Spartan RX™

User Manual

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Intended Uses

This Spartan RX CYP2C19 *2 System (or simply Spartan RX System) made by Spartan Bioscience Inc. is for Limited Release only. This device is only to be used by Qualified Investigators.

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1. Introduction

Thank you for choosing to purchase the Spartan RX System. Spartan Bioscience Inc. is committed to bringing fast and accurate DNA analysis to point-of-care applications. This system is designed to provide the user with a patient's CYP2C19 *2 genotype. Spartan believes that successful operation of this System will lead to a significant improvement in patient management. Knowing a patient's CYP2C19*2 genotype will enable health care providers to choose the best anti-platelet treatment strategy.

This manual is designed for users of the Spartan RX System. The manual includes general information about components of the System, as well as detailed protocol instructions to ensure quality of results.

If there are any questions or concerns that occur during the operation of the system, please contact your Authorized Spartan Dealer at your earliest convenience. In the event your dealer is unable to solve your problem contact Spartan Bioscience by e-mail at support@spartanbio.com or by telephone from 9am-5pm EST at +1.613.228.7756.

2. Precautions

2.1.General

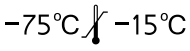
It is important to follow the protocol instructions and complete all necessary training prior to performing the tasks described in this manual. If there is uncertainty or unexpected events, please refer to the protocol instructions, the troubleshooting guide, or contact you Authorized Spartan Dealer.

Please note that some residual risks exist that are associated with the use of this System. For information on these risks please see Section 9.4 of this manual.

2.2. Symbols

Symbols are used throughout the supporting material for the Spartan RX System, including this document, labels, packaging and instruction guides. Symbols are used as a visual signal to point out

important information. Below is the legend of symbols used, along with a brief description of their meaning.

	Warning, Risk of Danger – This symbol is used to indicate that non-compliance with the instructions or procedures may lead to physical injury, or even death, or could damage the instrument,
	Important Note – This symbol is used to bring the user's attention to an important annotation.
	Biohazard – This symbol is used to indicate that certain precautions must be taken when working with potentially infectious material.
	DC (Direct Current)
	This symbol indicates the Manufacturer of the device or system component.
	CE Mark (European Union)
	Caution, Risk of Electrical Shock – This symbol is used to indicate that certain precautions must be taken to avoid electrical shock.
	Do not reuse a product containing this symbol (use the product only once).
	Use until (indicates the expiry date of the product)
	The lot or batch of the product
	Device serial number
	Manufacturing date
	Read the documentation before proceeding.
	The product must be maintained between -75°C and -15°C until immediately before use.
	Protect the product from light.
	Part number or catalogue number.

EC REP	Authorized Representative
Σ	Sufficient material for N tests
IVD	In Vitro Diagnostic (indicates the material is an In Vitro Diagnostic or part of an In Vitro Diagnostic Device)

2.3.Electrical

The Spartan RX System contains an Analyzer that is an electromechanical instrument. There is a potential danger to the user of an electrical shock or physical injury if the instrument is not used according to the instructions given in this manual. Observe all general safety precautions which apply to electrical instruments.

- The power supply cord must be inserted into a power outlet with a protective earth contact (ground).
- Unplug the power supply cord from the power outlet before cleaning the instrument.
- Only use the supplied power cords or cables. If any of the cables become damaged or inoperable, please contact your Authorized Spartan Dealer for a replacement.
- Do not use the instrument near water or immerse in water.
- The instrument should be operated only with the type of power source indicated on the marking label of the power supply.
- The instrument should be used only with the supplied power supply. If the power supply becomes inoperable, please contact your Authorized Spartan Dealer for a replacement.
- Always plug the power supply into the instrument, and then plug the power supply into the power outlet.
- Do not allow anything to rest on the power cord.
- Do not install the instrument where the cord may be walked upon.
- To reduce the risk of electrical shock, do not disassemble the instrument. Refer servicing to Spartan authorized service personnel.
- Do not overload power outlets because this can result in risks of fire or electrical shock.
- Unplug the power supply cord from the power outlet and refer to Spartan authorized service personnel if one or more of the following conditions exist:
    - The power supply cord or plug is damaged or frayed.
    - Liquid has been spilled onto the instrument.

  - The instrument has been exposed to water.
  - The instrument does not operate normally by following the operating instructions.
- Slots in the front and back of the instrument are provided for ventilation. To protect the unit from overheating, these openings **must not** be blocked and a 5 cm gap must be maintained. Adequate ventilation should be verified at the start of each day.

2.4. Biological

Be aware for your own safety that all biological samples such as buccal material have the potential to transmit infectious diseases. Follow all applicable local, state/provincial, and/or national regulations. Wear appropriate protective clothing and gloves.

If you suspect the instrument may have been exposed to any hazardous material, the instrument must be decontaminated. If you are unsure about suitability of the decontamination or cleaning agent specified in your laboratory decontamination procedure, please contact Spartan by e-mail at support@spartanbio.com or by telephone from 9am-5pm EST at +1.613.228.7756.

Material Safety Data Sheets (MSDS) for the Spartan reaction tubes are available upon request.

 After the swab has been used, it may contain infectious agents. Please be sure to safely dispose of the swab shaft and the post-run reaction tubes. For more information see Section 11 of this document on disposal.

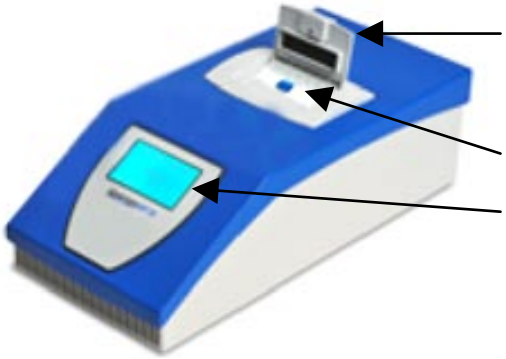
3. Overview of System Hardware and Maintenance

The Spartan RX System consists of a netbook computer, an inkjet printer, an Analyzer device, and their required cables.

3.1. Analyzer

The Analyzer device is a 2-well thermal cycler with optical detection capability, designed for determining an individual's CYP2C19*2 genotype. The device is portable, light-weight, sensitive, and robust. The unit has two optical detection channels (green and red) that detect the wild-type and *2 alleles, respectively. The device has been customized to maximize accuracy for this application.

The unit is uniquely identified by a serial number on the back.



3.2. Netbook

A netbook computer is part of the System. The netbook serves as a connection between the Analyzer and the printer. Software on the netbook allows the user to log in to the System with a User ID and password. Once logged in, the user may input critical information, such as the Patient ID, which will appear on post-analysis result printouts.

3.3. Printer

Standard sized A4 sheets of paper will be printed after each patient sample is analyzed or after a Status Check has been performed. Note that a patient sample run will result in two (2) identical 1-page reports being printed.

3.4. Maintenance

The Analyzer does not require cleaning of any kind. If the instrument becomes dusty use a dry static free cloth to clean the surface of the instruments. At no time should solids or liquids be allowed to fall into an open well. If this does happen, or you suspect it has happened, please contact Spartan by Telephone from 9am-5pm EST at +1.613.228-7756. As a preventative measure, keep the ejector lid closed at all times, except when samples are being loaded or unloaded.

⚠

Slots in the front and back of the instrument are provided for ventilation. To protect the unit from overheating, these openings **must not** be blocked and a 5 cm gap must be maintained. Adequate ventilation should be verified at the start of each day.

The netbook computer does not require maintenance of any kind. The user may clean the screen using a clean, dry, and lint-free cloth.

The printer will require maintenance typical of a commercial printer. Paper outages, paper jams and toner shortages could occur. Paper and toner levels must be maintained by the user.

4. Equipment Specifications

4.1. Performance Specifications

When used according to the manufacturer's recommendations, the Spartan RX System has the following performance specifications.

Metric	Performance Specification	Definition
Inconclusive Rate	<7%	Number of times that the test produces an inconclusive result, divided by the total number of tests performed (expressed as a percentage).
Diagnostic Sensitivity*	>98%	Number of *2 true positive results, divided by the sum of *2 true positive and *2 false negative results (expressed as a percentage).
Diagnostic Specificity*	>98%	Number of *2 true negative results, divided by the sum of *2 true negative and *2 false positive results (expressed as a percentage).

* Excludes inconclusive results.

4.2. Instrument Specifications (ratings)

Specification	Min	Typ.	Max	Comments
System Warranty	1 year			
Electrical Compatibility				100 – 240 VA, 50-60 Hz
Max Electrical Power	150W		500W	100W peak for Analyzer 40W peak for netbook 9W or 360W peak (printer choice)
Operating Voltage	11.4V	12.0V	12.6V	12 +/- 5% as per power adapter spec
Operating Current			6.5A	Max current
Operating Temperature	20		25	degrees Celsius
Operating Humidity	20		50	% RH Non-condensing
Operating Altitude	0		2000	meters
System Life (upon arrival)	2 years			

5. Equipment Unpacking and Setup

5.1. Unpacking

The Spartan RX equipment is shipped in two cardboard containers. The containers should be carefully inspected for damage and the carrier immediately notified before taking receipt of the System. Spartan recommends that the unpacking instructions below are fully read and understood before starting the unpacking. If there are any questions or concerns that are not covered by this guide, please contact your Authorized Spartan Dealer at your earliest convenience or Spartan by e-mail at support@spartanbio.com or by telephone from 9am-5pm EST at +1.613.228.7756.

5.2. System Contents

- Analyzer
- Power adapter for Analyzer
- Netbook computer
- Power adapter for netbook
- Printer
- Power adapter for printer
- Netbook – Printer USB cable
- Local power cables
- Ethernet cable
- Spartan RX Quick Guide

5.3. Operating Requirements

- This instrument is designed for indoor use only.
- Operate in ambient temperature between 20°C and 25°C.
- Do not operate in a cold room or a refrigerated area.
- Operate in ambient relative humidity of 20 to 50%.
- These specifications have been calculated for altitudes between 0 and 2,000 meters.
- Ensure adequate front and rear ventilation.

5.4. Setup

When fully set up, the Spartan RX System requires a minimum of 80 cm of desk space and three electrical power outlets (as outlined in the electrical ratings in Section 4.2). The installation is easily completed by following the steps below.

- Remove the Analyzer from the box labeled “1 of 2” and place it upright on the desk. Obtain the Analyzer power adapter and plug it into the wall outlet and the back of the Analyzer. The screen should illuminate in approximately 30 seconds.
- Obtain the Ethernet cable from the Analyzer box and plug one end into the back of the Analyzer.
- Remove the printer from within the box labeled “2 of 2” and place it upright on the desk. Obtain its power adapter and plug it into the wall outlet and the back of the printer.
- Obtain the printer/netbook USB cable from the printer box and connect the appropriate end of the cable into the port on the printer.
- Load the printer with paper and turn the printer on.
- Remove the netbook from within the box labeled “2 of 2” and place it upright on the desk (or on top of the printer as space allows). Obtain its power adapter and plug it into the wall outlet and the back of the netbook. Connect the appropriate end of the printer – netbook USB cable into its port on the netbook.
- Plug the free end of the Ethernet cable into the Ethernet port of the netbook. Turn on the netbook.
- Log into the netbook. The Spartan RX software should automatically start within 30 seconds (See Section 12 for default password).
- Print a status report (See section 8.2).
- Perform a genotyping test on an individual to ensure that the System is functioning properly.

5.5. Location

The System should be set up in an area that meets the criteria below. Failure to adhere to these constraints will result in poor performance of the Spartan RX System.

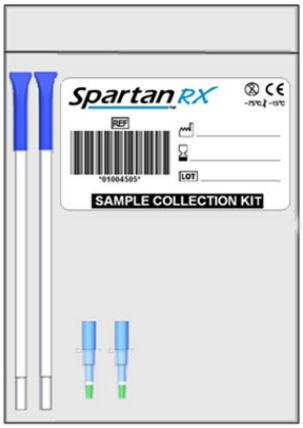
- The System must be set up in a location with ambient temperature **20°C to 25°C** and ambient relative humidity of **20 to 50%.**
- The Analyzer must have adequate front and rear ventilation. To protect the unit from overheating, the openings at the front and rear of the unit must not be blocked and a **5 cm** gap must be maintained.
- The System must be set up in a location that is in close proximity to the patient. You must be able to start the run within **5 minutes** of collecting the first patient sample.

6. Overview of System Consumables

The Spartan RX requires the use of a consumable product called a Sample Collection Kit. This product is described below and its proper use is explained in the protocol (Section 9).

6.1. Sample Collection Kit

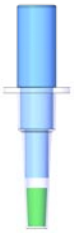
A Sample Collection Kit is required for each patient tested. Since two samples are collected for each patient, a Sample Collection Kit includes the following:



- A clear 12.5 cm x 17.5 cm resealable plastic bag
- Two frozen reaction tubes with blue caps (reagents are colored green for illustrative purposes – the actual reagents are clear)
- Two Spartan swabs with caps
- An identification label
- A laminated package insert with visual instructions

Upon receipt, Sample Collection Kits must be stored between -75°C and -15°C in a **non frost-free** freezer. Immediately prior to collecting samples from a patient, the user obtains a Sample Collection Kit from the freezer (See Section 7.1. Receiving Sample Collection Kits).

6.2. Reaction Tubes



The Analyzer is designed to work with Spartan reaction tubes. These tubes have been optimized to provide superior performance. Spartan supplies frozen reagents in Spartan tubes. Each tube consists of the cap (blue plastic), the tube (clear plastic), and the frozen reagents (typically clear but coloured green in the adjacent figure). These reaction tubes must be stored in a non frost-free freezer between -75°C and -15°C.

NOTE: If at any time the product has thawed, it must not be used.

6.3. Spartan Swab

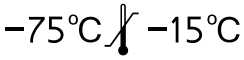
The Spartan swab has been designed and optimized to be used with the Spartan RX System. A Spartan cap (without the tube or reagent) is mounted to the end of each swab (with a protective blue cover) and the DNA sample is collected directly on the Spartan cap. The Spartan swab is specially designed to enable easy buccal sample collection and handling.

7. System Consumables Storage and Handling

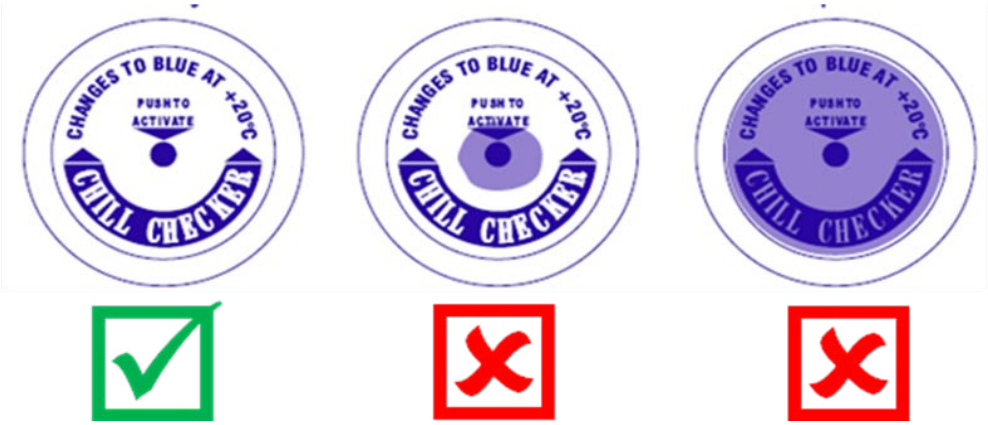
7.1. Upon Receipt

It is required that the Sample Collection Kits be placed in a non frost-free freezer at -15°C to -75°C within 15 minutes of arrival at the study location. **If the Sample Collection Kits have thawed at any time they must not be used**. The frozen reagents appear opaque. In contrast, thawed reagents appear clear. Please contact your Authorized Spartan Dealer for replacements.

7.2. Receiving Sample Collection kits



Immediately upon arrival of a Sample Collection Kit shipment, inspect the indicator disc on the shipping bag. The indicator is a “Chill Checker” device that provides a clear visual indication that the reagents did not thaw during transport. When the specified temperature is exceeded, the Chill Checker will stain a white paper inside the plastic capsule. As shown in the figure below, partial staining indicates that the Chill Checker was subjected to temperatures above its set point. The shipment should be rejected if any partial or full staining is observed.



Sample Collection Kits are shipped on dry ice to keep them frozen. Dry Ice is solidified carbon dioxide and presents hazards to the user.

- Dry Ice is much colder than regular ice and can burn skin similar to frostbite. Avoid contact with skin and eyes. Always handle with insulated gloves..
- Never eat or swallow dry ice.
- Avoid inhaling the carbon dioxide gas released as dry ice melts.
- Open the Spartan reagent shipping container only in a well ventilated space.
- Because dry ice can cause carbon dioxide gas to accumulate and build up pressure, do not dispose of dry ice in a sewer, garbage disposal, garbage chute, etc.
- Allow leftover dry ice to sublimate or evaporate in a well-ventilated area.

7.3. Storage and Stability

If the receiving protocol above (Section 7.1, 7.2) has been followed, the Sample Collection Kits will be stable up to the expiry date marked on the package. To obtain a single Sample Collection Kit for testing a patient, it will be necessary to briefly move the bag holding multiple Sample Collection Kits out of the freezer. This will not affect the stability of the remaining Sample Collection Kits within the storage bag, provided that the exposure to room temperature is less than 30 seconds.

The Sample Collection Kits have been shipped in an amber bag to protect them from light. Spartan recommends that the Sample Collection Kits be stored in the bag in which they are shipped to ensure they remain light-protected.

Exposure of the Sample Collection Kits to light immediately prior to use is acceptable, but the stability of the product will be compromised if the kits are stored outside of the amber bag in a freezer with a light that stays on during storage.

7.4. Lot tracking

Long-term stability of consumables is tracked by the manufacturing date and expiry date on the Sample Collection Kit labels. **Under no circumstance should the components be used beyond the expiry date.** Please contact your Authorized Spartan Dealer to order additional kits

8. Quality Control

The following steps are designed to ensure ongoing quality in the results from the Spartan RX System.

8.1.Training

Each user must undergo a training program under the supervision of qualified Spartan personnel or an approved representative. A training record should be maintained by the System administrator and should be completed and signed before a user is deemed qualified to use the System.

8.2. Daily System Status Checks

The Spartan RX System is configured to perform a series of Status Checks on the optical, thermal, and mechanical subsystems. This series of checks is performed automatically after every patient test. Every 24 hour period, the user should print a Status Check report. No patient test should be performed until the Status Check report is complete.

Pressing the “Print Status Check” button from the user interface will print an A4 paper report in less than 1 minute. A failed Status Check result will display “SYSTEM STATUS - FAILED” on the printed report. The user should contact their Authorized Spartan Dealer if this occurs. A sample of a passed status report is shown below.

```
**********************************************************
                    System Status Check
**********************************************************
Unit: C
Date: 2010/06/03
Time: 18:54
System Status Check Identifier: 112695-06185217-3.248998-3.122589

Heating System: PASSED
Cooling System: PASSED
Optical System: PASSED
Mechanical System: PASSED

System Status - PASSED
**********************************************************
```

8.3. Reagent Lot Tracking by Manufacturer

The reaction tubes in the Sample Collection Kits will undergo a quality control analysis at Spartan. To ensure traceability of the reagents, Sample Collection Kits are labeled with a Spartan part number, manufacturing date, and expiry date, to ensure traceability of the reagents. The Spartan part number and manufacturing date ensure that the reagents are consistent batch to batch. The expiry date ensures that the user does not use consumables which may have inferior performance. No Sample Collection Kits should be used after their expiry date.

8.4. Reagent Lot Quality Control Test

For each new Sample Collection Kit lot, it is strongly recommended that the user perform a quality control test of the reaction tubes at the site by testing a person with a confirmed genotype. The criterion of acceptance is that the printed result is consistent with the known genotype. It is also strongly recommended that a copy of the lot quality control test printout be stored. New Sample Collection Kit lots should not to be distributed for use until the lot quality control has been completed.

8.5.Software Confirmation and Controls

The netbook software includes the following controls:

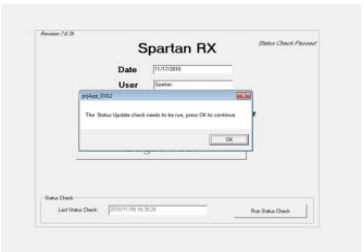
- In order to start a test, the user must log in to the netbook computer. Only users who have completed the appropriate training should be given passwords (See Section 12).
- The software will check to ensure a valid Status Check has been completed within the past 24 hours.
- In order to start the test, the user must enter the Patient ID using the netbook. A valid patient ID can be up to 20 alpha-numeric digits. If a patient report already exists for the Patient ID number, the user will be prompted to confirm the duplication of the patient report.

9. Spartan RX Test Protocol

Performing a test on the Spartan RX System has a preparation stage and 8 simple steps. These are described in detail below.

IMPORTANT: Each patient test requires **two (2) samples**

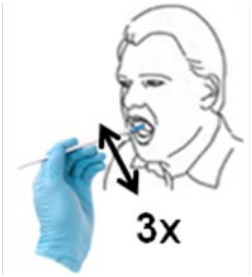
- **Steps 1 – 6** must be completed within **5 minutes**
- **Steps 7 – 8** must be completed within **5 minutes**

PREPARATION	Plug in the Spartan RX System, Analyzer, netbook, and printer. Ensure that the printer and Analyzer are both connected to the netbook. **IMPORTANT:** - Follow the System setup instructions in Section 5 of this manual. - Ensure the Analyzer is adequately ventilated (see Section 5.5).	
	Switch on the printer. Ensure that paper is loaded.	
	Switch on the netbook, and then log in using your username and password. After ~20 seconds, the Spartan RX screen will appear. *Tip: For details of how to create new user accounts, see Section 12.*	
	When the Spartan RX screen appears on the netbook, you may be prompted to run a Status Update Check. **If prompted** - select "OK". The Status Update Check will take less than 30 seconds to complete and a printout will be generated. In the event that a Status Update Check fails, please consult the troubleshooting guide of this manual.	

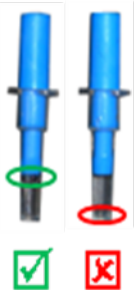
COMPLETE STEPS 1 – 4 WITHIN **5 MINUTES**

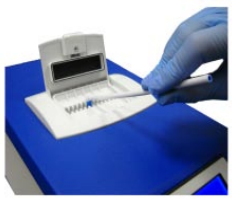
1	Put on a pair of gloves, and then obtain one Sample Collection Kit from the freezer. **IMPORTANT:** - If the tubes in the Sample Collection Kit have thawed at any time - **do not use the Sample Collection Kit**. - If the expiry date is no longer valid – **do not use the Sample Collection Kit.**	
	Bring the Sample Collection Kit to the patient. If the tubes have not thawed by this time, thaw by rolling them between your finger tips. *Tip: When tubes are thawed, the liquid in the tube will appear clear. When tubes are frozen, the liquid will appear opaque.*	
2	While wearing gloves pick up one of the swabs and one of the tubes – hold one in each hand.	
	Remove and discard the cap from the tube.	
3	Remove and discard the cover from the swab.	

COMPLETE STEPS 1 - 4 WITHIN **5 MINUTES**

4	Immediately prior to collecting a sample, ask the patient to rinse his or her mouth with water. *Tip: The patient may swallow or spit the water in conformance with hospital pre-operative requirements.*	
	Using moderate pressure, scrape inside of the patient's cheek with the blue end of the swab. Scrape the cheek using three up and down strokes. **IMPORTANT:** Visually confirm that the swab tip is wet after sample collection. During swabbing, verify that the blue swab cap has not become dislodged.	

COMPLETE STEPS 5 – 8 WITHIN **5 MINUTES**

5	Grip the swab in your fingers and place your thumb on top. Then insert the swab into the tube and push down firmly.	
6	Hold the swab **vertically** and **firmly tap** the tube **3 times**. Tap using the **tip** of a **single finger,** as shown. **IMPORTANT:** - Tapping should be sufficiently firm to cause the liquid in the tube to move and make contact with the blue tip of the inserted swab. - Avoid excessive force – **do not** dislodge tube from the swab. - If bubbles form at the bottom of the tube, re-tap the tube again until they move to the top. **Bubbles at the bottom of the tube will cause inaccurate or inconclusive results**. *Tip: When tapping the tube, hold the swab at the top. This will help to ensure that the liquid in the tube makes contact with the blue tip of the inserted swab.*	 

		Repeat Steps 2 – 6 for the second swab and tube in the Sample Collection Kit.	**REPEAT STEPS 2-6**
COMPLETE STEPS 5 - 8 WITHIN **5 MINUTES**	7	Bring the two samples to the Analyzer. Open the lid of the Analyzer.	
		Insert the two samples into the Analyzer one at a time, as follows: i. Insert the end of the tube into the well. ii. Grip the swab shaft tightly with your fingers and place your thumb on top. Push down on the top of the swab with your thumb and slide your fingers upwards. *Tip: You should feel the outer portion of the swab shaft slide upwards.* iii. Bend the swab shaft to a 90° angle until it separates from the tube. *Tip: When bending the shaft portion of the swab to separate it from the tube, use a twisting and bending motion. This will make it easier to remove the shaft portion.* iv. Close the Analyzer lid.	i)  ii)  iii)  iv) 

COMPLETE STEPS 5 - 8 WITHIN **5 MINUTES**	8	In the netbook, enter the run and patient details. - Patient ID - Patient date of birth (month and year) *Tip: The Patient ID can be up to 20 digits (alpha-numeric).* *Tip: The arrow keys can be used to quickly scroll up and down when entering patient details.* *Tip: The TAB key can be used to scroll through the options.*	
		Select "Begin Test" to start the run. The run time is approximately 60 minutes. Once the run is complete, two identical results pages will print. You may now remove the tubes from the Analyzer, discard the tubes and close the Analyzer lid. If the printout reveals an "Inconclusive" result, we recommend verifying that you have fully complied with the protocol and then repeat the test (for more detailed instructions consult the troubleshooting guide of this manual – Section 10)	

9.1. Spartan RX System Result Printout

The printed result of a patient test has two sections. The top section is a summary of the patient test result and the bottom section displays the full details of the Spartan RX System run.

The top section of the result printout displays the following:

- **Patient ID#** - 20 digit alpha-numeric, entered during the Spartan RX System run setup.
- **Result** – Patient result, which will be one of the following:
  - ****2 Negative*** *– The patient is not a carrier of the CYP2C19*2 allele*
  - ****2 Positive*** *– The patient is a carrier of the CYP2C19*2 allele*
  - ***Inconclusive*** *– The patient test needs to be repeated*

The bottom section of the result printout displays the following:

- **Unit** – Spartan RX System identifier

- **Test Complete Time** – Time at which the Spartan RX System run finished
- **Date** – Date of the patient test (YYYY/MM/DD)
- **User** – Username of the person who logged in to the Spartan RX System to begin the run
- **Time Sample Taken** – Time at which the user presses "Begin test"
- **Patient ID#** - Patient ID (20 digit alpha-numeric), entered during the run setup
- **DOB** – Date of Birth of the patient (YYYY/MM), entered during the run setup
- **Run Identifier** – 12-digit alpha-numeric identifier, unique to each Spartan RX System run. The format of the Run identifier is: **Unit-YYMMDDHHMM**

  Where:
  YYMMDD - Date of the Spartan RX System run
  HHMM - Time at which the Spartan RX System run started (24 hour clock)

- **Result** – The detailed patient result, which will be one of the following:
  - ***CYP2C19*1/*1*** *– The patient does not carry any CYP2C19*2 allele*
  - ***CYP2C19*2/*1*** *– The patient carries one CYP2C19*2 allele*
  - ***CYP2C19*2/*2*** *– The patient carries two CYP2C19*2 alleles*
  - ***Inconclusive*** *– The patient test needs to be repeated*

9.2. Spartan RX System Interfering Substances

Certain substances present in a patient sample may interfere with the Spartan RX System test result. These interfering substances may be intrinsic or extrinsic to the patient. Examples of possible intrinsic interfering substances include enzymes, polysaccharides, or other molecules naturally occurring in saliva. Examples of possible extrinsic interfering substances include particles or chemicals originating from food or drink consumed by the patient prior to sample collection. Asking the patient to rinse his or her mouth with water prior to sample collection is required to minimize any effects of intrinsic and extrinsic interfering substances. The patient may swallow or spit the water in conformance with hospital pre-operative requirements.

9.3. Spartan RX System Sample Cross-contamination

Due to the design of the Spartan RX System, inaccurate test results caused by cross-contamination are unlikely. Cross-contamination from extrinsic materials entering the reaction tubes is possible (e.g., human cells from the user performing the patient test or the surrounding environment), although this has not be observed in Spartan's validation studies. To further reduce any risk of this unlikely cross-contamination, it is required that system users wear clean gloves when performing patient tests.

9.4. System Residual Risks

The Spartan RX system has been designed with the intent to minimize all possible risk associated with the operation of the System. However, some residual risk remains. The following represents possible residual risks.

- There is a very remote possibility that the cap may become dislodged from the swab shaft during swabbing. In the event this occurs, it may become a choking risk. Please be aware of this risk and communicate the risk to the patient.
- There is a very remote possibility that a patient may obtain a cold or virus from the swab.
- There is a very remote possibility that a patient has an allergic reaction to the medical grade TPE contained in the cap.

10. Troubleshooting

If problems occur in the usage of the Spartan RX System, please contact your authorized Spartan Dealer or Spartan Bioscience Inc. at +1.613.228.7756 to assist in resolving the issue. Common troubleshooting solutions are provided below.

Issue Description	Resolution
Daily Status Update Check does not print.	- Ensure paper tray is not empty. - Ensure power is supplied and all devices are powered. - Ensure netbook is connected to printer.
Patient test result does not print.	- Ensure paper tray is not empty. - Ensure power is supplied and all devices are powered. - Ensure netbook is connected to printer.
“STATUS CHECK FAILED” displayed on unit.	- This indicates that the Analyzer has failed a Status Update Check. Do not use the unit. Please call your authorized Spartan Dealer and a representative will assist you.
“SYSTEM STATUS - FAILED” on the Status Update Check printed result.	- This indicates that the Analyzer has failed a Status Update Check. Do not use the unit. Please contact your Authorized Spartan Dealer and a representative will assist you.

Printer / netbook / Analyzer does not power on.	- Ensure power is supplied.
Unable to log in to netbook.	- Check that the correct user account was chosen and the password is correct. - Set up a new user account (see Section 12) if required.
Spartan RX System will not begin the run.	- Ensure Analyzer lid is closed. - Check all cables and ensure they are properly connected
Spartan RX System stalls / will not complete a run.	- Ambient temperature outside acceptable range of 20 – 25°C (59 - 77°F). - Ambient relative humidity outside acceptable range of 20 – 50%. - Inadequate ventilation of the Analyzer – ensure that there is at least a 5 cm gap surrounding the Analyzer.
Run takes significantly longer than 60 minutes to complete.	- Ambient temperature outside acceptable range of 20 – 25°C. - Ambient relative humidity outside acceptable range of 20 – 50%. - Inadequate ventilation of the Analyzer – ensure that there is at least a 5 cm gap surrounding the Analyzer.
Only one copy of the patient test result prints.	- Ensure paper tray is not empty.
Patient test result is “Inconclusive”.	- Sample Collection Kit thawed during storage – repeat patient test using a new Sample Collection Kit. - Sample Collection Kit expired – check expiry date and repeat patient test using a new Sample Collection Kit. - Patient was not swabbed correctly – ensure that: i) Three up and down strokes are performed; ii) Blue tip of the swab is visibly wet after swabbing. - Protocol time constraints were not met – ensure that: i) Steps 1-4 are completed within 5 minutes; ii) Steps 5-8 are completed within 5 minutes. - Bubbles present at the bottom of the tubes – ensure that any bubbles present at the bottom of the tube are removed by firmly tapping the tube until they move to the top.

	- Insufficient / improper tapping of tubes – Ensure that tapping is sufficiently firm so that the liquid in the tube moves and makes contact with the blue tip of the inserted swab. - Patient did not rinse their mouth with water prior to sample collection – repeat the patient test. - Ambient temperature outside acceptable range of 20 – 25°C (59 - 77°F). - Ambient relative humidity outside acceptable range of 20 – 50%. - Inadequate ventilation of the Analyzer – ensure that there is at least a 5 cm gap surrounding the Analyzer.
Test results for a single patient are consistently “Inconclusive”.	- Try swabbing the patient with more force. - On rare occasions (less than 1 in 100 patients), the Spartan RX System may be unable to produce a conclusive result. This may be due to factors intrinsic to the patient, e.g., interfering salivary substances.
Test results for multiple patients are consistently “Inconclusive”.	- Sample Collection Kits have thawed at some point during storage - obtain a new batch of Sample Collection Kits. Check that storage location is appropriate (-15°C - 75°C). - If test results are still “Inconclusive” after new Sample Collection Kits have been tested, there may be a problem with the Spartan RX System. Please contact your Authorized Spartan Dealer and a representative will assist you.

11. Proper Disposal of the System

Spartan supports European Union Directive 2002/96/EC regarding the waste of electrical and electronic equipment (WEEE). As such, final holders and resellers can return the electrical and electronic waste of the Spartan RX System free of charge. Arrangements may be made by contacting Spartan at +1.613.228.7756 or support@spartanbio.com.

All used components of the Sample Collection Kit, including swab shafts and tubes, should be disposed of as regular waste in accordance with local and national regulations.

12. Creating a User Account

The notebook in the Spartan RX System comes preloaded with one User Account with the username “Spartan” and the password “RX”. This user account has full administrator rights to the netbook. Therefore, the owner of this account may create other user accounts as per the normal procedure with Microsoft Windows. It is recommended that the administrator change the Spartan account password as per good security practices. The Spartan RX User Interface has been loaded on the netbook and it will automatically run upon login by any user.

Administrators **must not** make any Operating System changes other than modifications to the user account information.