

User Manual Immunodiagnostic Analyzer Element i+

For Veterinary In-Vitro Diagnostic Use Only



Introduction

Thank you for purchasing the Element i+™ Immunodiagnostic Analyzer.

The Element i+ Immunodiagnostic Analyzer is a veterinary diagnostic device used to perform immunological analyses using proprietary Element i+™ Cartridges.

This product is for veterinary use only.

Before using this equipment, please read this manual carefully and follow the precautions for correct operation.

The Element i+ Immunodiagnostic Analyzer is manufactured for Heska Corporation by MBio Diagnostics, Inc. (MBio), Boulder, Colorado, USA.

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1 Safe Usage and Handling Precautions

This section contains safety precautions which must be followed for safe operation of the Element i+ Immunodiagnostic Analyzer (also called Element i+ Analyzer in this manual). The Element i+ Analyzer is used in conjunction with Element i+ Cartridges. Please refer to instructions included in this manual and contained in the Quick Steps Guide for test-specific information.

1.1 Precautions before Operating this Equipment

CAUTION

Before using this equipment, read this Product Manual carefully to ensure correct operation of the equipment.

CAUTION

Whenever operating this equipment, observe the precautions described in this manual. Failure to do so may result in injuries, cause property damage, or produce incorrect results.

CAUTION

The Element i+ Analyzer is for veterinary use only. The intended use is to quantify biological markers in animal serum or plasma samples using Element i+ Cartridges. Do not use the equipment for other purposes. Please refer to instructions included in this manual and contained in the Quick Steps Guide.

CAUTION

This equipment is to be operated by personnel appropriately trained for its intended use and correct operation.

1.2 Biohazards and Waste

Wear appropriate personal protective equipment for the sample type being tested when using the Element i+ Analyzer.

Used cartridges, tips, and contaminated swabs or cloths used for cleaning equipment are potentially infectious waste and disposal must follow applicable local, state, or federal regulations.

When discarding the equipment that may be contaminated with sample, disposal must follow applicable local, state, or federal regulations.

When handling samples and cleaning the equipment, always follow biohazard procedures (e.g., wear gloves, lab coat, and eye protection), referring to the sample handling rules of your facility.

1.3 Electrical Hazards

The power supply voltage applied to the equipment is AC100–240 V–1.5 A, 47–63 Hz. The Element i+ Analyzer is only to be supplied power from the power supply included in the package. To avoid electrical shock, observe the following precautions:

- Avoid installation sites where water or other liquids may splash on the equipment.
- Make sure that the equipment is properly grounded to a protective earth lead for indoor wiring.
- Make sure that all cables have been properly connected.

Plug the power cable into an outlet with a grounding receptacle.

When plugging the cable in or removing it from an outlet, be sure to hold onto the plug, not just the cable, to prevent damage to the cable.

The equipment is not designed to be user serviceable. Do not remove covers or other parts to avoid electrical shock or injury from moving parts.

1.4 Declaration of Conformity / Electromagnetic Compatibility (EMC)

The Element i+ Immunodiagnostic Analyzer complies with the Essential Requirements of the Low Voltage Directive 2014/35/ EU and with EMC Directive 2014/30/EU. The Analyzer was tested according to EN 61010–1, UL 61010–1, and to EN 60825–1. The Element i+ Analyzer complies with Part 15 of FCC regulations and FDA regulations 21 CFR 1040.10 and 1040.11, except for deviations pursuant to Laser Notice No. 50.

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

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.

FCC RF Radiation Exposure Statement: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure limits. This transmitter must not be co-located or operating with any other antenna or transmitter.

1.5 Laser Warning

The equipment includes an embedded laser. The equipment complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

The Element i+ Analyzer is considered a Class 1 laser product per IEC 60825–1: 2007. Do not open the Element i+ Analyzer. The Element i+ Analyzer has no user serviceable parts. Any unauthorized opening of the instrument can cause potential hazards, can expose hazardous laser radiation, and will invalidate warranty claims.

The Element i+ Analyzer is a Class 1 laser device that has the following protective measures: a light-tight enclosure and a safety interlock which prevents the internal laser source from emitting should the cartridge slot door be opened when a cartridge is not present.

If the enclosure is damaged, immediately stop using the analyzer to prevent possible exposure to hazardous laser radiation.

CAUTION

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.


1.6 Other Safety Warnings

 **EXPLOSIVE HAZARD:** Do not use flammable and explosive gas around the equipment.

 Do not place fingers into the Element i+ Analyzer cartridge opening.



Cartridges are single use only. Do not reuse cartridges. Used cartridges should be handled as waste and disposed of according to all local laws and regulations for disposal of waste.

 Only insert cartridges supplied by Heska Corporation. Do not insert damaged cartridges into the analyzer.

1.7 Table of Symbols

 FCC mark



Recycle



Caution, consult accompanying instructions for safety related information



Consult instructions for proper use



DC electrical power rating



Biological risks



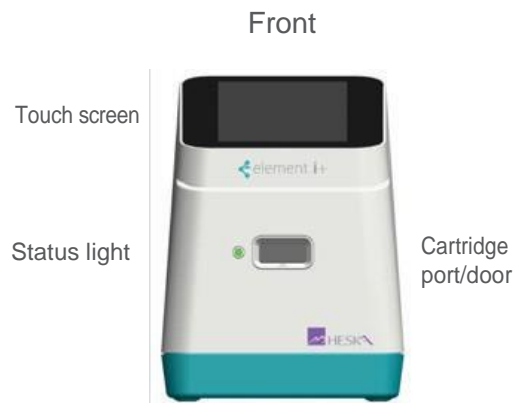
Serial number



Catalog number

2 Overview

2.1 Components and Labeling



Analyzer label found on the bottom of analyzer



2.2. Specifications

Detection System	Fluorescence Immunoassay
Cartridge	Element i+ compatible
Procedure time	Specific to test cartridge
Instrument electrical power rating	+15 DC/4.65 A max
Wall Power	100–240 V~ —1.5A _{max} , 47–63 Hz, Overvoltage Category II
Laser classification	Laser Class 1 (per IEC 60825–1)
Operating temperature	59–86°F (15–30°C) indoors
Operating relative humidity	25–65%, non-condensing
Storage temperature	32–113°F (0 –45°C)
Storage humidity	5–95%, non-condensing
Physical dimensions	6.5 in (W) x 8.75 in (H) x 9 in (L) 165 mm (W) x 222 mm (H) x 229 mm (L)
Weight	5.51 lbs (2.5 kg)
Pollution Degree	2 max
Altitude	Up to 2000 meters

2.3. Calibration

The Element i+ Analyzer is factory calibrated and does not require any further calibration or verification operations.

3 Transport, Unpacking, and Installation

3.1 Packaging

The Element i+ Analyzer ships in a custom-designed box. Transportation of the analyzer must only be in this protective box.

3.2 Unpacking

- Unpack the Element i+ Analyzer and place on a level, stable surface. Inspect for any obvious signs of damage. Report any damage immediately.
- Remove protective film from touchscreen if present.
- Before using, allow the analyzer to equilibrate to the surrounding temperature for at least 30 minutes.

3.3 Parts List


The following items are supplied with your Element i+ Analyzer:

- Element i+ Analyzer
- Power supply and cord
- Fixed-volume (100 μ L) pipettes

4 Analyzer Operation

4.1 Turning the Analyzer On and Off

The power toggle button is located on the lower back side of the analyzer. Press and release the button one time. The indicator light on the front of the analyzer will turn on and go into “breathing” mode during the boot-up sequence. When initially powered, the analyzer will run through a series of self-diagnostic checks. When boot-up is complete, the indicator light will glow steady and the login screen will appear.

The analyzer should be powered down using . If a hard re-start is required, hold the power button on the back of the analyzer in for 7 seconds.

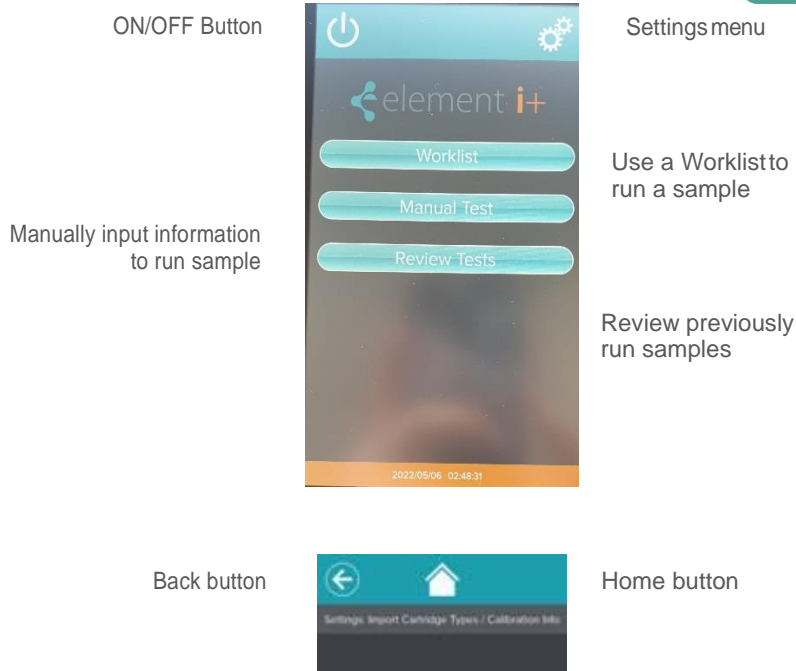
4.2 Main Screens and Controls on the User Interface

Power on/off



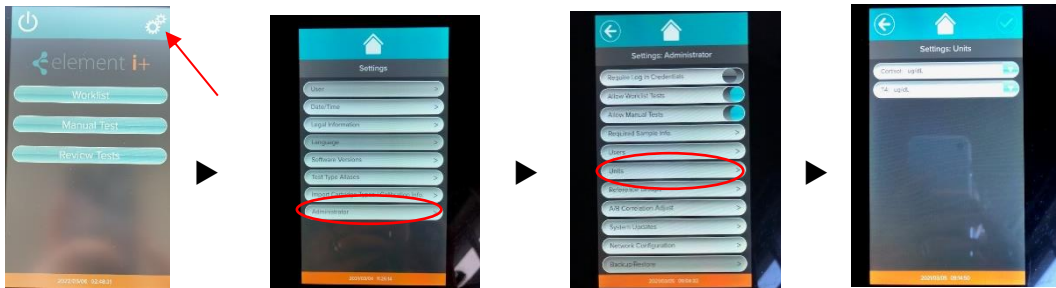
Check box is enabled on all screens when required data entry is complete

Keyboard appears when a data entry field is selected



4.3 Adjust Units and Reference Ranges

- If you want to set the units, you must first go to the settings. Then go to the Administrator and there you will find the Units button. In this menu you can change the units as you need them.



- If you want to set the reference areas you must first go to the settings. Then go to the administrator and there you will find the button reference groups. In this menu you can change the reference groups of the different species as you need them or even add them.



4.4 Import a Cartridge Type/Calibration Information

Each lot of Element i+ Cartridges is factory calibrated and has a unique, lot-specific calibration file that must be loaded into the analyzer software. Lot-specific calibration data are contained on an electronic Cartridge Definition File (CDF) written to a USB flash drive supplied with each cartridge box. The electronic data file will have the format #####.cdf.xml. Cartridges cannot be read on the analyzer until this file is loaded. Use the following procedure to load the CDF.


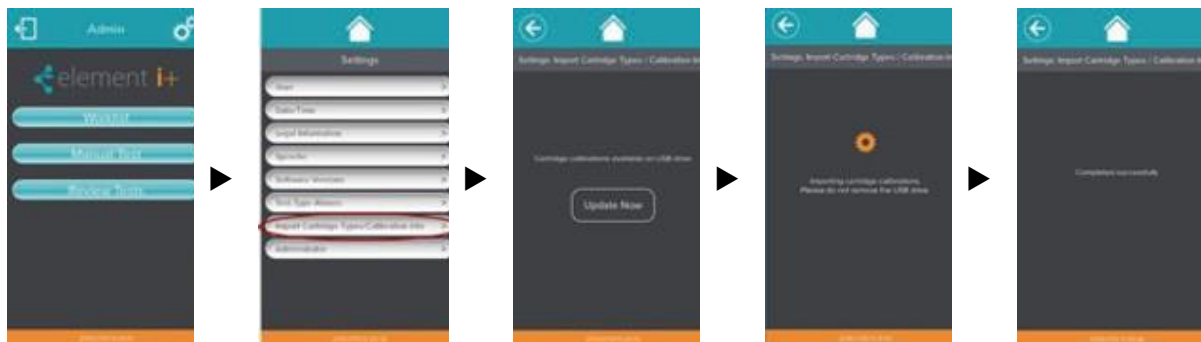
1. Insert the provided USB flash drive (Figure 1) with cartridge lot calibration information into any of the four USB ports on the back of the analyzer. Figure 2
2. From the Home screen, touch .
3. On the Settings screen, touch IMPORT CARTRIDGE TYPES/CALIBRATION INFO.
4. The analyzer will detect the cartridge calibration information on the USB drive.
5. Touch CHECK USB DRIVE to import the calibration information. The analyzer will import the cartridge calibrations. Do not remove the USB drive until the screen displays "Completed successfully." Then touch the Home icon and remove the USB drive.



Figure 1

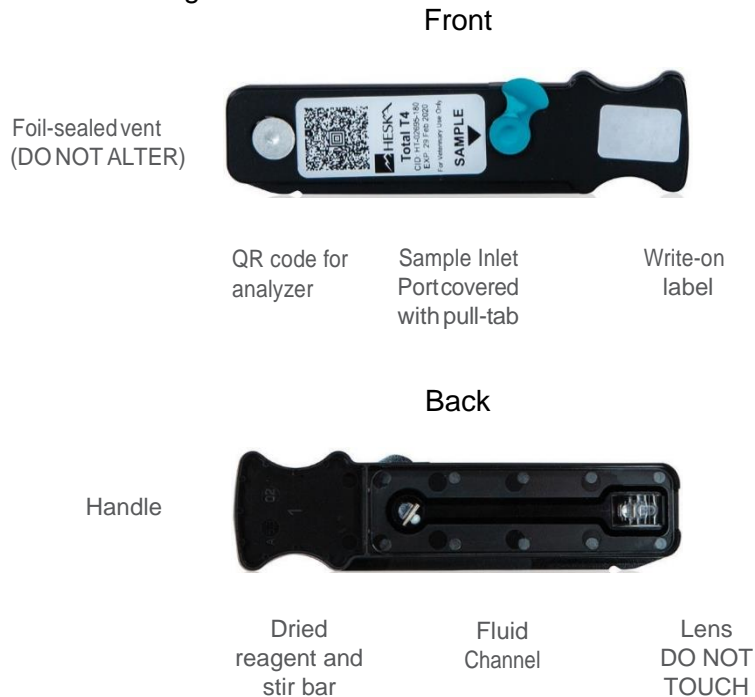


Figure 2



4.5 Cartridge Overview

The Element i+ Analyzer is designed to run exclusively with test-specific Element i+ Cartridges. Each production lot of cartridges is factory calibrated. Lot-specific calibration data are contained on an electronic Cartridge Definition File (CDF) written to a USB flash drive supplied with each cartridge box.



AVOID TOUCHING THE CARTRIDGE BOTTOM • THE ANALYZER READS THROUGH THE BOTTOM

NOTE:

- Use the handle when manipulating the cartridge.
- Keep the bottom of the cartridge free from fingerprints, smudges, and other contamination. Fluorescence illumination and imaging are through the clear plastic component on the bottom of the cartridge.



4.6 Running a Sample

This section assumes that you have logged into the analyzer and successfully loaded the Cartridge Type/Calibration Info for the lot of Element i+ Cartridges you will be using (see previous sections).

Materials

- Cartridge – Store at 35.6–77.0°F (2–25°C)
- 100 µL fixed volume pipette (provided with analyzer)
- Disposable pipette
- Element i+ Analyzer with Cartridge Definition File already loaded
- Sample

4.7 Running a Test

1. Obtain a serum or lithium heparinized plasma sample.
2. On the main screen, touch Worklist or Manual Test. Figure 3
3. In Worklist Mode, confirm that all fields have correct information and then touch  to proceed. In Manual Mode, enter sample information in the required fields. Touch  to proceed. Figure 4

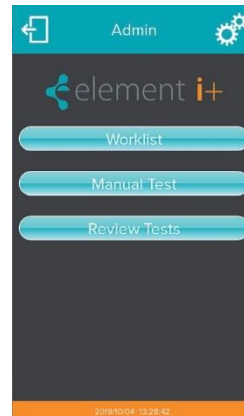


Figure 3

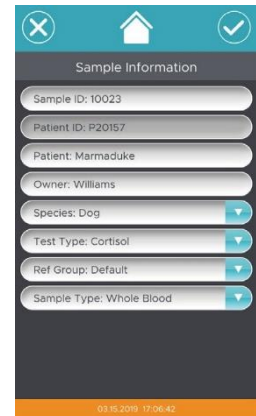


Figure 4

4. Open the pouch by tearing at the notch. Carefully remove the cartridge by the handle and place it on a flat surface. Figures 5 & 6

NOTE:

Do not touch the bottom of the cartridge.

NOTE:

If the cartridge was refrigerated, allow to warm to room temperature for at least 15 minutes before opening the pouch.

NOTE:

Cartridge must be used within 1 hour of removal from pouch.



Figure 5



Figure 6

5. With the cartridge flat on the bench, remove the pull-tab from the sample inlet port and discard. Use the cartridge handle to steady the flat cartridge while removing the pull-tab. Figure 7



NOTE:

Cartridge must be used within 15 minutes of removing pull-tab.

6. NOTE INSTRUCTIONS FOR T4 ONLY (OTHER TESTS SKIP TO 7.) Dilute patient sample using supplied Heska T4 Diluent.
 - a. Use supplied 100 µl fixed volume mini-pipette to aspirate 100 µl of serum or plasma sample.
 - b. Flick or tap the Heska T4 Diluent tube to ensure there is no liquid adhering to the Diluent tube inner cap surface.
 - c. Dispense the full 100 µl patient sample into the Diluent tube. Ensure proper mixing by then aspirating and dispensing 5x using the same pipette tip.
 - d. Aspirate 100 µl of the diluted sample using the mini-pipette and same pipette tip, insert the pipette tip into the T4 cartridge sample inlet port hole, and dispense the full amount into the hole. (Skip to 8.)

- Affix a tip to the 100 μ L fixed volume mini-pipette. Aspirate 100 μ L of sample, insert the pipette tip into the inlet port hole, and dispense the full sample amount into the hole. Figure 8



Figure 8

- Touch ✓ on the Prepare Sample screen to open the analyzer door. Figure 9. Insert the cartridge until you feel a click and hear a beep. Figures 10 & 11



Figure 9



Figure 10



Figure 11

- The test will run automatically.

A status bar and countdown timer will display on the screen and the indicator light on the front of the analyzer will blink to indicate a test is running. Figure 12

NOTE: To cancel during the run, touch X at the upper right of the screen.

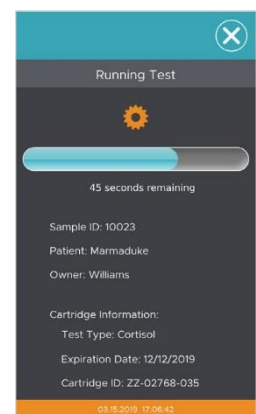


Figure 12

10. Upon test completion, patient results will display on the screen. Touch HOME to exit results screen. Figure 13

The screen will provide an indication when it is safe to remove the used cartridge. Figure 14

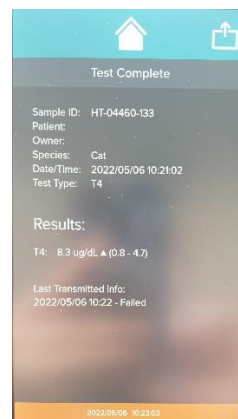


Figure 13

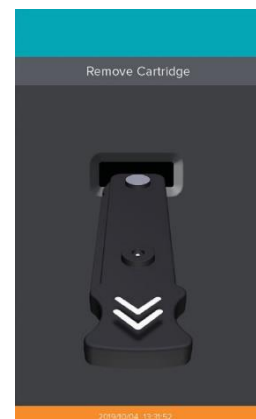
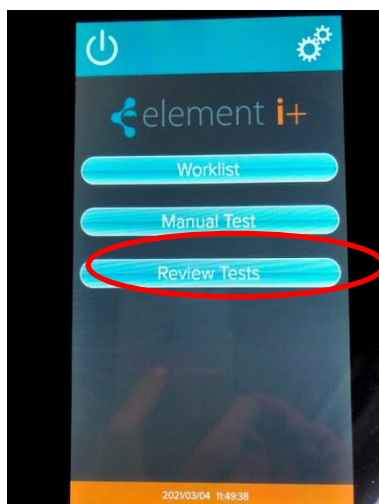


Figure 14

4.8 Review Test Results



1. Click on the button "Review Tests"
2. Now you can see all your Test results and you can sort them by Patients Name, Owner or Date.
3. Click to one test you want to review it

5 Maintenance and Cleaning

The Elementi+ Analyzer is a maintenance-free instrument and has no user serviceable parts. When encountering analyzer failures or damage, please contact service.



CAUTION

Do not try to open the Analyzer for cleaning or servicing.

5.1 Cleaning Outside Surfaces

Use a soft cloth to clean the Element i+ Analyzer. If required, the analyzer can be cleaned by wiping with a mild detergent, 70% solution of ethanol or isopropyl alcohol in water, or 10% bleach solution.



CAUTION

Do not directly spray the Analyzer with cleaner. Apply cleaning solutions to a cloth and then wipe the instrument.

5.2 Cleanable Air Filter

The air filter on the back of the Analyzer should be cleaned periodically. Remove the snap cover and then simply pull the foam filter out of its housing. Remove gross contaminants and clean by running under warm water. Allow the filter to dry before inserting back in the instrument.

6 Troubleshooting

6.1. Error Handling

When an error occurs, a dialog box appears displaying the error message. The table below describes the warnings and error messages that may be displayed, as well as suggested actions to take. If you are unable to resolve the problem by following this troubleshooting guide, please contact your local Technical Support Services.

6.2. Table of Common Error Messages

Error Message	Error Type	Action
The inserted cartridge has already been run.	Used cartridge.	A cartridge can only be run one time. Get a new untested cartridge and re-run the sample.
The inserted cartridge has expired.	Cartridge shelf life exceeded.	Dispose of expired cartridge and run sample on a non-expired cartridge.
The inserted cartridge contains an invalid barcode.	Did not recognize the barcode.	Select a new cartridge.
Unable to read the barcode from the inserted cartridge.	Barcode not read.	Verify that barcode is not damaged and retry the cartridge. If error persists, select a new cartridge.
The inserted cartridge is of an unknown test type.	Cartridge Definition File not loaded in Analyzer Software.	Load the Cartridge Type/Calibration Info for that specific cartridge lot (see instructions in this User Manual). The Cartridge Definition File is provided on a USB flash drive in cartridge box or contact your local Technical Support Services.
Wrong Cartridge Inserted – Do you wish to proceed?	Cartridge inserted does not match requested test.	Update the sample information to indicate test type matching the cartridge type.
Calibration information needed.	Instrument has no record of cartridge lot information.	Install the corresponding Cartridge Definition Files for the cartridge lot being used.
There was an unknown error processing the cartridge.	General error.	Must run a new cartridge. If the problem repeats, re-start the instrument.

Error Message	Error Type	Action
Error connecting to hardware.	Internal instrument communication.	Restart the instrument. If problem persists, contact Heska Technical Support Services.
Unexpected error editing reference range.	General error.	Confirm reference ranges are set in the Administrator settings.
Unexpected error deleting reference range.	General error.	Confirm reference ranges are set in the Administrator settings.
Auto communication failed, please check connection.	Network not connected.	Verify the network is available and that the Ethernet cable, or Wi-Fi is connected and configured properly.