TRUFORMA®

Instructions for Use

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1. OVERVIEW OF TRUFORMA SYSTEM

1.1 System Overview

The TRUFORMA immunoassay analyzer system is intended to detect specific proteins or biomarkers in liquid samples in a point-of-care use model. The system consists of a portable, reusable instrument (Figure 1.1) and a one-time use cartridge containing the assay (Figure 1.2). The liquid sample is obtained from the patient then dispensed into the sample port of the application-specific, single-use cartridge. The cartridge contains a carousel loaded with all the reagents necessary to perform a detection assay. The cartridge is pre-calibrated at the time of manufacturing and contains a bulk acoustic wave (BAW) transducer (biosensor) and two microfluidic channels that direct the sample and the reagents to flow across the biosensor. After the sample is introduced to the cartridge, the cartridge is inserted into the instrument.

The instrument performs several checks while initializing. Once initialized, the instrument manipulates the cartridge to move fluid from the sample port and reagents from the cartridge carousel across the biosensor. As the fluids flow across the sensor, the instrument excites the BAW biosensor with a Radio Frequency (RF) signal and detects changes in the resonance frequency. If the analyte or protein antigen of interest is present, mass will accumulate on the surface of the BAW biosensor, and the frequency will shift. The shift in frequency is translated to a concentration which is relevant for interpreting the presence of the biomarker.

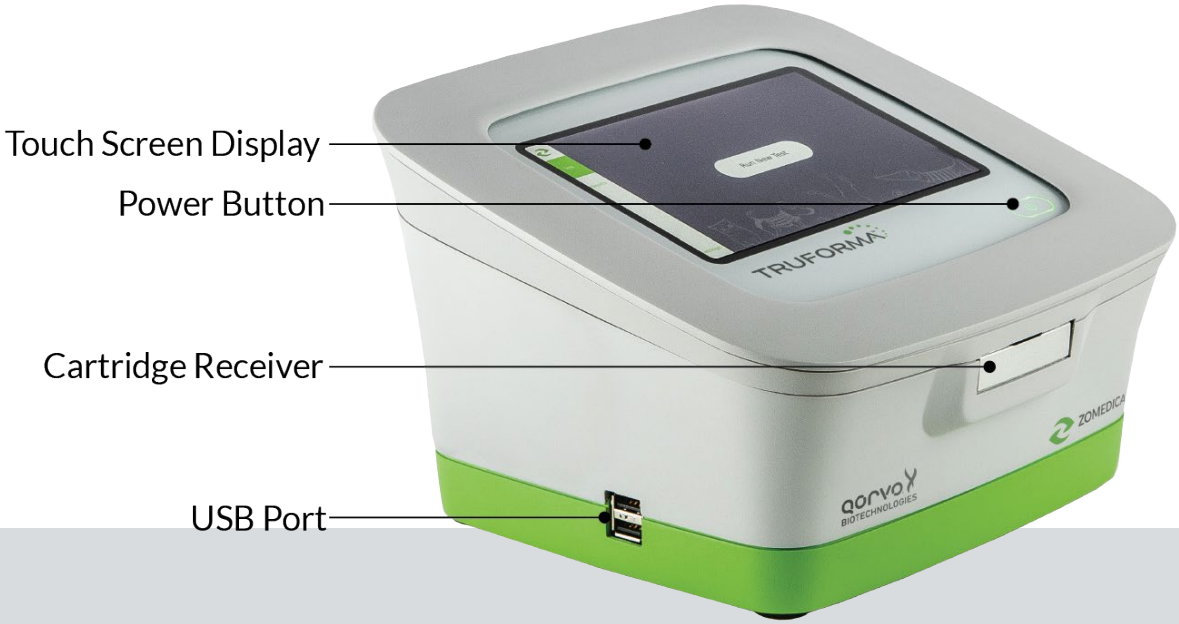

Figure 1.1

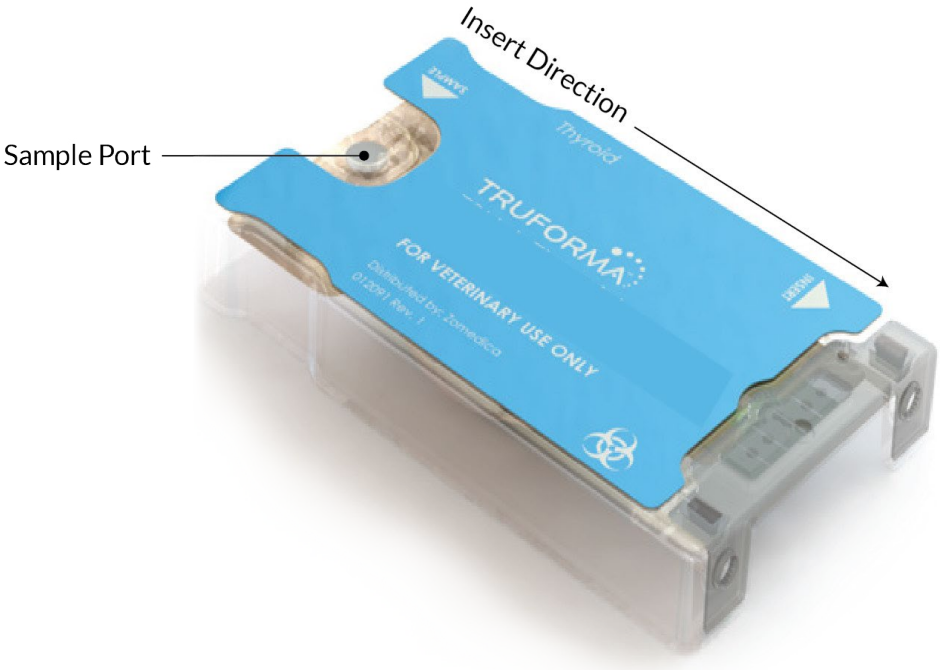

Figure 1.2

1.2 Precautions and Instrument Technical Specifications

- If the equipment is used in a manner not specified in this document, the protection provided by the instrument may be compromised.
- Only use power cords provided by the manufacturer.
- Only use consumables that are within their expiration date.
- Follow universal precautions regarding proper personal protective equipment (PPE) for sample handling and waste disposal to avoid biohazardous exposure.
- In case of any sample/reagent spills, clean the area with 10% bleach solution or a 30% isopropyl alcohol solution.
- 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.

1.3 Carton Contents

Instrument (1)
Power Supply (1)
Instructions for Use (1)
Quick Start Guide (1)
Replacement Air Filters (5)

1.4 Instrument Dimensions

Width: 10 inches
Depth: 9 inches
Height: 6.5 inches
Weight: approximately 7 pounds

1.5 Power Supply Requirements

Output rated: 18.0 volt, 2.22 amperes. 40 watts
Input rated: voltage 100-240VAC, ±10%, 47-63Hz, 1Ø
Current 115VAC: 1.2A, 230VAC: 01.6A

1.6 Input/Output Connections

USB, RJ-45 and power

1.7 Operating Conditions

Altitude: ≤ 10,000 ft above sea level
Temperature: 15 - 30°C (59 - 80°F)
Humidity: 30 – 80%, non-condensing

1.8 Shipping/Storage Conditions

Shipping Temperature: -29 - 60°C (-20 - 140°F)
Storage Temperature: 0 - 45°C (32 - 113°F)

2. SETTING UP THE INSTRUMENT

2.1 Using the Touchscreen

- Do not rest your hand on the touchscreen, as the screen is highly sensitive.
- Tap screen gently while using.
- Never touch the screen with a sharp or abrasive object.

2.2 Installing the Instrument

1. Remove the instrument from the carton and place it on a clean level surface in a well-ventilated area. At least a one-foot clearance surrounding the instrument should be maintained to allow adequate ventilation.
2. Connect the two pieces of the power supply cord together.
3. Attach the DC end of the power supply cord to the back of the instrument, then plug the grounded AC end of the power supply cord into a grounded electrical outlet. **Use only the power supply cord provided with the TRUFORMA instrument– any other power supply may damage the instrument and void the warranty.**

2.3 Powering the Instrument On and Off

1. To power up the instrument, press the power button on the top of the instrument. It takes approximately five minutes to reach the required internal operating temperature of 37 °C (99 °F). Once the operating temperature is reached, the home screen will be visible (Figure 4.2). It is recommended to leave the instrument on for the period of the working day.
2. To power down the instrument, press the power button. Once the button is pressed, a prompt will appear on the screen and the user must select to confirm the power off. If the power button is held for a minimum of three seconds, the instrument will power off without requiring the user to confirm the on-screen prompt.

2.4 Accessing the Instrument Settings

Figure 2.1

From the home screen, the user can access the *Settings* menu to make desired device adjustments. (Figure 2.1).

2.5 Description of Settings Screens

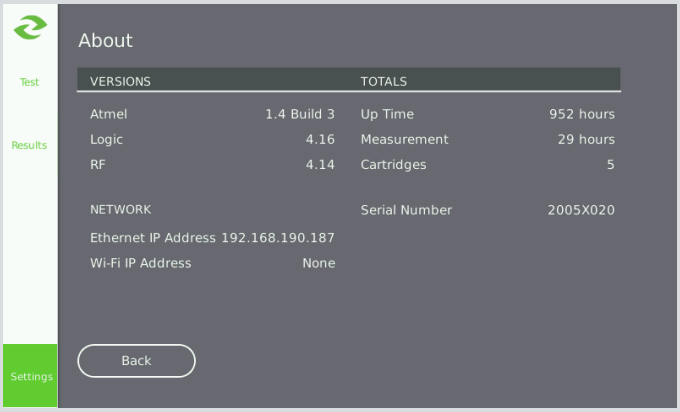

Figure 2.2

The *About* screen provides information on the instrument and associated software. The total instrument uptime, measurement time and number of cartridges run by the instrument are also captured (Figure 2.2).

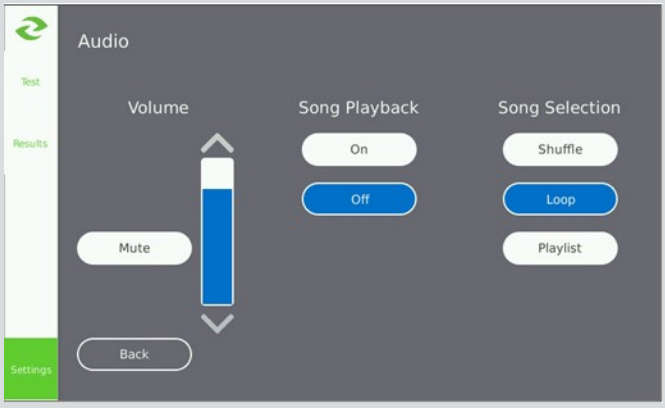

Figure 2.3

The *Audio* screen allows the user to select songs to be played at the completion of each test that is run (Figure 2.3). Volume and song selection can be adjusted on the screen.

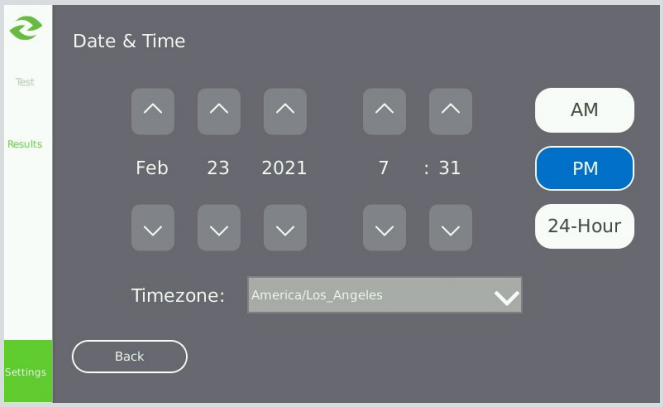

Figure 2.4

The *Date & Time* screen allows the user to set the current date, time, and time zone (Figure 2.4). The current date and time are displayed with each test result.

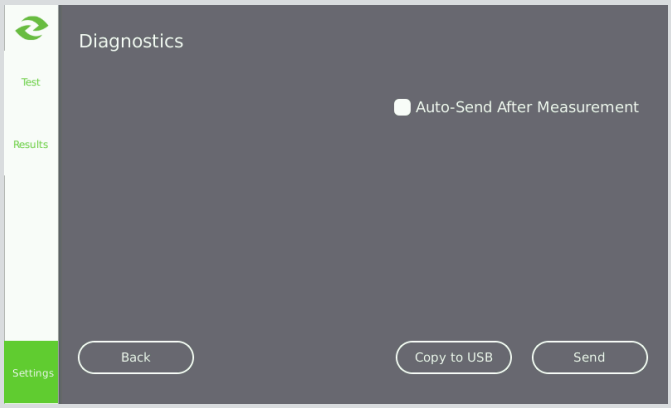

Figure 2.5

The *Diagnostics* screen allows the user to send a file, via Wi-Fi, Ethernet, or USB, in the event the data is required to troubleshoot issues with the instrument and/or cartridge (Figure 2.5).

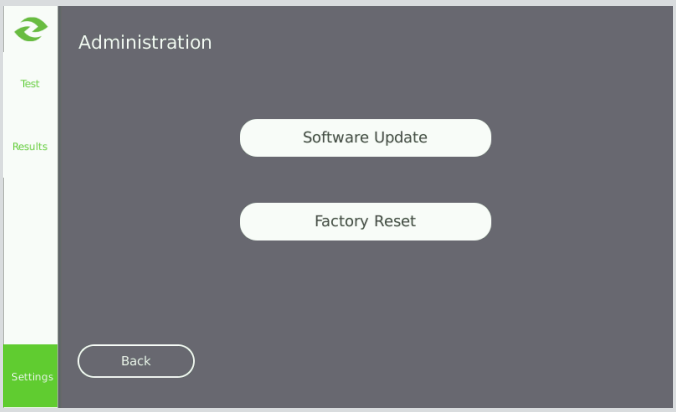

Figure 2.6

The *Administration* screen allows the user to perform a Software Update or Factory Reset (Figure 2.6). Prior to accessing the *Administration* screen, a prompt will appear to enter the Username and Password. Once these have been entered, the machine will navigate the user to *Administration* where the user can update the device software via USB Flash Drive or reset the device to its factory state removing all results.

Figure 2.7

The brightness of the display can be adjusted through the *Backlight* screen (Figure 2.7).

Figure 2.8

It is important to connect the instrument to the internet via Ethernet or Wi-Fi. The TRUFORMA instrument is Wi-Fi enabled. To configure Wi-Fi, access the *Network* screen and enter the Username and Password (Figure 2.8). The instrument supports the Wi-Fi protocol WPA2-PSK with CCMP group cipher. When connected to the internet, results will automatically be sent to MyZomedica.com once a test is complete (Section 6).

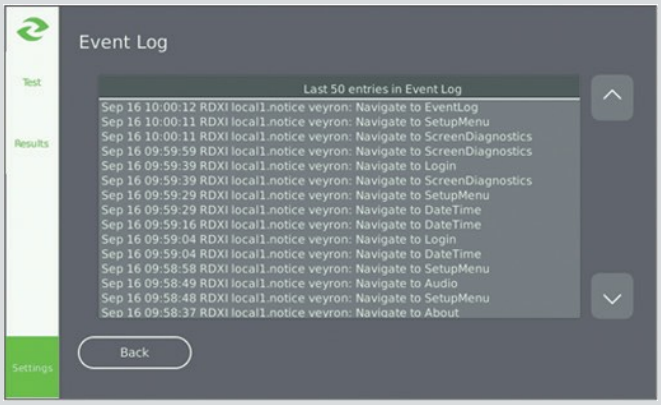

Figure 2.9

The *Event Log* records all events that occur with the instrument, including successful and error-related events (Figure 2.9). The scroll bar on the right of the screen allows the user to view recent events recorded.

3. CARTRIDGE AND SAMPLE PREPARATION

Cartridges are single-use and assay-specific with the assay name clearly marked on the cartridge labels. The cartridge pouch should not be opened unless it is ready to be used. See the cartridge package insert for sample handling instructions. The following steps must be performed to ensure accurate sample analysis:

1. Confirm that the cartridge has not expired by reviewing the expiration date on the pouch label.
2. While wearing gloves to limit contamination, remove the cartridge from the pouch. The pouch and included desiccant can be disposed of as normal waste.
3. Using the supplied bulb pipette, dispense the sample (approximately 150 µL) into the cartridge sample port. Recommended technique for dispensing sample: With sample-filled bulb pipette (Figure 3.1), wet the sample port filter by placing the bulb pipette on top of the sample port filter and lightly squeezing the main bulb of the pipette (Figure 3.2), dispensing a small amount of sample. Lift the bulb pipette off the sample port filter, then dispense remaining sample into sample port as shown in Figure 3.3.
4. Ensure all sample has been absorbed into the sample port with no pooling (Figure 3.4). Sample pooling in the port may be an indicator that the port has been overfilled. Do NOT overfill sample port.
5. Place the cartridge into the instrument by holding the sample port-end of the cartridge with the label facing up and following the direction of the arrow indicating "INSERT" that is displayed on the cartridge label. Gently push the cartridge into the Cartridge Receiver until the instrument accepts and draws in the cartridge.
6. After the test is completed, the results will be displayed on the TRUFORMA system results screen and will also be electronically sent to MyZomedica.com.

Used cartridges and bulb pipettes are to be disposed of in a biohazardous waste container.

Figure 3.1

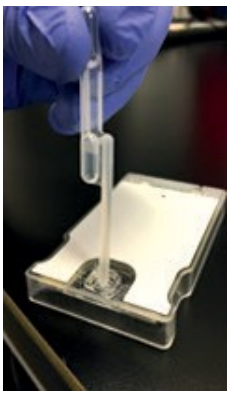

Figure 3.2

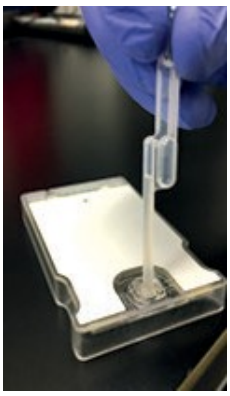

Figure 3.3

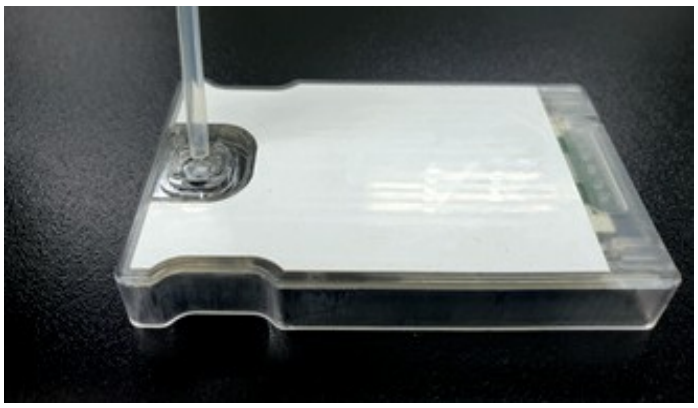

Figure 3.4

4. PERFORMING A PATIENT TEST

Figure 4.1

The graphic interface on TRUFORMA guides the user through entering the required information for each test. After the instrument is powered up it takes about five minutes for the required internal temperature to be reached. The startup screen (Figure 4.1) is displayed during this time.

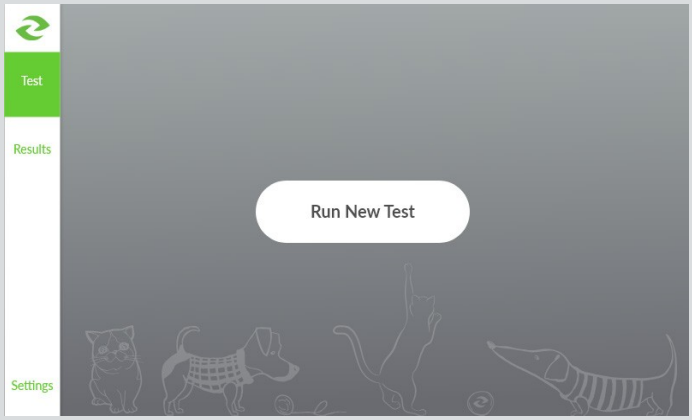

Figure 4.2

Once the instrument is ready to analyze a sample, the home screen will be displayed informing the user that a new test can be performed (Figure 4.2).

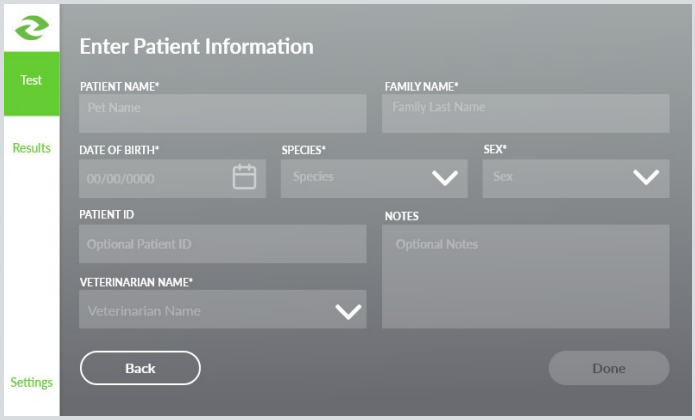

Figure 4.3

If the user selects "Run New Test", the user will then be required to enter the patient information associated with the sample (Figure 4.3). The following information is required to be entered for each sample:

- Patient Name
- Family Name
- Date of Birth
- Species (canine or feline)
- Sex
- Veterinarian Name

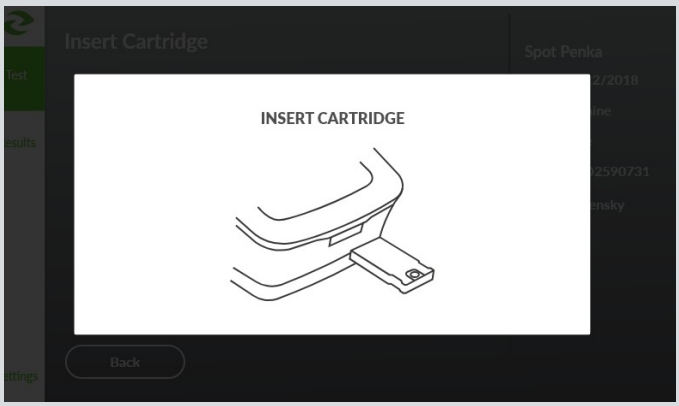

Figure 4.4

After the patient information is entered, a new screen will inform the user to insert the cartridge (Figure 4.4). (See section 3 for how to insert cartridge.)

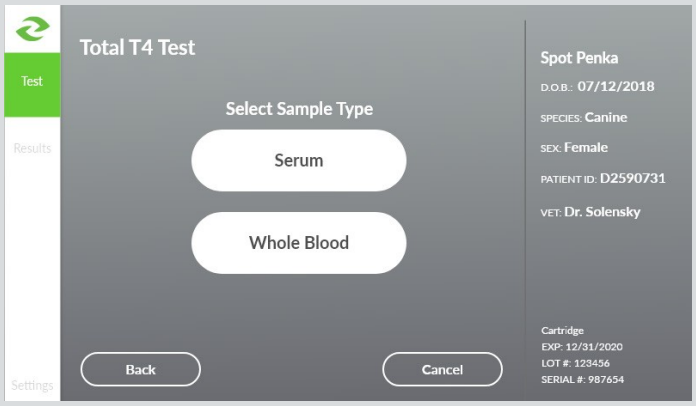

Figure 4.5

The cartridge has a Radio Frequency Identification (RFID) tag that informs the instrument which test to perform. The user, however, still needs to select the sample type (Figure 4.5).

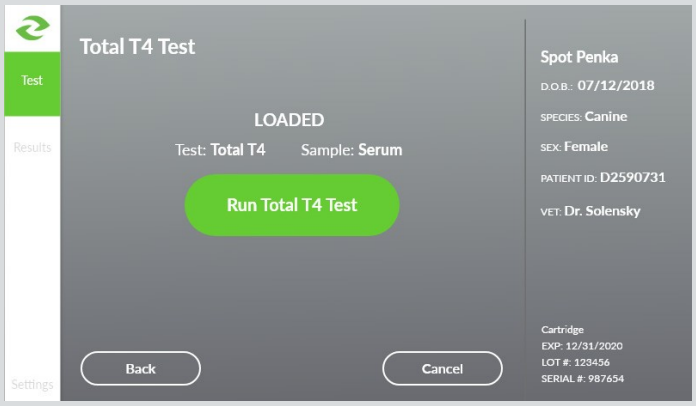

Figure 4.6

The user is then required to confirm and run the test (Figures 4.6 and 4.7).

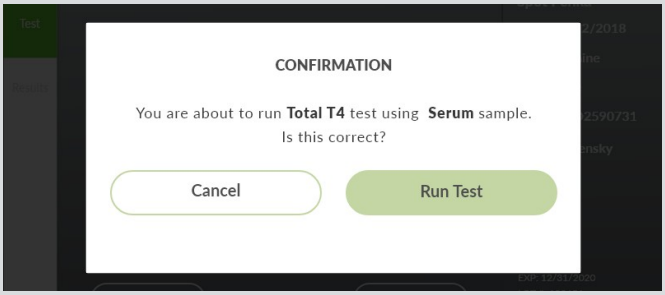

Figure 4.7

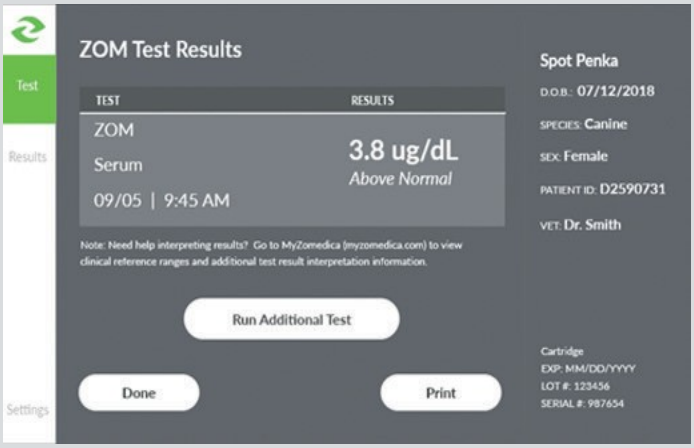

Figure 4.8

After the analysis is complete, the results screen is presented (Figure 4.8). For most assays the test results will be reported as "Normal" if within the reference range, "Above Normal" if above the reference range, and "Below Normal" if below the reference range of the assay. If the value is outside of the measurable range of the assay, the result will be reported as greater than the upper Limit of Quantification (>LOQ),
less than the lower Limit of Quantification (< LOQ), or less than the Lower Reportable Limit (< LRL). Results are automatically sent to MyZomedica.com for interpretation. Once the sample is analyzed, another sample from the same patient can be analyzed by selecting Run Additional Test, then preparing and running a new assay cartridge.

5. REVIEWING PRIOR RESULTS

Figure 5.1

Prior results obtained from the instrument can be reviewed by activating the Results button on the left menu screen. The scroll bar on the right of the screen allows the user to view the last 100 results obtained (Figure 5.1).

6. VIEWING RESULTS REMOTELY

6.1 View Test Results on MyZomedica.com

Results can be viewed remotely by navigating to www.MyZomedica.com. MyZomedica.com is a web-based resource for veterinary teams to review test results, access diagnosis decision support materials, and more. MyZomedica.com can be accessed from any internet connected tablet, laptop, or desktop computer using the following browsers:

- Chrome
- Edge
- Internet Explorer 11
- Safari

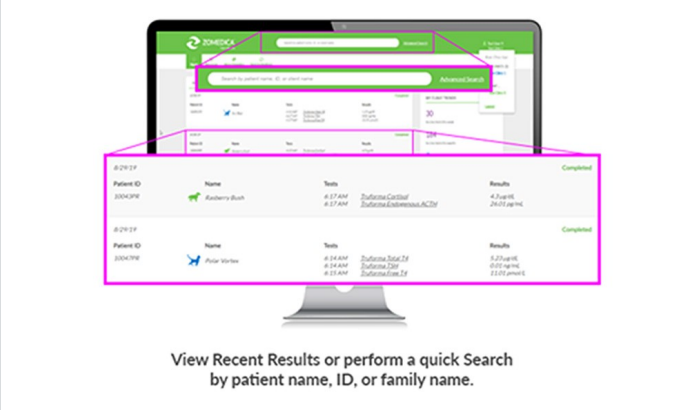

Figure 6.1

The most recent test results will be displayed on the home screen. Select the test result to view result details and additional information regarding TRUFORMA test reference ranges. The user can locate the most recent results on the home page or search for historical results (Figure 6.1).

6.2 Additional Help

Check out the Help Guide on MyZomedica.com. Additional instructional material is also available under the Resources tab on MyZomedica.com.

7. QUALITY CHECKS

The TRUFORMA instrument does not require regularly scheduled Quality Control (QC) runs or calibration due to the unique attributes of the BAW technology and cartridge design.

- Unlike optical sensors, the BAW sensor does not require alignment. TRUFORMA performs a power on self-test and run time calibration on each cartridge. As a result, there is negligible instrument-to-instrument variability and drift, eliminating the need for regular maintenance.
- The software includes test limits on all parameters for each step of the running assay. If a cartridge or instrument runs outside of these set limits, an error is triggered, stopping the test.
- Each lot of cartridges (and included reagents) is factory calibrated. The calibration is encoded on the cartridge RFID, eliminating the need for user calibration.
- Each cartridge contains a reference sensor in addition to the test sensor that is used as a built-in control to remove run-to-run noise associated with sample viscosity, temperature variation, etc. TRUFORMA completes a power on calibration before running a cartridge. No user calibration is needed or possible.

8. PERIODIC MAINTENANCE AND SERVICE

8.1 Instrument Reboot

The instrument should be powered off and powered back on once a week.

8.2 Cleaning the Outer Case

The exterior of the instrument should be cleaned on a weekly basis. Do not apply detergents or solutions directly onto the outer case. Clean the outer case with a soft cloth, dampened with a mild, non-abrasive detergent or cleaning solution such as 10% bleach solution or 30% isopropyl alcohol solution.

8.3 Cleaning the Touchscreen

Clean the screen periodically using a soft, lint free cloth dampened with glass-cleaning fluid.

8.4 Replacing the Air Filter

The air filter should be replaced monthly regardless of how often the instrument is in use. As shown in the figure below (Figure 8.3) the back of the instrument contains a fan filter (part number FILI-8000-A) and retainer (part number FANI-7000-A).

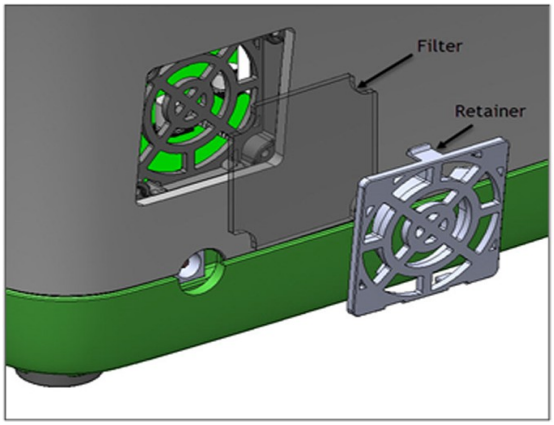

Figure 8.3

To access the filter, first remove the retainer. Use a flat-head screwdriver to remove the retainer, taking care to ensure it can be replaced in the same orientation. Set the retainer aside and use the same flat-head screwdriver to remove the used filter. Discard the used filter as normal waste, then insert a new filter. The filter is symmetrical in shape and has no designated front or back. Once the new filter is in place, replace the retainer in its original orientation.

8.5 Returning the Instrument for Service

If the instrument needs to be returned for service, please contact Zomedica Customer Success at 734-369-2555, Option 1.

8.6 Instrument Disposal

Please perform appropriate cleaning, handling, and disposal of industrial and electronic waste in accordance with local regulations. DO NOT dispose of the instrument in the trash.

9. SYMBOLS AND LABELS

The following symbols are found on the TRUFORMA and cartridges.

Symbol	Explanation	Symbol	Explanation
	Protect instrument from moister		Indicates the date after which the cartridge is not to be used (Expiration Date)
	Consult the instructions for use		Indicates that the cartridge is intended for single use
	Indicates the temperature range for use/storage		Indicates possible biological risk
	Indicates serial number so that the instrument can be identified		Underwriters Laboratories Approved
	Indicates the manufacturer's product number so the instrument can be identified		Federal Communications Commission
	In-Vitro Diagnostic Medical Device		

9.1 Instrument Labels

There is a label on the bottom of the instrument as well as one on the external carton. The labels contain the serial number, part number and other information related to instrument storage and use environments.

9.2 Cartridge Labels

There is a label on the cartridge and on the external pouch indicating which assay the cartridge will perform. The pouch label includes information specific to lot number, product number, product storage, and expiration date.

10. TROUBLESHOOTING

If an issue with the instrument or cartridge is identified, an appropriate error code will be displayed on the instrument screen.

10.1 Cartridge Error Codes

The following error codes are associated with cartridges. Refer to the Error Description for the first steps in troubleshooting. If the error persists, contact Zomedica Customer Success.

Error Code	Error Name	Error Description
0010	Cartridge Cannot be Read	The RFID on the cartridge cannot be read. Insert a new cartridge. If the error persists, contact Zomedica Customer Success.
0020	Cartridge is Incompatible	The cartridge is not supported by this instrument. Insert a supported cartridge.
0030	Cartridge is Expired	The cartridge has expired and cannot be used for measurement. Insert an unexpired cartridge.
0040	Cartridge has been Used	The cartridge has been previously used and cannot be used for measurement. Insert an unused cartridge.
0080	Insufficient Sample	The cartridge did not have a sufficient sample amount. A new cartridge needs to be used. Confirm that the pipette is full and sample is completely dispensed into the new cartridge.
0081	Liquid Dispense Error	Conductivity was out of range during liquid dispense. Try repeating the test with a new cartridge. Contact Zomedica Customer Success if the error persists.
0090	Insufficient Reagents	The cartridge did not have sufficient reagents to complete the measurement. Try repeating the test with another cartridge. Contact Zomedica Customer Success if the error persists.
0130	Conductivity Error	Bad Solution Conductivity. Try repeating the test with a new cartridge. Contact Zomedica Customer Success if the error persists.

In these scenarios the error code will be presented on the screen and the cartridge will be ejected from the instrument. Accepting the error code will take the user back to the *Patient Information* screen where new information can be entered, and a new cartridge analyzed.

10.2 Instrument Error Codes

The following error codes are associated with the instrument. Refer to the "Error Description" for the first steps in troubleshooting. If the error persists, contact Zomedica Customer Success.

Error Code	Error Name	Error Description
0050	Instrument is Tilted	The instrument cannot be tilted during measurement. Ensure the instrument is within 30 degrees of level. Repeat the test with a new cartridge. Contact Zomedica Customer Success if the error persists.
0060	Instrument Temperature is Too Hot	The instrument is too hot to perform a measurement. Check that the fan filter is clean and not blocked. Try placing the instrument in a cooler location. Repeat the test with a new cartridge. Contact Zomedica Customer Success if the error persists.
0100	Pressure Error	An error is detected with the Pump Head pressure. Try repeating the test with a new cartridge. Contact Zomedica Customer Success if the error persists.
0110	Thermal Error	An error is detected with an over or under temperature condition. Check that the fan filter is clean and not blocked. Ensure the instrument is in a location where the ambient temperature is within specified operating conditions. Repeat the test with a new cartridge. Contact Zomedica Customer Success if the error persists.
0120	Cartridge Error	The cartridge is not fully engaged. Try repeating the test with a new cartridge. Contact Zomedica Customer Success if the error persists.
0140	BAW Hardware Error	The BAW sensor is not functioning correctly. Try powering off the instrument and repeating the test with new cartridge. Contact Zomedica Customer Success if the error persists.
0150	Software Corrupted	The instrument has detected that the software has unexpectedly changed. This may be due to a hardware error. Measurements cannot be performed. Turn the instrument power off and back on. Contact Zomedica Customer Success if the error persists.
0170	Conductivity Sensor Error	An error is detected with the conductivity sensor. Turn the instrument power off and back on. Contact Zomedica Customer Success if the error persists.
0180	Motor Error	An error occurred while running a motor. Repeat the test with a new cartridge. Contact Zomedica Customer Success if the error persists.

Error Code	Error Name	Error Description
0220	Low Temp Error	The instrument was not able to warm up to measurement temperature within five minutes. Turn the instrument power off and back on. If that does not work, replace the air filter then restart instrument. Contact Zomedica Customer Success if the error persists.
0230	POST Error	The instrument detected an error during power-on self-test. Measurements cannot be performed. Turn the instrument power off and back on. Contact Zomedica Customer Success if the error persists.
0250	Data Transmission Error	The instrument was unable to transmit Diagnostics data. Verify the instrument has an Internet connection and the Diagnostics settings are correct.
0300	Login Error	Incorrect login credentials.

10.3 Connection Errors

In order to connect to an internet-exposed network via an Ethernet interface: ensure the IP automatic update setting is on. This setting option can be found by selecting “Settings” on the side bar, then selecting “Network”, then selecting “IP”, to turn “Auto IP” on.

If the user is connected to an Ethernet interface, but still unable to access the internet: ensure the WI-FI setting is turned off. This setting option can be found by selecting “Settings” on the side bar, then selecting “Network”, then selecting “WIFI”, to turn “WIFI” off.

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