T-COR 8™

Quick Start Guide

PLM-0666-1

Date of Issue: 2024/06

Catalog #: TC-5015-001 (Four Channel), TC-5028-001 (Five Channel), TC-5049-001 (Five Channel with User Replaceable Battery), TC-5018-001 (Magnetic Mixer)

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How to Use This Guide

Purpose of This Guide

The *T-COR 8™ Quick Start Guide* provides basic information needed to operate the T-COR 8™. This guide assumes that the user:

- Is familiar using Google Chrome™ web browser.
- Has a general understanding of hard drives and data storage, file transfers, and copying and pasting.

Before operating the T-COR 8™, review the information in the *Tetracore T-COR 8™ Hardware Manual (*PLM-0665) and the *Tetracore T-COR 8™ Software Manual (*PLM-0667).

Text Conventions

This guide uses the following conventions:

- **Bold text indicates a label. For example, a page title or text box.**
- **[Bracketed] text indicates a button. For example: Press the [Start Run] button.**
- <u>Underlined</u> **text indicates emphasized importance. For example: To avoid loss of data, never turn off the T-COR 8™ until <u>all</u> runs have completed.**
- *Italicized* **text indicates a reference to further information. For example: See *Physical Safety Hazard*.**
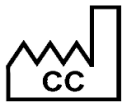
Related Documentation

Soft copy versions of the manuals listed in Table 0-1 are available in the T-COR 8™ software user interface. The manuals can be accessed from the web browser of an external device, and are not available in Stand Alone mode. The manuals can be opened by navigating to [Menu], opening [Information], and pressing the [Manuals] button.

Document	Part Number	Description
T-COR 8™ Software Manual	PLM-0667	The *Tetracore T-COR 8™ Software Manual* provides the information needed to operate the T-COR 8™.
T-COR 8™ Hardware Manual	PLM-0665	The *Tetracore T-COR 8™ Hardware Manual* provides the information needed to utilize the T-COR 8™.
T-COR 8™ LIS Connectivity Specification	PLM-0668	The *Tetracore T-COR 8™ LIS Connectivity Specification* documents the HL7 message sent from the T-COR 8™ device to a LIS server.

Symbol Definitions

The following table describes symbols that may be used on the T-COR 8™ device, on its packaging or in the associated documentation.

Symbol	Description
	Indicates the device manufacturer.
CC	Indicates the country of manufacture. The date of manufacture may be added adjacent to this symbol.
	Indicates the entity importing the device into the locale.
	Indicates the entity distributing the device into the locale.
SN	Indicates the manufacturer's serial number so that a specific device can be identified.
REF	Indicates the manufacturer's catalog number so that the device can be identified.
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates a device that is intented for single use only.
Σ	Indicates the total number of tests that can be performed with a device.
i	Indicates the need for the user to consult the instructions for use. An eIFU indicator for the location of the instructions for use may be added adjacent to this symbol.

Symbol	Description
	Indicates a device that needs to be protected from moisture.
	Indicates the temperature limits to which the device can be safely exposed.
CE	Indicates a device in compliance with all applicable EU legislation including In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR), Directive 2014/35/EU for Low Voltage (LVD), Directive 2014/30/EU for Electromagnetic Compatibility (EMC), and Directive 2011/65/EU (consolidated version) of the European Union on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS). This includes amendments introduced by Delegated Directive 2017/2102. Conformance to the IVDD 98/79/EC, LVD 2006/95/EC, and EMCD 2004/108/EC is applicable to catalog numbers TC-5015-001 & TC-5028-001.
IVD	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
	Do not dispose of this product as unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provisions to reduce the environmental impact of Waste Electrical and Electronic Equipment (WEEE). European Union customers: Call a Tetracore technical representative for equipment pick-up and recycling.
EC REP	Indicates the authorized representative in the European Community.

Symbol	Description

	U.S. EMC Standard:
	• **Class A: This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.**
	• **Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the 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 in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:**
	    ○ **Reorient or relocate the receiving antenna**
	    ○ **Increase the separation between the equipment and receiver**
	    ○ **Connect the equipment into an outlet on a circuit different from that to which the receiver is connected**
	Consult the dealer or an experienced radio/TV technician for help

How to Obtain More Information

Contact Information

Tetracore, Inc.
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Suite 600
Rockville, MD 20850-3986
United States of America

Tel: +1 240.268.5400
Fax: +1 240.268.1107
E-mail:
customersupport@tetracore.com
www.tetracore.com

CE IVD

EC | REP

EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Important Safety Instructions

Always comply with the following precautions to avoid dangerous situations and ensure proper T-COR 8™ performance.

The following symbols are found throughout Quick Start Guide:

⚠ **CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or damage to the equipment.**

⚠ **WARNING Indicates a potentially hazardous situation which, if not avoided, may result in serious injury or death.**

ⓘ **NOTE Provides information pertinent in using T-COR 8™. Please read note carefully before using the product.**

ⓘ **IMPORTANT! Provides information necessary for proper T-COR 8™ operation.**

When reading this Quick Start Guide:

- **Read all instructions.**
- **Keep all instructions.**
- **Heed all warnings.**
- **Follow all instructions.**

Reporting a Serious Incident

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Intended Use

The T-COR 8™ is a semi-automated real-time thermocycler that is intended for use with PCR, RT-PCR, Isothermal and other Nucleic Acid Amplification in vitro diagnostic tests. The T-COR 8™ measures real-time nucleic acid amplification signals from DNA or reverse-transcribed RNA samples and provides a qualitative result. The T-COR 8™ is intended for use by laboratory professionals.

⚠️ **WARNING** The T-COR 8™ is For Export Only. It is not for use in the United States.

Clinical Performance Characteristics

Clinical performance characteristics are specific to the sample type, sample processing method, and assay.

It is the responsibility of Tetracore's T-COR 8™ customers (i.e. users, distributors) to develop and validate the use of third-party kits and reagents to generate diagnostic results associated with genetic sequencing, amplification, detection and analysis. This responsibility also includes validating the specimen type(s) that can be analyzed, including stability such as storage, where applicable specimen transport conditions and, with a view to time-critical analysis methods, information on the timeframe between taking the specimen and its analysis and storage conditions.

This would still be the case should Tetracore develop its own assays to run on the T-COR 8™, i.e. the relevant diagnostic parameters would be established and validated as part of the assay technical development though using the T-COR 8™ as an instrument platform.

Applicable Software Versions

This guide is applicable to the Iona software releases.

Unpacking and Accessories

To unpack the device remove the packing tape and unfold the sides of the shipping box

With the foam end caps still attached to the device, remove the device from the box. Once removed from the box, pull the left and right foam end caps off of the instrument. Remove the roll up insert from the box.

Foam End Caps
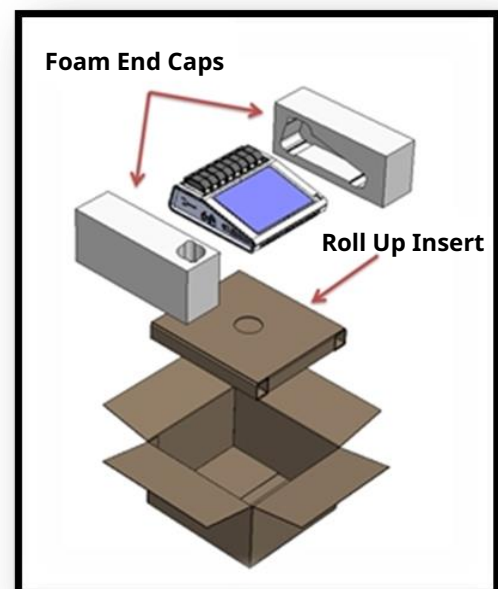
Roll Up Insert

Unfold the large flap on the roll up insert to access the accessories.

Check package for the following items:

- **T-COR 8™ Device**
- **AC Adapter**
- **Power Cord**
- **Ethernet Cable**
- **T-COR 8™ Tube Rack**
- **Magnetic Mixer (optional)**
- **USB-A to USB-mini (optional)**

If the device or any accessories are missing or damaged, contact Tetracore.

⚠ **CAUTION USB is only designed for use with Tetracore recommended accessories. Use of any USB accessories other than those recommended by Tetracore could result in damage to the T-COR 8™ or the USB accessory.**

Accessible through the software on-board the instrument:
- **Hardware Manual**
- **Quick Start Guide**
- **Software Manual**
- **LIS Connectivity Specification**

Required Consumables (not supplied)

T-COR 8™ tubes are required to use T-COR 8™ and are not supplied. The T-COR 8™ tube is a polypropylene tube for use only with the T-COR 8™ real time thermal cycler. It is a required single-use, disposable accessory to hold samples for use with PCR, RT-PCR, Isothermal, and other Nucleic Acid Amplification in vitro diagnostic tests. To order items, contact a Tetracore representative.

Item	Catalog Number
T-COR 8™ Reaction Tube	**TC-5029-500**

⚠ **WARNING User should not substitute required consumables with other options without possible safety and performance consequences.**

Set-Up Requirements

Environmental Conditions

⚠ **WARNING: Physical Injury Hazard. Use this product only as specified in this manual. Using this device in a manner not specified by Tetracore may result in personal injury or damage to the device.**
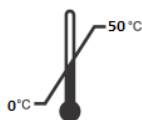
Required working conditions are between 0°C (32°F) and 50°C (122°F).

Ensure the device lies atop a flat, sturdy surface that can sustain at least 7 kg (15 lbs.).

⚠ **CAUTION Do not obstruct within 6 inches (15.24 cm), push objects into, or allow dust to accumulate in the air vents. Do not store the device in a low-airflow environment, such as a closed briefcase, while it**

is running. Restricting the airflow can damage the T-COR 8™ and/or cause a fire.

This device is <u>not</u> waterproof or water resistant. Keep T-COR 8™ away from liquids to avoid damage to device.

Connecting to Electrical Outlet

⚠ **CAUTION The AC adapter will only operate using a mains electricity supply within the range of 100-240VAC and 47-63Hz. However, AC power plugs and sockets vary among countries. Using an incompatible power plug or improperly connecting the cable to the power strip or electrical outlet may cause fire or equipment damage.**

⚠ **CAUTION Do not use any type of inverter with this device as it could cause fire or equipment damage.**

⚠ **CAUTION Do not use any type of car charger with this device because it could cause fire or equipment damage.**

❗ **NOTE Only use a mains power source (e.g. wall power) that can provide a minimum of 220 watts. Most standard mains electricity meets this requirement.**

Connect the power cord to the AC adapter <u>before</u> connecting the male DIN connector to the T-COR 8™. To connect the AC adapter to the T-COR 8™, align the indentation on the male DIN connector with the caret mark on the device and insert fully into the female DIN connector. To safely disconnect power, disconnect the male DIN connector on the AC adapter from the female DIN connector on the device.

❗ **NOTE When disconnecting the AC adapter from the T-COR 8™, grasp the connector, not the cable itself, and pull firmly but gently without twisting to avoid damaging the cable and/or connector.**

Powering the Device

Press the power button to turn the device on and off. The LED ring will illuminate around the button when the device is powered on. Likewise, the LED will not illuminate when device is powered off.

> ❗ **NOTE** To avoid loss of data, never turn off the T-COR 8™ until <u>all</u> runs display the message "Run Complete".

> ❗ **NOTE** After turning device off, wait at least 15 seconds <u>before</u> powering the device on again.

Magnetic Mixer Accessory

The T-COR 8™ Magnetic Mixer is an optional accessory which can be purchased separately. It is designed exclusively for use with Tetracore's T-COR 8™, and T-COR 8™ Reaction Tube. The Magnetic Mixer is USB-powered and operated via the T-COR 8™.

Connecting to the T-COR 8™

If you plan on running any assay that will need the use of the magnetic mixer then you must follow this procedure.

1. Power down the T-COR 8™.
2. Identify the USB Cord: Male Type-A to Male Type-B Mini (5-pin) provided with mixer.
3. Connect the Male Type-B Mini (5-pin) end of the USB cable to the magnetic mixer.
4. Connect the Male Type-A end of the USB cable to the T-COR 8™.

5. Power on the T-COR 8™.

> 🛑 **NOTE Magnetic mixer must be connected to the T-COR 8™ before the instrument is powered on.**

> 🛑 **NOTE Magnetic mixer will sound for approximately 20 seconds when powered on.**

> ⚠ **CAUTION The magnetic mixer is for use with the T-COR 8™ only. Use of this mixer with any other machines could cause equipment damage.**

Device Utilization

Overview of Device Utilization

There are four ways to use the T-COR 8™ device:

1. Stand Alone mode
2. Direct Connection mode
3. Access Point Connection mode
4. Network Connection mode

In Stand Alone mode, the T-COR 8™ touchscreen is used – this does not require an external device (for example, a computer). In Direct Connection mode, an Ethernet cable and an external device with the Google Chrome™ web browser installed on any operating system is needed. For Access Point Connection mode, a Wi-Fi capable external device with the Google Chrome™

web browser installed on any operating system is needed. For Network Connection mode, a network of any type (wired or wireless) and an external device with the Google Chrome™ web browser installed on any operating system is needed.

> **!** **NOTE Internet connection is not required to access the device.**

Pre-installed User Accounts

The T-COR 8™ has two pre-installed user accounts, *user* and *admin*. The Tech role is assigned to *user*, and the Admin role is assigned to *admin*. When the T-COR 8™ is removed from its original packaging, neither *user* nor *admin* require a password. It is possible to change the password. For more information, see *User Administration* in the *Tetracore T-COR 8™ Software Manual*. Green text indicates roles with access to specific features.

Stand Alone Mode

In Stand Alone mode, the device does not require an external device (for example, a computer) to set-up or view data. Stand Alone mode allows for device portability. The T-COR 8™ has a touchscreen that utilizes an on-screen keyboard when needed. In Stand Alone mode, the idle screen timer is set to dim the screen automatically after 30 seconds (only when running off battery) which can be reversed by simply tapping the touchscreen. All software features are accessible in standalone mode with the exception of the Reports, Temperature Graph, Touchscreen Calibration, License Page, and Direct Zip Download which can only be accessed via Google Chrome™ on an external device.

1. Set up the device on a dry, flat area.

   ⚠ **CAUTION** Do not obstruct within 6 inches (15.24 cm), push objects into, or allow dust to accumulate in the air vents. Do not store the device in a low-airflow environment, such as a closed briefcase, while it is running. Restricting the airflow can damage the T-COR 8™ and/or cause a fire.

2. Turn on the device by pressing the power switch located on the right side panel. When the LED ring illuminates, the device is ON.

   ❶ **NOTE** If the light does not turn on, then the battery has been fully discharged. In this case, do the following:
   1. Press power switch again to turn off device. Ensure the power switch button is flush with the outer ring.
   2. Connect the power cord to the AC adapter <u>before</u> connecting the male DIN connector to the T-COR 8™.
   3. Align the indentation on the male DIN connector of the AC adapter with the caret mark on the device and insert DIN fully into the female DIN connector.
   4. Wait 15 seconds <u>before</u> powering on the device again.
   5. Press power switch again to turn on device.

3. **Device is ready for use.**

Direct Connection Mode

Direct Connection mode allows the user to access the T-COR 8™ software from a computer via Ethernet cable instead of using the touchscreen on the device. It is <u>required</u> that the computer has Google Chrome™ installed in order to access the T-COR 8™ software. All software features are accessible when using Direct Connection mode. To access the software in Direct Connection mode:

1. **Set up the device on a dry, flat area.**

   ⚠ **CAUTION Do not obstruct within 6 inches (15.24 cm), push objects into, or allow dust to accumulate in the air vents. Do not store the device in a low-airflow environment, such as a closed briefcase, while it is running. Restricting the airflow can damage the T-COR 8™ and/or cause a fire.**

2. **Connect one end of the Ethernet cable into an Ethernet port on a desktop or laptop computer. Connect the other end of the Ethernet cable into the Ethernet port located on the left side panel.**

3. **Turn on device by pushing the power switch located on the right side panel. When the LED ring illuminates, the device is ON.**

   🛈 **NOTE If the light does not turn on, then the battery has been fully discharged. In this case, do the following:**

   1. **Press power switch again to turn off device. Ensure the power switch button is flushed with outer ring.**
   2. **Connect the power cord to the AC adapter <u>before</u> connecting the male DIN connector to the T-COR 8™.**
   3. **Align the indentation on the male DIN connector of the AC adapter with the caret mark on the device and insert DIN fully into the female DIN connector.**
   4. **Wait 15 seconds <u>before</u> powering on the device again.**
   5. **Press power switch again to turn on device.**

4. On the touchscreen, log in and go to [Menu] -> [Wifi and Networks] -> [Ethernet Settings], and ensure the Direct Connect Mode is "On". Wait until the device's IP address appears in the bottom right of the touchscreen.

5. Using the connected computer, open the Google Chrome™ web browser.

6. Enter the IP address of the device into the URL box of the browser.

> **❗ NOTE** When directly connected to a computer via Ethernet cable, the IP address will always be 192.168.8.2.

7. Device is ready to use.

Access Point Connection Mode

Access Point Mode allows the user to access the T-COR 8™ software from a Wi-Fi client device, such as a phone or laptop. It is required that the client device has Google Chrome™ installed in order to access the T-COR 8™ software. All software features are accessible when using Access Point mode. To access the software in Access Point mode:

1. Set up the device on a dry, flat area.

> **⚠ CAUTION** Do not obstruct within 6 inches (15.24 cm), push objects into, or allow dust to accumulate in the air vents. Do not store the device in a low-airflow environment, such as a closed briefcase, while it is running. Restricting the airflow can damage the T-COR 8™ and/or cause a fire.

2. Turn on device by pushing the power switch located on the right side panel. When the LED ring illuminates, the device is ON.

> **❗ NOTE** If the light does not turn on, then the battery has been fully discharged. In this case, do the following:
> 1. Press power switch again to turn off device. Ensure the power switch button is flushed with outer ring.
> 2. Connect the power cord to the AC adapter <u>before</u> connecting the male DIN connector to the T-COR 8™.

3. Align the indentation on the male DIN connector of the AC adapter with the caret mark on the device and insert DIN fully into the female DIN connector.
4. Wait 15 seconds <u>before</u> powering on the device again.
5. Press power switch again to turn on device.

3. On the touchscreen, log in and go to [Menu] -> [Wifi and Networks] -> [Switch to AP Mode]
4. Using the client device, connect to the new open Wi-Fi network. The SSID is the device's serial number. Wi-Fi security is not an option at this time. Open the Google Chrome™ web browser on the client device.
5. Enter the wireless IP address of the T-COR 8™ into the URL box of the browser.

> 🛈 **NOTE** When directly connected to a computer via Access Point mode, the IP address will always be 192.168.8.3.

6. Device is ready to use.

Network Connection Mode

In Network Connection mode, the T-COR 8™ allows for remote access, control and data analysis via a wired or wireless network. An external device with Google Chrome™ installed must be connected to the same network as the T-COR 8™ in order to access the device. After a successful network connection is established, the IP address assigned to the T-COR 8™ will be displayed in the lower right corner of the touchscreen. Open the browser and enter the appropriate IP address into the URL box. All software features are accessible when using Network Connection mode.

1. Set up the device on a dry, flat area.

> ⚠ **CAUTION** Do not obstruct within 6 inches (15.24 cm), push objects into, or allow dust to accumulate in the air vents. Do not store the device in a low-airflow environment, such as a closed briefcase, while it is running. Restricting the airflow can damage the T-COR 8™ and/or cause a fire.

2. **Turn on the device by pushing the power switch located on the right side panel. When the LED ring illuminates, the device is ON.**

3. **Connecting to network via Ethernet cable or Wi-Fi:**
    a. <u>**Ethernet Cable**</u>**: Connect one end of the Ethernet cable into an Internet access point (for example, a modem or wall Ethernet drop). Connect the other end of the Ethernet cable into the Ethernet port located on the left side panel.**
    b. <u>**Wi-Fi**</u>**: Press the [Menu] button located on the bottom right of the display in the software. Press the [Wifi and Networks] button in the window. Press [Rescan] to search for available Wi-Fi networks. Select the network to connect to.**

4. **Using any computer connected to the same network, open the Google Chrome™ web browser.**

5. **Enter the IP address of the device into the URL box of the browser.**

🛈 **NOTE The IP address of the device can be found in the lower right corner of the touchscreen.**
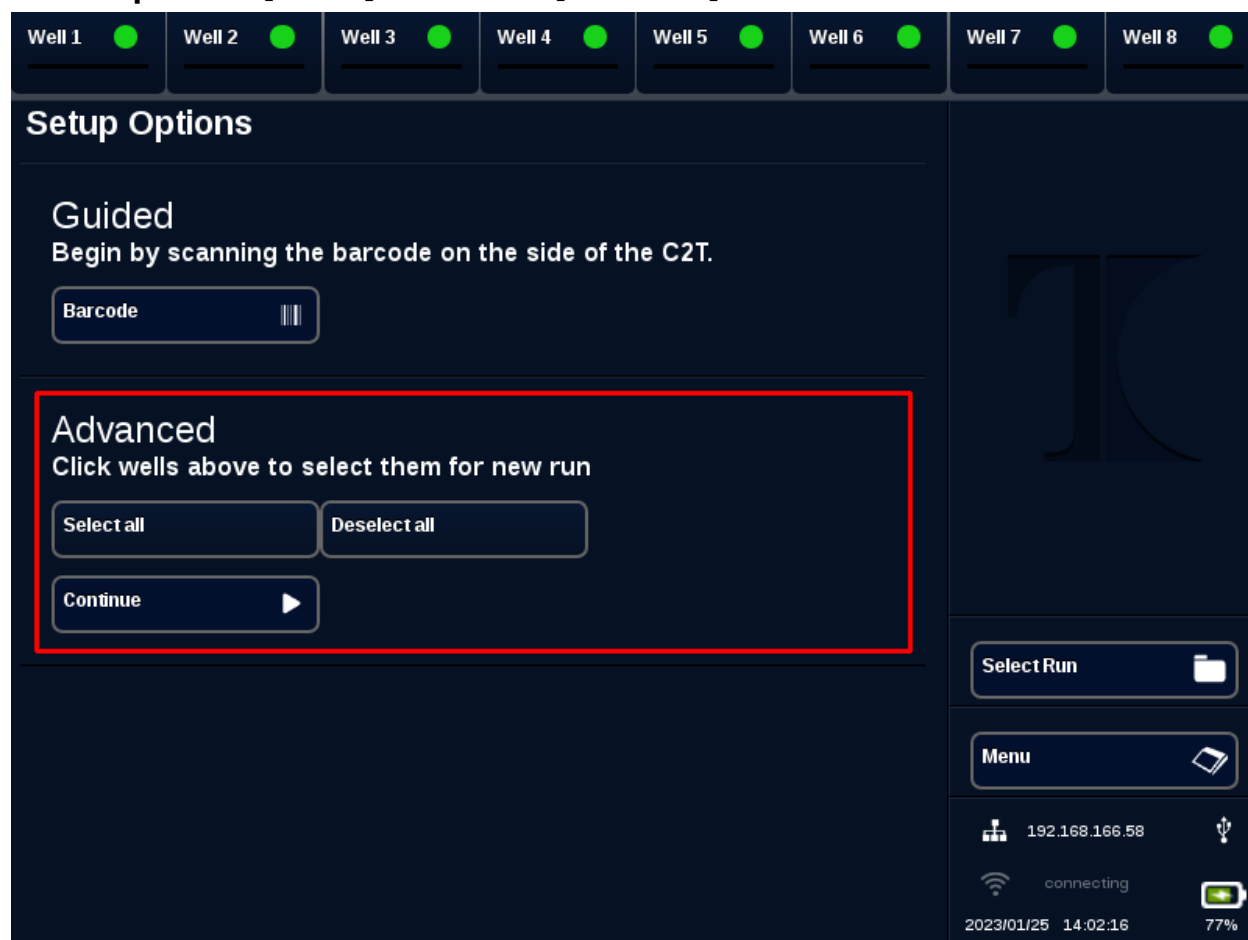
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6. **Device is ready to use.**

A Quick Guide to Run Setup

The instructions below are only a basic overview. For detailed information about each screen and functionality, see *Tetracore T-COR 8™ Software Manual*.

Creating a New Run

1. **Sign in to the T-COR 8™**
2. **Open the [Menu] and select [New Run].**

3. **Select well(s) to be used by highlighting the corresponding well header(s). Highlighted well headers will have a green circle. [Select all] selects all available wells. [Deselect all] deselects all wells.**

   ⓘ NOTE When wells are currently running, those wells will be highlighted with a red bar. These wells are not available until the current run(s) are completely finished.

4. **Select [Continue] to proceed onto the New Run Summary page.**
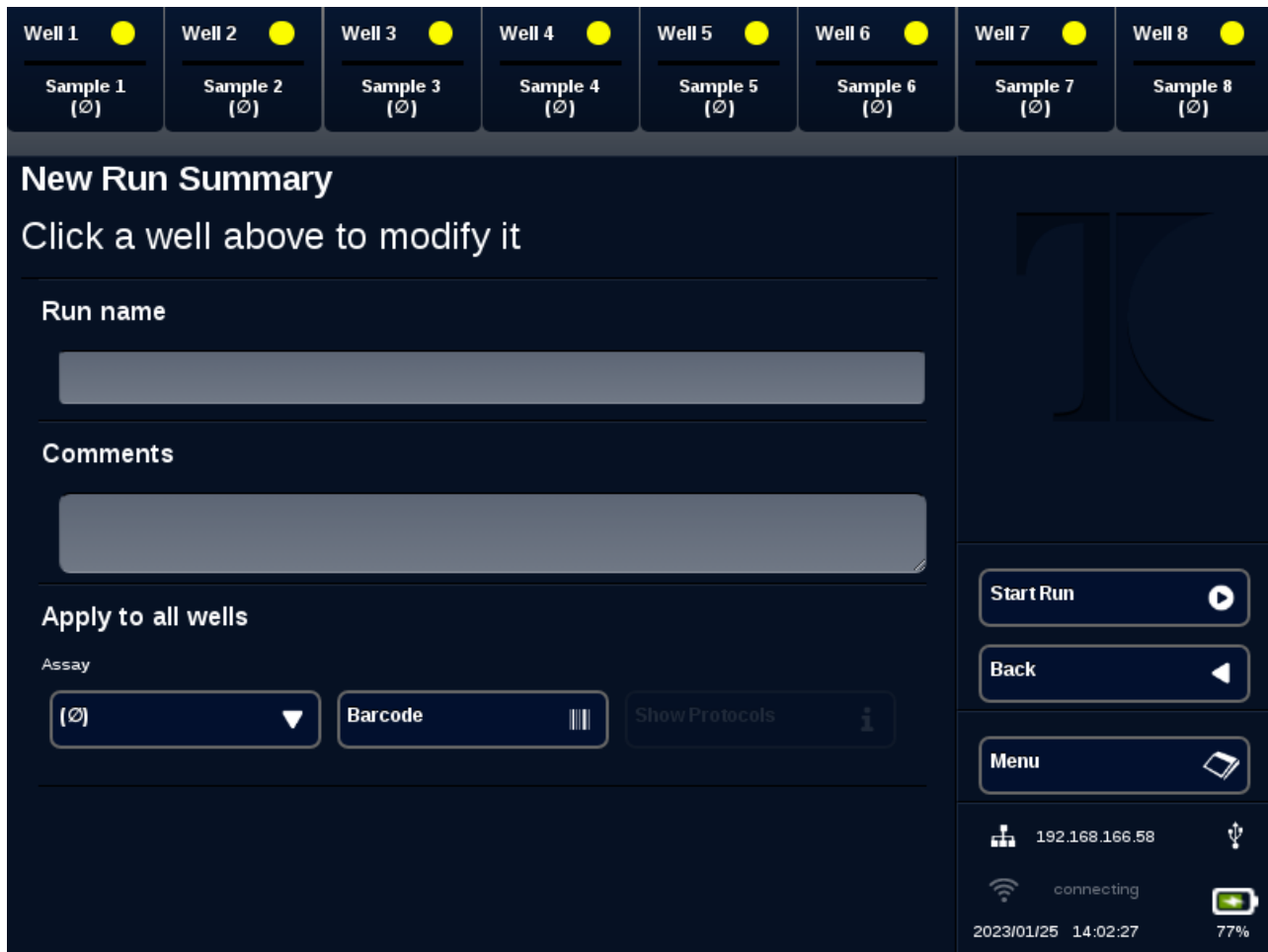
5. **Enter a Run Name (optional). Enter any Comments (optional). This can be altered after the run has started, but cannot be altered after the run has completely finished.**
6. **Choose an assay to be used for this run from the dropdown menu underneath Assay to apply to all wells. Each well may also be assigned with different assays (see step 7).**

    🛈 NOTE Assays must already be pre-defined. If an assay is not listed, create an assay before creating a new run (see *Editors*). This can only be accessed by Admin and Lab Director roles.

7. **Should you choose to run more than one assay, select the well with a yellow circle well header.**

Enter Sample name for that well and choose an assay to be used for this well from the dropdown menu next to Assay. If available, an assay can also be scanned by pressing the [Barcode] button next to the Assay header. Press [Close] to save and exit the window.

8. Repeat step 7 for each well to be used in the run.

> ⓘ **NOTE If a barcode for the assay is available, it can be scanned into the device using the barcode reader located on the right panel of the device. Press the appropriate [Barcode] button to initiate the barcode reader. Hold barcode approximately 3 inches (7.62cm) away from scanner. The barcode scanner will terminate scanning after 10 seconds if no reading is captured.**

> ⚠️ **WARNING: Laser Radiation. Do not stare into beam. Never direct laser at other people, highly reflective surfaces, or any other object not intended for designated use.**

9. Press the [Start Run] button.

After the run has been started, the software will automatically display a summary table of the samples and their assay(s). Data can also be viewed and analyzed by selecting a particular [Graph] channel (only available for Admins, Directors, and Molecular Directors). The Run Name, Comments, and Sample information can be altered while the run is in progress under [Run Info]. Once

the run is completed, user cannot change Run Name, Comments, or Sample information. Previous runs can be viewed while runs are in progress.

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