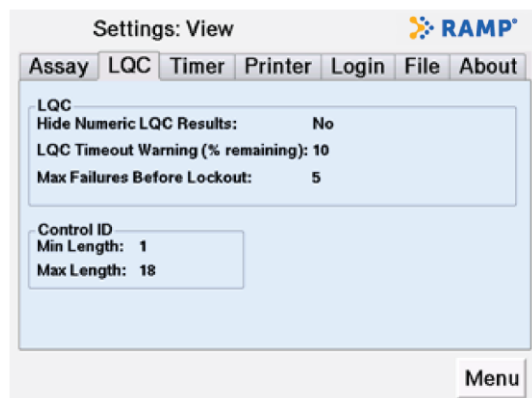
You must use the RCU to edit the LQC tab settings. They cannot be edited in the CM.

Default: Timer Reset (hours) = 0, LQC will not time-out.

To **Hide Numeric LQC Results** and report only PASS/FAIL.
　　　Set as **Yes** or **No**.
　　　　Yes: Pass/Fail appears in place of results.
　　　　No: Actual result appears.
　　　　Default: No.

If LQC is required, display **LQC Timeout Warning (% remaining)**:
Before LQC expires (for any Assay), the LQC warning icon appears when the user-defined **LQC Timeout Warning** counts down to its specified percentage. Default: 10%.

If LQC is required, display **Max Failures Before Lockout**:
The number of LQC failures allowed before Assay is locked out. Can be set from 1-9. Default: 1.

Control ID

String length can be set from 1 to 18.

Default: Min Length = 1, Max Length = 18.

Timer Tab

Settings: View RAMP®

Assay | LQC | **Timer** | Printer | Login | File | About

Timer Intervals
Menu Idle Timeout (minutes):　　　　8
Update/Upload Start Date/Time:　　2006–12–31 17:00:00
Update Interval (minutes):　　　　　1
Upload Results Interval (minutes): 0
Auto IQC Interval (minutes):　　　　0
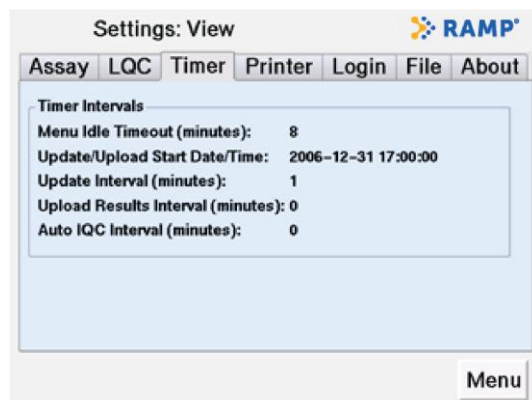
Menu

Use this tab to view the time and timer interval settings.

> **NOTE:** The ability to edit the settings of the Timer tab varies by item.

Timer Intervals

Menu Idle Timeout – Edit on the CM. Cannot edit through the RCU.

Amount of idle time before the RAMP® 200 returns to the home screen. To disable, enter **0**. Range: 0 - 10 minutes. Default: 5 minutes.

Update/Upload Start Date/Time – Edit through the RCU only.

The date and time used to calculate the start of the following intervals:

1. Update Interval – Edit through the RCU only.

Interval at which the Reader checks for changes to settings in a networked environment. Disable by entering **0**. Range: 0 - 1440 minutes. Default: 1.

2. Upload Results Interval – Edit through the RCU only.

Interval at which the Reader sends additions to the result and event logs in a networked environment. To disable, enter **0**. Range: 0 - 1440 minutes. Default: 0 (Disabled).

> **NOTE:** Only new results not previously transferred are transferred during an upload. Data is not deleted from the CM upon transfer. When the CM database is full, the oldest result is over-written.

3. Auto IQC Interval – Edit on CM and through the RCU.

The interval between automatic IQC self-diagnostics in either local or networked environment. To disable, enter **0**. Range: 0 - 1440 minutes. Default: 0 (Disabled).

Printer Tab
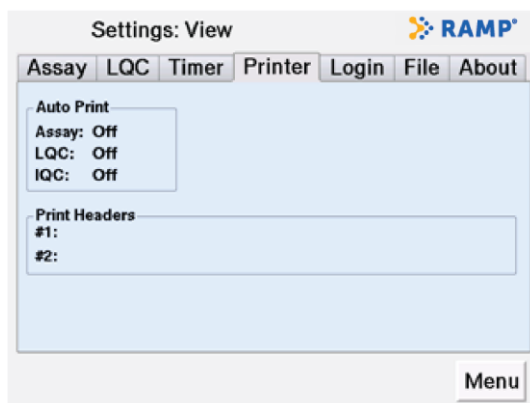
You must use the RCU to edit the Printer tab settings. They cannot be edited in the CM.

Auto Print

Automatic printing can be enabled independently for Assay, LQC and IQC results.

On: Prints the result automatically when the Assay is done.

Off: Does not print the result automatically. - Default: Off

Print Headers

Customized print header information that is visible on every printout.

Login Tab

You must use the RCU to edit the Login tab settings. They cannot be edited in the CM.

Device Name

Name that has been assigned to the device.

Default: Blank.

Lockout

Disable Reader

Device Locked: Assays cannot be run.

Device Unlocked: Assays can be run (default).

Login Requirements

Login requirements can be set independently for operators and supervisors requiring ID and password, ID only, password only or none. If none, an operator ID cannot be entered when running Assays.

Default: Operators = None; Supervisors = ID and Password.

Privilege Requirements

Defines the access privileges for each user level.

All Operators: Operators and supervisors have access.
Supervisors only: Only supervisors have access.

Default values: **Run Assay:** All Operators
View Results: All Operators
Run LQC: All Operators
Run IQC: All Operators
Settings: Supervisors Only

File Tab
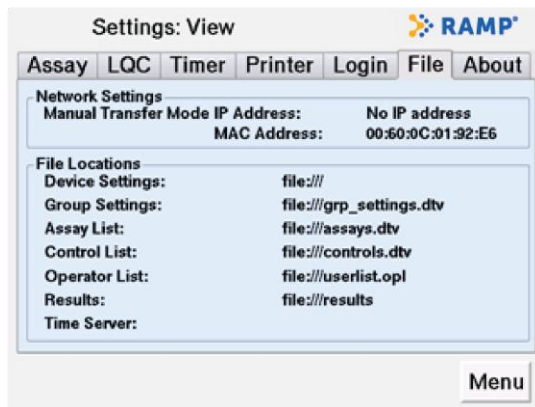
You must use the RCU to edit the network settings for the Reader tab settings. They cannot be edited in the CM.

Network Settings

Manual Transfer mode: The RAMP® 200 is used without connection to a shared network.

IP Address: By default, the IP address is auto assigned when the RAMP® 200 is connected to a network and in Auto transfer mode. Alternatively, a static IP address can also be assigned (see *IP tab* on page 82).

MAC Address (Machine Address Control address): This static address is the network identity of the RAMP® 200. Default: Manual Transfer Mode.

File Locations

Displays the location where the RAMP® 200 files reside, defined when implementing connectivity through the RCU. Consult your local IT administrator or the RCU help manual for information and help on how to use these settings.

About Tab
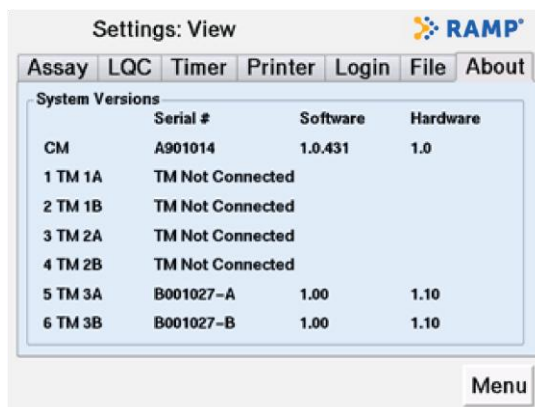
This tab displays the details of the serial number, software and hardware versions of the system. This information is important during discussions with Response Biomedical Technical Support.

Settings: Edit Screen Tabs

This section describes the individual tabs in the **Settings: Edit** screen. For overview instructions on editing settings, see *Editing system settings* on page 45.

To access these tabs, select **Menu** > **Settings** > **Edit Settings**. The **Settings: Edit** screen appears.

Timer Tab

IQC Interval (minutes)

Use this field to specify the interval between completing automatic IQC self-diagnostics. You can edit this value either on the CM or in the RCU.

Range: 0 – 1440 minutes
Default: 0 (Disabled)

Menu Idle Timeout (minutes)

Use this field to specify the amount of idle time before the RAMP® 200 returns to the home screen. Default: 5 minutes.

You must use the CM to edit this field value. You cannot edit the value in the RCU.

> **NOTE:** The ability to edit the settings of the Timer tab varies by item.

File Tab

Tab Guidelines

Use this tab to specify the locations for the device, group and time server settings.

You can edit these values either on the CM or in the RCU.

Consult your local IT administrator and the RCU help manual for guidance on how to configure these settings.

Date/Time Tab

Tab Guidelines

Use this tab to set the current date and time on the system.

You can only edit these values on the CM. They cannot be edited through the RCU unless NTP is enabled.

If you are in Auto Transfer Mode, the RAMP® 200 date and time may be synchronized with the NTP server.

The date format in the Reader is variable. The date format in the RCU is the same as for other applications running on that PC.

Periodically check that the clock is correct and has not inadvertently changed.

To configure the values of the Date/Time tab:

1 In the drop-down menu, scroll through times zones and select the time zone offset for your location.

Use the touchscreen keyboard and enter the current time.

Switch the CM off and then on again to reset the values.

> **NOTE:** When you adjust for changes in daylight savings time, remember to set the accurate Time Zone offset and not just the accurate current time.

Language Tab

Tab Guidelines

Use this tab to set the display language for the RAMP® 200.

You can only edit these values on the CM. You cannot edit them in the RCU.

CM software V1.3 supports the following languages: Chinese, French, German, Italian, Portuguese and Spanish. CM software V1.2 only supports English.

The barcode scanner does not support scanning of the extended character sets on the Alt. Keyboard (ALT. KEYS).

Misc. Tab

Network Transfer Mode

You can only edit these values on the CM. You cannot edit them in the RCU. Default: Manual Transfer Mode.

Manual Transfer Mode: the RAMP® 200 is set up for stand-alone operation.
Auto Transfer Mode: the RAMP® 200 is set up for network operation.

Sound

You can only edit these values on the CM. You cannot edit them in the RCU.

> **NOTE:** There is no volume adjustment feature.

Test: Select to hear indicator.

On: The audio indicator is ON and sounds at the completion of an Assay and when a USB device is connected or disconnected.

Off: The audio indicator is OFF.

IP Tab

Tab Procedure

1   Before you begin, ensure that the **Manual/Auto Transfer Mode** option is set to **Manual Transfer Mode** (select **Menu** > **Settings** > **Edit Settings** > **Misc.** tab).

Consult your local IT administrator and the network setup guide for the information you need to configure these settings.

Return to the **Misc**. tab and set the **Manual/Auto Transfer Mode** option to **Auto Transfer Mode**.

> **NOTE:** The IP screen is only available on CM software V1.2 and above.

IP Mode

You can only edit this setting on the CM. You cannot set it in the RCU. Default: DHCP.

DHCP: IP address assigned dynamically by host network.

Static IP: A fixed IP address is assigned on this screen.

USER AGREEMENT & WARRANTY M

User Agreement and Warranty

This User Agreement and Warranty (this "Agreement") is an agreement between you and Response Biomedical Corporation ("Response") and governs the purchase and use of your RAMP® 200 System. The RAMP® 200 System comprises the Control Module ("CM"), Control Module software ("CM Software") one or more Test Module(s) ("TM(s)"), the Reader Configuration Utility Software ("RCU Software"), the power supply and interconnect cable, the USB flash drive; and optionally includes USB devices supported by the RAMP® 200 System such as the barcode printer and barcode scanner ("Optional USB Devices") (collectively "RAMP®"). Software Updates (defined below), which are released subsequent to the date of purchase of RAMP® are not included as part of RAMP® and are not subject to the terms of this Agreement except as expressly set forth below. This Agreement sets out Response's warranty of RAMP®, exclusions and limitations of Response's liability to you, provisions governing the recall, and exchange policies for RAMP®, and other important provisions. If you do not agree with any term of this Agreement, you must not use RAMP®, and may return RAMP® to the RAMP® distributor from which you purchased RAMP® within 30 days of the date of receiving RAMP® ("Date of Receipt"). If you use RAMP®, you are deemed to have agreed to the terms of this Agreement.

Return Policy

Returns must be marked as RETURN and must include proof of purchase and the bill of lading. Returns must be received by Response within 30 days of the Date of Receipt. Upon acceptance of the terms of this Agreement, all sales are considered final.

Receipt of Delivery

The entire order is guaranteed to be correct. It is the purchaser's responsibility to open the package and inspect the items upon delivery. Packages that appear to be damaged should be immediately reported to the freight carrier. Damage due to shipping is the sole responsibility of the freight carrier and all claims are to be made by the purchaser directly with the carrier immediately upon recognizing a problem. Shipping carriers may not honour late claims. Response will not accept Returns or Exchanges due to shipping damage.

In the case of wrong-shipped items ("Wrong-Shipped Items"), the purchaser should notify the distributor of the error as soon as possible, but not later than 30 days from the Date of Receipt (the "Exchange Period"). Exchanges for Wrong-Shipped Items are handled in accordance with the Exchange Policy noted below.

Exchange Policy

The Exchange Policy applies only to newly purchased RAMP®, including any newly purchased Optional USB Devices, and is in effect for the Exchange Period only. Upon the expiry of the Exchange Period, the Warranty provisions of this Agreement, if applicable, govern.

All exchanges, whether for defect or otherwise, are to be made through the distributor where the item was purchased. Response will not accept any exchange claims directly from the purchaser. For purposes of requesting an exchange, the purchaser should contact the local distributor's Technical Support Representative as soon as possible, but not later than 30 days from the Date of Receipt. All exchange requests should be handled in accordance with this Exchange Policy.

In the case of Wrong-Shipped Items, Response will work with the distributor to replace these items with the proper items, at no charge to the purchaser. In the case of defective items ("Defective Items"), where said defect was NOT caused by shipping damage, misuse, neglect, unauthorized attempts to open, repair or modify RAMP®, or use of RAMP® with accessories or other products that are not authorized by Response, Response will work with the distributor to replace the Defective Item.

Prior to shipping any item for exchange, whether the item is defective or otherwise, the distributor must first contact Response to obtain written authorization for the exchange. Response will provide the instructions on how to ship the return. Response will not accept shipments without a confirmed, written authorization. All the return items authorized for exchange must be in the original (or equivalent) packaging and in compliance with the freight carrier's requirements. Response will pay the shipping charges for the product exchange.

Replaced items will be shipped to the purchaser (or distributor where appropriate) upon receipt and inspection of the Defective or Wrong-Shipped Items by Response. Replacement of all items remains subject to in-stock availability.

Warranty

Response warrants to the original purchaser that RAMP® will be free from defects in material and workmanship on the date of purchase and substantially conform to the material functional specifications contained in this Owner's Manual for a period of one (1) year from the date of the original purchase from Response or an authorized distributor ("Warranty Period"). This limited warranty is non-transferable. This warranty is conditioned upon observance of the published directions included in this Owner's Manual. This warranty is further conditioned upon observance of directions accompanying the products specifically designed for use with RAMP® and authorized for use with RAMP® by Response (including Test Cartridges, control Cartridges and Kits containing same) (the "RAMP® Products").

This warranty does not apply if the defect or malfunction in RAMP® was caused by misuse, neglect, unauthorized attempts to open, repair or modify RAMP®, use of RAMP® with accessories or other products that are not RAMP® Products or any cause other than the intended normal use of RAMP®.

If RAMP® becomes defective during the Warranty Period, and the Exchange Period has expired, the purchaser's sole and exclusive remedy, and Response's sole obligation, will be to repair or replace RAMP®. Repaired or replaced products or parts may be new or reconditioned, and are subject to this limited warranty through the end of the original Warranty Period. Non-warranty work is charged at the standard repair rate.

To obtain warranty service, the purchaser must contact the distributor during the Warranty Period, provide the distributor with a dated proof of original purchase, and ship RAMP® to Response in its original (or equivalent) packaging only after receiving an authorization notice in writing from either Response or the distributor. The purchaser is responsible for shipping costs to Response.

Exclusions

TO THE FULL EXTENT ALLOWED BY LAW, THIS LIMITED WARRANTY IS THE PURCHASER'S SOLE AND EXCLUSIVE REMEDY, AND NO OTHER WARRANTIES, CONDITIONS OR GUARANTEES OF ANY KIND SHALL APPLY, WHETHER STATUTORY, WRITTEN, ORAL, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES, CONDITIONS OR GUARANTEES OF MERCHANTABILITY, NON-INFRINGEMENT, FITNESS FOR A PARTICULAR PURPOSE, PERFORMANCE, QUALITY, OR DURABILITY, ALL OF WHICH ARE DISCLAIMED.

Liability Limitations

IN NO EVENT WILL RESPONSE BE LIABLE FOR ANY SPECIAL, EXTRAORDINARY, INDIRECT OR CONSEQUENTIAL DAMAGES OF ANY KIND WHATSOEVER, INCLUDING WITHOUT LIMITATION DAMAGES FOR LOSS OF DATA, LOST PROFITS, LOSS OF OPPORTUNITY, PATENT INFRINGEMENT, BUSINESS INTERRUPTION, PERSONAL INJURY OR DEATH, OR ANY OTHER LOSS ARISING OUT OF, RELATING TO, OR IN CONNECTION WITH RAMP® EVEN IF RESPONSE IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IF, AS A RESULT OF OR IN CONNECTION WITH, ANY USE OF RAMP®, WHETHER IN CONJUNCTION WITH RAMP® PRODUCTS OR OTHERWISE, RESPONSE BECOMES LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY DAMAGES, LOSSES, COSTS, EXPENSES, OR OTHER LIABILITIES WHATSOEVER, AND REGARDLESS OF THE FORM OF ACTION (IN CONTRACT, TORT OR PURSUANT TO STATUTE), THEN RESPONSE'S AGGREGATE LIABILITY TO ALL SUCH PERSONS WILL BE LIMITED TO AN AMOUNT EQUAL TO THE PURCHASE PRICE PAID FOR RAMP® AND YOU HEREBY RELEASE RESPONSE FROM ANY AND ALL OBLIGATIONS, LIABILITIES, CLAIMS OR DEMANDS IN EXCESS OF THIS LIMITATION.

The exclusion of certain conditions and warranties and the limitation of certain liabilities are prohibited in some jurisdictions, so these limitations and exclusions may not apply to some purchasers.

Recall Policy

Recalls are actions taken by Response to remove certain serial or lot numbers of RAMP® or specific RAMP® components ("RAMP® Parts"), from the market. Recalls may be conducted on Response's own initiative, or by the request of a regulatory body. Response will inform the distributor of the necessary recall information in writing via email or fax. Only lot or serial numbers of RAMP® or RAMP® Parts (the "Recalled Product") that fall within the recall will be included.

The distributor will take full responsibility for collecting all Recalled Products from their customers and for taking proper actions to discard, destroy, or send the Recalled Products to Response-designated destinations as instructed.

Upon return of the Recalled Product to the distributor, the purchaser's sole and exclusive remedy, and Response's sole obligation will be to, at Response's option repair the Recalled Product or replace the Recalled Product with a an equivalent Response product (if available) of equal or lesser value. Failure to return the Recalled Product may result in Response, at their sole discretion, deciding not to repair or replace the Recalled Product.

End User License Agreement

Subject to the terms and conditions of this Agreement, Response grants to the purchaser a limited, non-exclusive license to use RAMP® for its intended purpose, and to use the CM Software solely as preinstalled on the CM and the RCU Software solely to enable purchaser's use of the CM. The CM Software and RCU Software are together referred to as "Software". This license may be terminated by Response effective upon notice to the purchaser if the purchaser fails to pay in full all fees for RAMP®. Response reserves all rights not expressly granted to the purchaser in this Agreement, including all proprietary rights in and to all designs and other technology and information pertaining to RAMP®. Response further retains all right, title, and interest, including all intellectual property rights, in and to the Software. The Software is licensed, not sold, to the purchaser by Response and its suppliers. The purchaser will not have any rights in or to the Software except as expressly granted in this Agreement. The limited end user license granted hereunder is not transferable and is limited to the purchaser of RAMP® from Response or its duly authorized distributor, except that this end user license may be transferred together with the permanent transfer of RAMP® and associated documentation so long as (a) the purchaser does not retain any copies of the Software, (b) the transferee agrees to be bound by the terms and conditions of this Agreement, and (c) the purchaser provides Response with written notice of the transfer within thirty (30) days of the transfer date. Except as expressly provided in this Agreement, the purchaser will have no right to, and specifically agree not to, (i) disassemble, reverse engineer, decompile, decrypt, or otherwise reduce RAMP® or the Software to a human perceivable form to gain access to trade secrets or confidential information in RAMP® or the Software (except to the extent that such restrictions are prohibited by applicable law); (ii) modify or adapt or otherwise make error corrections to RAMP® or the Software or create derivative works based upon RAMP® or the Software, or permit third parties to do the same; (iii) make or distribute any copies of RAMP® or the Software; and (iv) use the CM Software except as embedded or preinstalled on the CM or the RCU Software except to configure the CM.

Software Updates

Response may, in its sole discretion, provide replacements, updates, modifications, or bug fixes for the Software to the purchaser or a transferee ("**Software Updates**"). Each Software Update is provided "as is" with no warranty of any kind. Software Updates will be deemed part of the Software solely for purposes of the sections of this Agreement entitled LIABILITY LIMITATIONS and END USER LICENSE AGREEMENT.

Feedback

Any materials, including but not limited to feedback, comments, suggestions, or identifying potential errors, improvements, ideas or other information provided by you in the form of email or other submissions to Response (collectively "**Feedback**"), are non-confidential and you hereby grant to Response and its subsidiaries and affiliates a nonexclusive, royalty-free, perpetual, irrevocable, and sublicensable right to use your Feedback for any purpose without compensation or attribution to you.

Governing Law

This Agreement is governed solely by the laws of the Province of British Columbia, Canada and applicable federal laws of Canada, and expressly excludes the United Nations Convention for the International Sale of Goods, and any rules of private international law or conflict of laws which would lead to the application of any other laws. Any dispute arising from, connected with or relating to this Agreement will be resolved by the courts of British Columbia, Canada and the parties hereby irrevocably submit and attorn to the original and exclusive jurisdiction of those courts in respect to such matters. This Agreement is in the English language. In the event this Agreement is translated into any other language and any inconsistency or contradiction in meaning or interpretation results wherefrom, the English language version shall prevail and be controlling as between Response and the purchaser. This Agreement constitutes the sole and exclusive agreement between the parties regarding RAMP® and the Software. If any provision of this Agreement is held invalid or unenforceable, the remainder of this Agreement will continue in full force and effect.

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