

# element AIM

Automated Artificial Intelligence Microscopy Product Manual



## Manual Introduction

This manual contains the following sections.

Preface: General introductory information and explanations of:

- Using this manual
- Contents overview
- Definitions and abbreviations
- Symbols

Safety: Explains the safety labels and precautions.

- Intended use
- User profile
- Application limits
- Information on product liability
- Warnings for intended use
- Safety instructions on the device
- Product description
- Product overview
- Delivery package and contents
- Features
- Analyzer identification

Installation: How to connect power and USB cables and how to accomplish the basic set-up.

Operation: Contains instructions for operating the analyzer.

Maintenance and Care: Explains how to perform basic care activities and regular maintenance tasks performed by Heska's Field Support Team, such as optics cleaning. It also contains general advice for storage and shipping.

Troubleshooting: How to troubleshoot error messages that appear on the display, and how to gather device information before you call service.

Transport, Storage and Disposal: Explains how to transport the analyzer to its intended location, as well as storage and disposal guidelines.

Technical Specifications: Lists the technical data for the device described in this manual.

Index: Lists keywords in alphabetical order, with pointers to pages where they occur.

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### 1.1 Using this Manual

Before starting to use the Element AIM® Automated Automated Artificial Microscopy Analyzer (Element AIM) read through this manual carefully and follow the instructions. Failure to follow safety information and instructions for use will result in voiding of the manufacturer warranty.

### 1.2 Definitions, Acronyms and Abbreviations

#### Acronyms

IFU Instruction For Use

RPM Revolutions Per Minute

RCF Relative Centrifugal Force: g-force in  $m/s^2$

### 1.3 Symbols



CAUTION or WARNING



Electric Shock



Biological Hazard



Important Information



Pinch Point: Risk of Entanglement



Refer to Instruction Manual

### 1.4 Safety Warnings

Not following these safety instructions can lead to hazardous situations that, if not avoided, could result in death or serious injury. Please observe all safety instructions.

#### Intended Use

The Element AIM is used for analysis of veterinary species' urine and fecal samples in specifically designed and approved cartridges.

The analyzer is exclusively intended for use indoors in a dust-free and stationary environment. All country-specific safety requirements for operating electrical equipment in the laboratory must be observed.

The analyzer and accessories may only be operated by trained personnel.

Before using the analyzer, carefully read this instruction manual in full to familiarize yourself with safe use and operation.


The safety of this analyzer is not guaranteed beyond the service life of the instrument (estimated 7 years from installation).

### 1.5 Product Liability Information

In the following situations, the protective systems and design of the analyzer might be affected. Liability for any resulting damage or personal injury is transferred to the owner:

- The analyzer is not used in accordance with the Product Manual.
- The analyzer is used outside intended use or intended operator.
- The analyzer is used with accessories or consumables that are not supplied or recommended by Heska Corporation.
- The analyzer is repaired or maintained by persons not authorized by Heska Corporation.
- Any unauthorized changes are made to the analyzer.


## 1.6 Warnings

 **WARNING.** Risk of entanglement and/or crushing.  
Do not stick fingers or attempt to touch components inside the analyzer via the cartridge loading port and door.

- Do not attempt to lever or manually open the cartridge loading door.
- After loading the cartridge, keep hands and fingers away from closing door.

 **WARNING.** Electric shock due to damage to the AC adaptor or mains/power cord.

- Do not use the analyzer if there is damage to the adaptor or power cord.
- Make sure that the AC adaptor is only plugged into a mains power outlet that has been properly grounded.
- In case of danger, disconnect the AC adaptor from the mains/power supply.

 **WARNING.** Lethal voltages inside AC adaptor.

If you touch any parts that are under high voltage you may experience an electric shock.

- Ensure the AC adaptor housing is undamaged and not open.
- Do not remove the housing.
- Ensure AC adaptor is kept clear of liquids.

 **WARNING.** Danger due to incorrect voltage supply.

- Only connect the AC adaptor to voltage sources which correspond with the specified electrical requirements.
- Only use earth/grounded sockets with a protective earth (PE) conductor.
- Only use the AC adaptor and main/power cord supplied or authorized by Heska Corporation. Do not use a mains supply cord of inadequate rating.

 **WARNING.** Damage to health due to infectious liquids and pathogenic agents.

Observe national regulations and biosafety level of your laboratory when handling urine and fecal samples containing potentially infectious or biohazardous agents.

It is the obligation of the operator to make sure that the proper protective equipment (PPE) is used.

For comprehensive regulations for handling biological material of risk group II or higher, please refer to the "Laboratory Biosafety Manual" (source: World Health Organization, Laboratory Biosafety Manual, the current edition).

 **CAUTION.** Poor safety due to incorrect accessories, spare parts or modifications.

Use only approved accessories or spare parts. Use of accessories and spare parts other than those authorized by Heska Corporation may impair the safety, function and precision of the analyzer. Heska Corporation cannot be held liable or accept any liability for damage resulting from the use of accessories and spare parts other than those authorized, or from improper use of such equipment.

Do not modify the centrifuge and its accessories in any unauthorized way.

 **CAUTION.** Damage to electronic components due to condensation.


Condensate may form in the device when it has been transported from a cool environment to a warmer one.

- After installing the analyzer, wait at least 4 hours before connecting to the mains power outlet.

 **CAUTION.** Damage to analyzer from liquid spill.

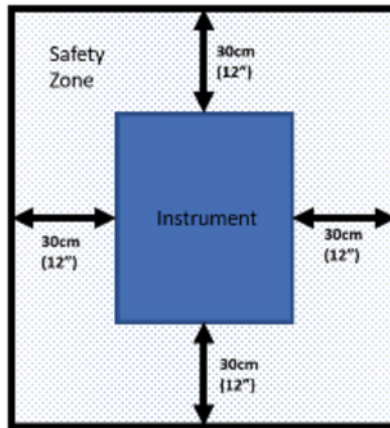
In case of a spill:

1. Switch off the analyzer.
2. Disconnect AC adaptor from the mains power outlet.
3. Carefully clean the analyzer and accessories in accordance with the cleaning instructions provided in this manual.


 **WARNING.** This analyzer contains a centrifuge.


Keep a safety zone of minimum 30 cm around the analyzer. Refer to figure below. Persons and hazardous substances must be kept out of this safety zone while analyzer is in use.


- Do not test substances or materials other than those indicated in Section 1.4 – Intended Use.
- Ensure only approved cartridges are used and filled as per instructions provided in section.
- Use of the instrument with flammable, explosive or materials which could react chemically as to cause a hazard is prohibited.

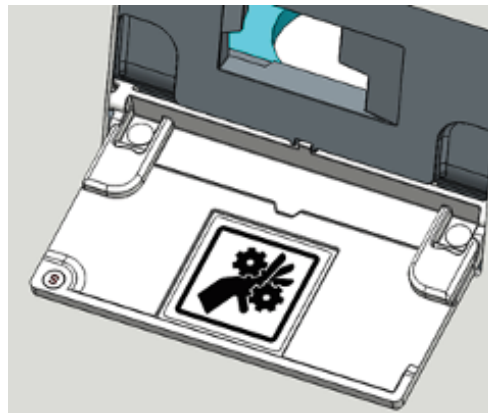


## 1.7 Safety Instructions on the Analyzer

 Indicates the need for the user to consult the instructions before use.

 Indicates the need for the user to consult the instructions for use for important cautionary information, such as warnings and precautions.

 Indicating risk of entanglement around cartridge loading door and port.



## 1.8 Declaration of Conformity

### EMC

2014/30/EU EMC Directive EN61326-1: 2013

CFR47 FCC Sub-Chapter A, Part 15B

**FC** This product 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.

Class A products are intended for use in non-residential/non-domestic environments. Class A products may also be utilized in residential/domestic environments, but in these environments the equipment may cause interference with radio communications services which may require the user to take adequate corrective measures. If this equipment does cause interference, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Re-orient the receiving antenna.
2. Relocate the analyzer with respect to the receiver.
3. Move the analyzer away from the receiver.
4. Plug the analyzer into a different outlet so that the analyzer and the receiver are on different branch circuits.



Heska has reviewed their analyzer product for compliance with REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation no. 1907 /2006 of the European Parliament and Council) and the presence of the two hundred and eleven (211) SVHC substances in the EU SVHC Candidate list as of 20th January 2021. The following assessments are being made:

No SVHC's exceeding 0.1% w/w were present in the product, except as noted below. This determination is based on engineering evaluation and supplier declarations and is correct to the best of Heska's knowledge.


#### NOTE:

1. Part numbers A001476 and A001654 from Nikon contain:
  - a. Lead [CAS 7439-92-1]
2. Part number A001902 from FUR contains:
  - a. Lead [CAS 7439-92-1]
  - b. BPA [CAS 80-05-7]
3. Part number A005000 from DOW contains:
  - a. Octamethyl Cyclotetrasiloxane [CAS 556-67-2]
4. Part number A010247 from Mean Well contains:
  - a. Lead [CAS 7439-92-1]
5. Part number A007127-000 from Venture contains:
  - a. Lead [CAS 7439-92-1]
  - b. Diboron trioxide [1303-86-2]
  - c. Lead monoxide [1317-36-8]
6. Part number A007110-110 from Tornik contains:
  - a. Lead [CAS 7439-92-1]
7. Part number A007128-000 from Venture contains:
  - a. Lead [CAS 7439-92-1]



## 1.9 Disposal

Cartridges and Fecal Prep devices are designed to be single use only. Used cartridges should be handled as biohazardous waste and disposed of according to all local laws and regulations for disposal of biohazardous waste.

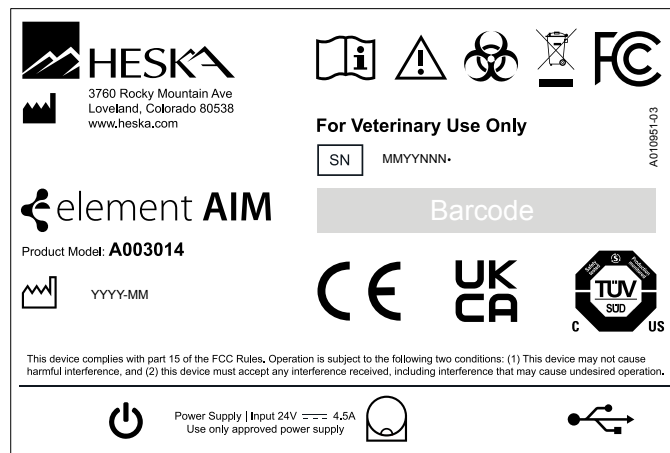
Element AIM bears the WEEE symbol  to alert customers in the EU that this instrument should not be disposed of in a landfill or with municipal or household waste. Please contact Heska or your local dealer for further information regarding proper procedures for discarding electrical and electronic equipment.

## 2.1 Product Overview

The Element AIM brings the convenience of automation and the learning capabilities of artificial intelligence to urine sediment and fecal flotation analysis for veterinary patients. Leveraging a unique and proprietary cartridge design, custom onboard centrifuge, state-of-the-art nanopositioning precision motor system, premium quality optical components, and high-powered computational analytics, the Element AIM dynamically captures microscopic images which are then categorized using artificial intelligence to identify specific objects of interest.

### 2.1.1 Analyzer Identification

Analyzer identification label can be found on the rear of the analyzer.



## 2.2 Technical Specifications

Technical Specifications	
Manufacturer	Heska Corporation
Manufacturer address	3760 Rocky Mountain Ave, Loveland, CO 80538, United States
Model name	Element AIM Automated AI Microscopy Analyzer
Model number	A003014
Power supply	External 24 V DC Adaptor
Adaptor input voltage range	85 – 264 V AC
Adaptor input current (maximum)	1 A
Adaptor power consumption	160 W
Adaptor overload	105 – 150% rated output
Adaptor over current protection	Hiccup mode – auto recover after overload condition removed
Analyzer input voltage	24 V DC
Analyzer input current (maximum)	4.4 A
Centrifuge type	Horizontal centrifuge with single fixed-angle, fixed rotor for use with approved cartridge only.
Maximum centrifuge speed (RPM)	2200 RPM
Maximum centrifuge force (RCF)	626 G
Kinetic energy (maximum)	81.1 J
USB communication	Yes
EMC compatibility	2014/30/EU EMC Directive EN61326-1: 2013 CFR47 FCC Sub-Chapter A Part 15B
Installation site	Indoors Only
Ambient temperature	50°F to 95°F (10°C to 35°C)
Humidity	< 80% (non-condensing)
Storage/transport environment	14°F–104°F (-10°C–40°C ) (RH 10%-90%)
Excess voltage category	II
Pollution degree	2
Safety area	11.8 in (300 mm)
Analyzer dimensions: Height (h) x Width (w) x Depth (d)	17.2 in h x 14.9 in w x 20.8 d in (438 mm h x 378 mm w x 528 mm d)
Max noise level (at 1m)	58.4 dBA
Analyzer weight	65 lbs (29.5 kg)
Shipping package weight	78 lb (~35.5 kgs)

### 3.1 Package Contents

Item	Quantity
Element AIM Veterinary Analyzer	1
Power adaptor	1
IEC power cord	1
USB 3.1 GEN 2 USB-C male-to-male cable (1 m)	1
Analyzer documentation	1
Dust cleaning cartridge	1
Element AIM computer	1
Element AIM monitor	1

 **WARNING**

The analyzer weighs 65 lbs (29.5 kg). Do not attempt to lift or move it without assistance.

 **CAUTION**

Allow the analyzer to warm up for at least 4 hours to the ambient temperature to prevent damage to the electronic components from condensation.



### 3.2 Installation Location Requirements

In selecting a location to install the analyzer, adhere to the following requirements:

- Maintain a safety zone of a minimum 300 mm around the analyzer. Persons and hazardous substances must be kept out of this safety zone while the analyzer centrifuge is spinning.
- The spinning centrifuge can cause vibrations. Do not store sensitive devices, dangerous objects or hazardous substances in the safety zone.
- The analyzer should be positioned on a level surface, such as a sturdy table or laboratory bench capable of supporting the weight of the analyzer 65 lbs (30 kg).
- The analyzer should be placed on a resonance free table able to resist vibration.
- Ensure all four feet of the analyzer are fully supported by the table surface. It is not permitted to put anything under the analyzer to compensate for an uneven surface.
- Locate the analyzer in an area with sufficient ventilation to allow for heat dissipation.
- Ensure there is clearance at the sides and the back of the analyzer to ensure air flow and cable entry at the back.
- Additional clearance may be required on the right side to allow access to the power switch located in the right rear corner of the analyzer.
- Ambient temperature during operation should not be lower than 50°F (10°C) or higher than 95°F (35°C). Relative humidity should not exceed 80% (non-condensing).
- The location of the analyzer should be protected against direct sunlight.
- Do not locate the analyzer near strong electromagnetic sources (*e.g.*, unshielded high frequency sources) as this could impede functioning of the analyzer.

### 3.3 Electrical Requirements

- The analyzer is powered by an external universal AC input 24 V DC adaptor supplied with the analyzer.
- Only connect the analyzer to voltage sources that correspond with the electrical requirements specified on the analyzer identification label.
- Only use earth/grounded outlets with a protective earth conductor.
- Only use the AC adaptor and main/power cord supplied or authorized by Heska Corporation. Do not use a mains supply cord of inadequate rating.
- The main power switch and outlet connecting to the AC adaptor must be easily accessible during operation and should be located outside the safety zone.

#### Power Supply

Mains power voltage range: 85~264 V AC

Mains frequency range: 47~63 Hz

AC current consumption: 1A

Power consumption max: 160 W

### 3.4 Moving the Analyzer

Before moving the analyzer ensure:

- The AC adaptor and USB cables are removed.
- The analyzer is lifted by two persons using recessed hand grips along either side of analyzer base.
- The analyzer is lifted into position. Do not drag or push the analyzer on its feet.



### 3.5 Unpacking

The shipping carton(s) should be inspected for shipping damage upon delivery. If damage is discovered, the delivery carrier should specify and sign for the damage on your copy of the delivery receipt.

Do not open the package and do not remove any contents unless expressly and specifically instructed to do so by Heska Corporation.

In situations where express consent has been given by Heska Corporation, open the package. Remove top layers of foam package and accessories box. Ensure all parts are included.

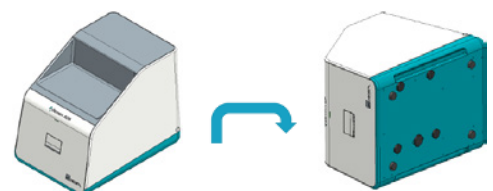
With two people, lift analyzer out of box using the recessed hand grips along either side of analyzer base and place on sturdy bench or table.

If damage is found following unpacking, report it to the carrier and request a damage inspection or specified procedure for when damage in shipment has occurred.

Keep the box and packing materials in case of service shipping.

### 3.6 Removing Shipping Locks

1. Place analyzer on its side on a protected surface.
2. Remove and retain the five dust caps shown in step 6. (Caps will be reinserted at the end of the lock removal procedure.)



3. Remove hex socket fastener (3 mm Allen wrench).

**!** IMPORTANT

Do not try to remove the outer lock (red) before the fastener – can result in analyzer damage.

**NOTE:** Retain fastener for return shipping reinstallation.

4. Using a flat head screwdriver, undo (counter-clockwise) the lock (red anodized sleeve).

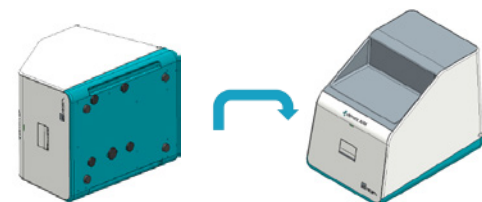
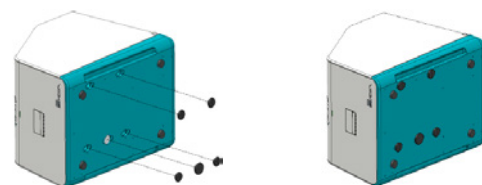
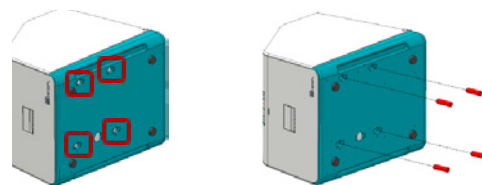
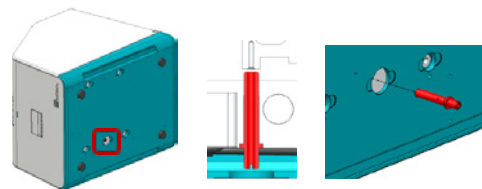
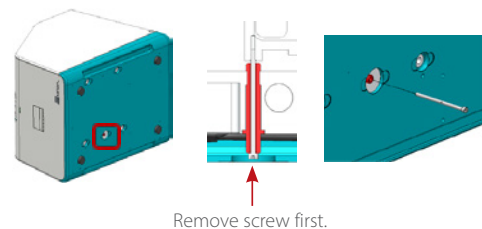
**NOTE:** Retain lock for return shipping reinstallation.

5. Undo the four hex fasteners (3 mm Allen wrench) until loose within each lock (the fasteners are retained by the locks) and remove by sliding out.

**NOTE:** Retain locks for return shipping installation.

6. Reattach dust caps.

7. Place analyzer back on its feet. Analyzer is now ready to be connected to the computer.



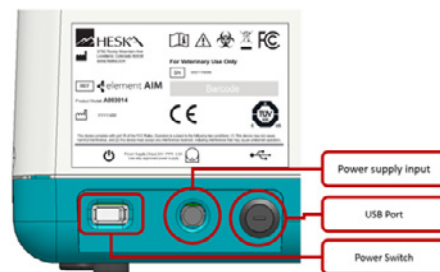
### 3.7 Connections and Operating Controls

#### 3.7.1 Computer and Analyzer Connections

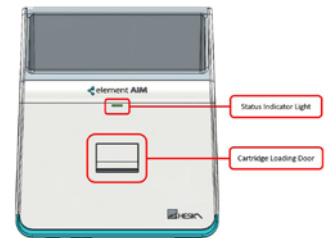
1. Connect monitor to the computer.
2. Connect supplied USB cable between the USB port on the back of the analyzer to a spare USB-C port on the computer.

#### 3.7.2 Mains Connection

1. Check that the mains power supply voltage and frequency match the requirements on the AC adaptor name plate.
2. Connect the DC plug on the AC adaptor to the corresponding socket beneath the on/off switch on the analyzer.
3. Connect the supplied mains power cable to the AC adaptor and plug into the mains outlet.



- Connect the supplied mains power cable to the computer and plug into a mains outlet.



### 3.8 Repacking for Shipment or Storage

**⚠ WARNING**

The analyzer weighs 65 lbs (29.5 kg). Do not attempt to lift or move it without assistance.

**⚠ WARNING**

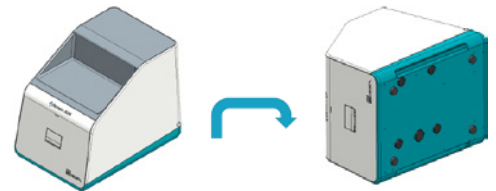
Cleaning and/or decontamination may be required as a safeguard before shipping the instrument. Contact Heska's Technical Support Services at 800.464.3752, option 3 for further guidance prior to repacking.

To prepare the analyzer for storage and/or shipment, please follow these guidelines.

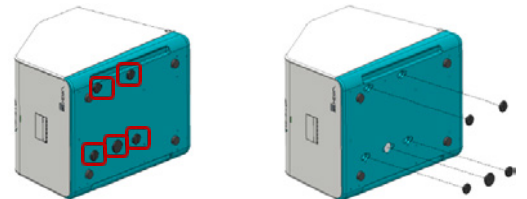
For shipment, the analyzer must be packed in Heska approved shipping container. For further assistance, please call Heska's Technical Support Services at 800.464.3752, option 3.

#### 3.8.1 Shipping Lock Installation Instructions

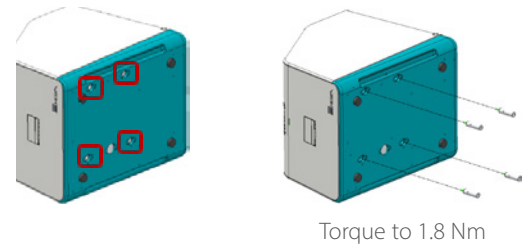
- Turn off power switch and remove power cable and USB-C cable from the back of the analyzer. Place analyzer on its side on a protected surface.



- Remove and retain the five dust caps shown below. (Caps will be reinserted at the end of the lock installation procedure.)



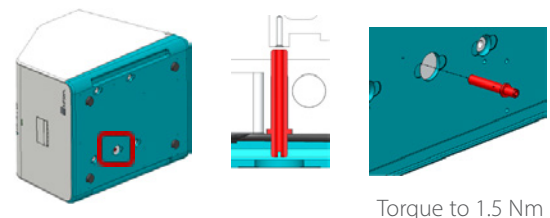
- Insert the four primary shipping locks (red anodized sleeves) and tighten the hex fasteners (3 mm Allen wrench) within each lock to 1.8 Nm.



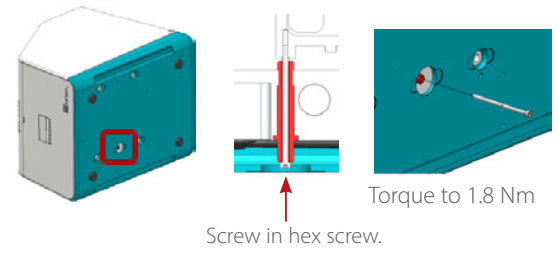
- Insert the remaining red anodized lock into the indicated hole and tighten (CW) using a flat head screwdriver to 1.5 Nm.

**⚠ IMPORTANT**

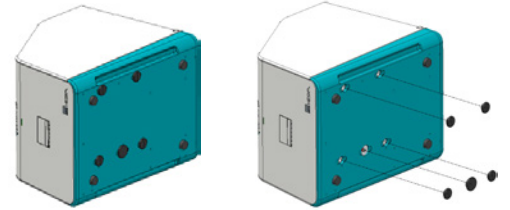
Ensure the lock is installed prior to the internal fastener – can result in analyzer damage if not.



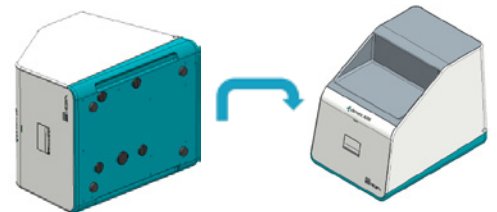
5. Screw the hex socket screw (3 mm Allen wrench) into the red anodized lock installed in the previous step. Tighten to 1.8 Nm.



6. Reinstall five dust caps.



7. Place analyzer back on its feet. Analyzer is now ready to be packaged for shipping.





## 4.1 Materials

- Element AIM Disposable Cartridge
- Element AIM Fecal Prep Device Kit (Sample tube, sample transfer device and filter)
- Urine or fecal sample to be analyzed



## 4.2 Cartridge Fill Procedure

### 4.2.1 Equipment

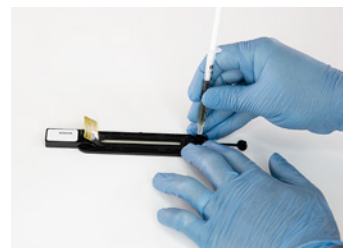
- Sample to be analyzed – urine or processed fecal preparation
- Syringe (with Luer slip tip) or authorized sample preparation/cartridge loading device supplied by Heska.
- New cartridge
- Safety glasses and examination gloves

#### NOTE:

- Ensure sample preparation is conducted on a dust free surface to avoid contaminating the lower film face of the cartridge.
- Optical windows are sensitive to contaminants. Avoid touching the clear windows of the cartridge.
- It is recommended that safety glasses and disposable examination gloves be worn during entire filling procedure.
- If the sample has been refrigerated, allow to come to room temperature before loading the cartridge to minimize risk of bubbles forming.
- If cleaning of the cartridge window is necessary, use of a lab tissue with isopropyl alcohol is recommended. **DO NOT** clean or allow contact with fluids containing methyl alcohol, acetone, ketones, ethers, aromatic or chlorinated hydrocarbons, aqueous or alcoholic alkaline solutions or ammonia.

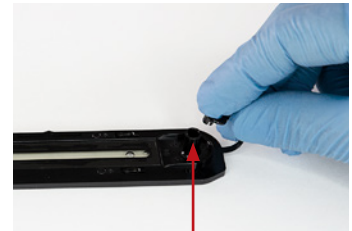
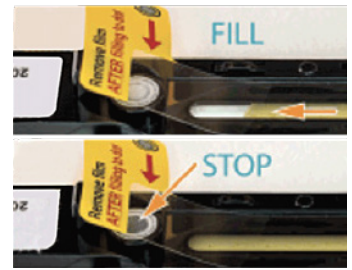
### 4.2.2 Preparation Procedure for Urine Samples

1. Use a new cartridge and a fresh urine sample that has not been centrifuged.
2. Remove cartridge from foil packaging.
3. Thoroughly mix urine sample to re-suspend any materials that may have settled. Using a syringe aspirate at least 550  $\mu$ l (0.55 mL) of the urine sample.
4. Insert syringe tip into cartridge filler port ensuring a secure connection with Luer fitting.
5. To minimize risk of bubbles, ensure cartridge is placed on a flat surface. Slowly depress syringe plunger while observing sample filling cartridge chamber. Continue filling until the filter just starts to become wet, darkening in color.



**NOTE:**

- Do not attempt to fill beyond wetting out of filter or if a distinct back pressure or resistance on syringe plunger is felt.
  - If air bubbles are introduced during filling do not attempt to remove them by attempting to push them out or suck them back out, rather discard cartridge and start process again.
6. Remove syringe from filler port and dispose of in biohazard waste or appropriate waste receptacle as locally regulated for potentially biohazardous materials.
  7. Insert cartridge cap in filler port and press down until a click is felt and cap is secured.



Press and click in place.

8. Remove protective film just prior to loading cartridge in the analyzer.

**NOTE:** Hold the cartridge by the handle only. DO NOT TOUCH top or bottom films.

9. When test has been completed, dispose of cartridge in a biohazard waste container.

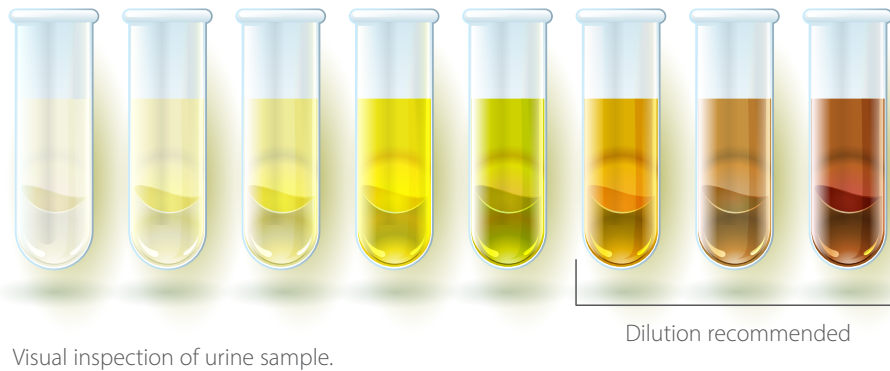


### 4.2.3 Urine Dilutions

Overtly hemolyzed and/or concentrated urine samples must be diluted. This prevents excessive cells from overlapping and interfering with the analyzer finding the cartridge fiducials that are required to orient and focus the cameras. In other words, the abundance of cells (RBCs in particular) may cause a cartridge error, such as, Failure to Find Focus Feature.

The Element AIM will not prompt the user to dilute a urine sample. Urine dilution prior to loading Element AIM cartridge is recommended in the following scenarios:

- If less than 0.5 mL sample is obtained from the patient.
- If upon visual inspection, the urine sample appears bloody or excessively concentrated.



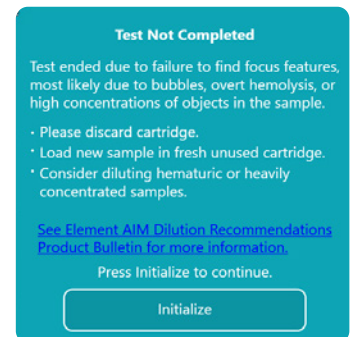
#### Failure to Find Focus Feature Error

**NOTE:** This error usually occurs within the first 2 minutes after loading the sample.

Appropriate sample handling is needed to prevent the error and prevent unnecessary waste of Element AIM cartridges.

Inspect the cartridge to ensure there aren't bubbles present.

- If bubbles are visible in the sample, discard the Element AIM cartridge and fill a new cartridge. Place cartridge on a flat surface, then slowly depress syringe plunger and fill cartridge until the filter changes color.
- If bubbles are not visible, discard the Element AIM cartridge and proceed with diluting the urine sample.



Failure to Find Focus Feature error alert.

#### Urine Dilution Process

**NOTE:** Saline has the potential to dissolve certain types of urine crystals. If crystalluria is suspected, and the sample requires a dilution, the user may benefit from reviewing a manual sample (pre-dilution) under normal microscopy methods to look for crystals.

Dilute the sample with normal saline.

1. Ensure the bottle of sterile saline is <30 days old. Older saline can cause false bacteria or contaminants.
2. Wipe the top of the saline bottle with alcohol prior to obtaining the saline for dilution to help reduce the possibility of contamination. Contamination may lead to bacteria growth in the dispensing saline bottle.

## Urine Dilution Ratios

Current dilutions available to notate on the Element AIM are 1:5, 1:10, 1:50 and 1:100.

- 1:10 is suggested if the sample grossly looked normal, but an error occurred.
- 1:50 is recommended for samples that visually appear bloody or very concentrated.
- Other dilution levels may be used at the user's preference.

Urine Dilution Calculator	1:5	1:10	1:50	1:100
<b>1 mL final volume</b>				
Add urine	0.2 mL	0.1 mL	0.02 mL	0.01 mL
To sterile saline	0.8 mL	0.9 mL	0.98 mL	0.99 mL
<b>3 mL final volume</b>				
Add urine	0.6 mL	0.3 mL	0.06 mL	0.03 mL
To sterile saline	2.4 mL	2.7 mL	2.94 mL	2.97 mL

### 4.2.4 Preparation Procedure for Fecal Samples

#### Materials

- Element AIM Cartridge
- Sample tube rack
- Sample tube
- Wooden sticks
- Fecal sample transfer device and filter
- Fecal float solution



#### Directions

1. Use a new cartridge, fecal prep kit, and a fresh fecal sample.
2. Remove fecal prep device from packaging.
3. Using wooden sticks, add feces to sample tube up to the Fecal Sample line.
  - Fill loosely to Fecal Sample line; avoid tightly packing sample.
  - Do not add more than the recommended amount of feces (2g).
  - For thin samples, use less sample (~1g); do not fill all the way to the Fecal Sample line.
4. Fill tube with flotation solution to the Liquid Fill 1 line.
5. Using wooden sticks, mix feces and solution thoroughly until homogenous.
 

**NOTE:** Ensure the filter is inserted correctly: cone pointed down, with no fecal matter above the filter.



6. Insert filter, pointing downwards, into tube.

**NOTE:** There will be issues with cartridge filling, sample processing, and transfer of any objects of interest if the fecal solution is not added to the proper volume recommended.

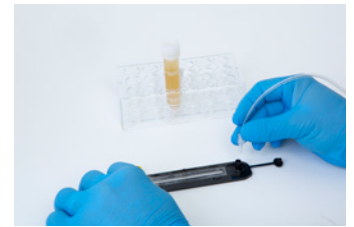


7. Add additional flotation solution to the Liquid Fill 2 line.
8. Cap tube and and a counter balance into centrifuge and spin at 650 xg (~1500 rpm) for 5 minutes.
9. Remove Element AIM cartridge foil packaging.



10. Attach fecal preparation device tubing to the cartridge.
11. Remove fecal float tube from centrifuge and remove cap.

If unsuccessful, please contact Heska's Customer Support Services at 800.464.3752, option 3 for additional help; standard floatation may be necessary.

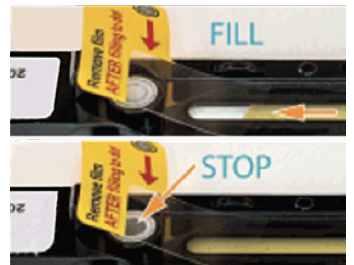


12. Attach the fecal prep device cap onto fecal float tube and twist SLOWLY to dispense sample into the cartridge until the filter just starts to become wet, darkening in color.
13. Remove tubing from filler port and dispose of the fecal prep kit in biohazard waste or appropriate waste receptacle as locally regulated for potentially biohazardous materials.
14. Insert cartridge cap in filler port and press down until a click is felt and cap is secured.



15. Remove protective film just prior to loading cartridge in the analyzer. Use previous section for reference.

**NOTE:** Hold the cartridge by the handle only. **DO NOT TOUCH** top or bottom films.



16. When test has been completed dispose of cartridge and fecal prep device in a biohazard waste container or appropriate waste receptacle as locally regulated for potentially biohazardous materials.



## 4.3 Running a Test

### 4.3.1 Status Indicator Button

A color-changing icon provides information on the analyzer status, with additional messaging in the status bar. The color of the Status Indicator button on the Element AIM screen will be the same color as the light on the front of the analyzer.

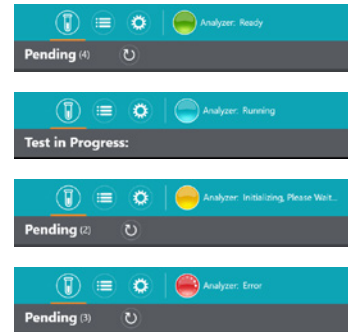
In general, the icon colors have the following indications:

Green: Ready, test completed/cartridge ejected.

Blue: Load cartridge, sample run in progress, sample results processing.

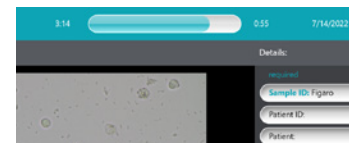
Yellow: Initializing, automatic resetting of analyzer functions.

Red: Error state, may require user attention – follow message prompts.






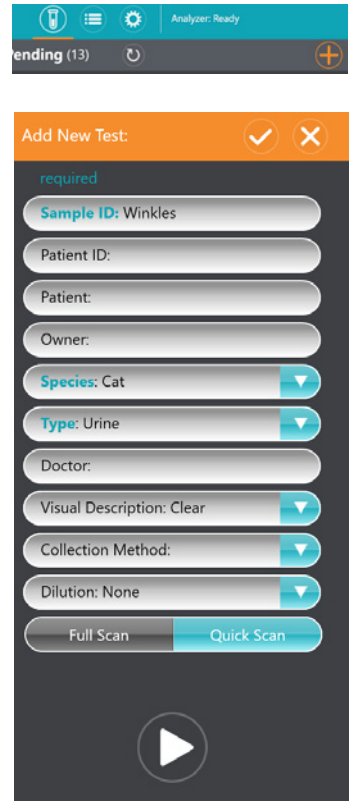
### 4.3.2 Progress Bar

The progress bar at the top of the Element AIM screen shows time elapsed on the left and time remaining on the right.



### 4.3.3 Running a Urine Sample

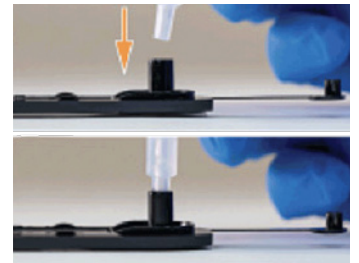
1. To add a new patient, touch  on the Pending Tests screen and the Add New Test window will appear.
2. Enter information into the teal colored required fields and any other information the user deems appropriate, including manually performed USG and dipstick information.
3. Choose Quick Scan or Full Scan profile.
4. Touch  to save to the worklist or  to run the sample.
5. Open the Element AIM cartridge pouch and label cartridge tab with patient information.
6. Thoroughly mix urine sample to resuspend any materials that have accumulated on the bottom.
7. Fill a syringe with at least 0.55 mL of urine.



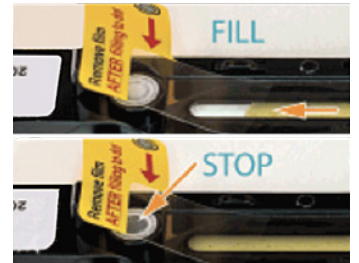


8. Load the Element AIM cartridge as described below:

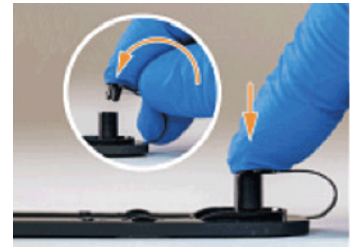
1) Connect the syringe to the port on the Element AIM cartridge.



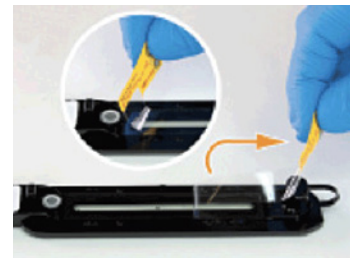
2) Inject ~0.5 mL of urine into the Element AIM cartridge, filling until the window is full of sample and the filter is discolored.



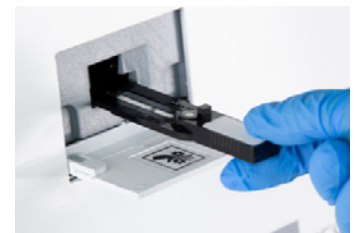
3) Remove syringe and cap the port securely.



4) Remove protective plastic film from the cartridge.



9. Touch **OPEN ANALYZER DOOR** and insert the cartridge into the analyzer once the door has opened.

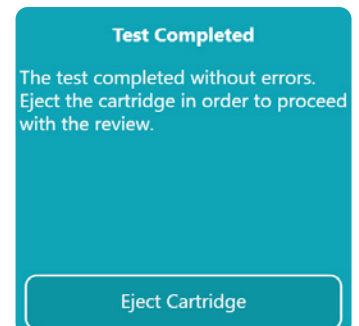


10. Once the cartridge has been detected, the cartridge will be pulled into the analyzer and the door will close automatically.




11. Once the scan is complete, the user will be alerted to remove the cartridge from the analyzer. Touch **EJECT CARTRIDGE** and the analyzer door will open automatically.

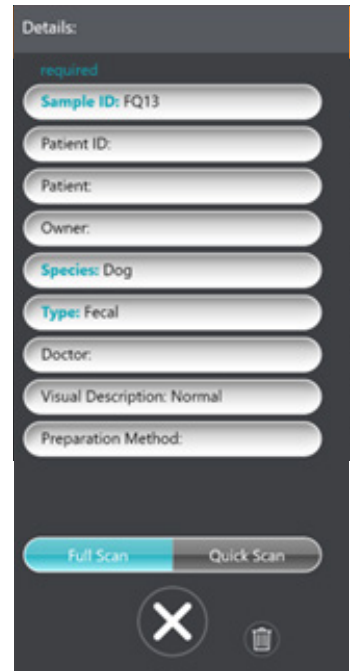
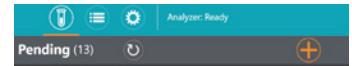
12. Remove the Element AIM cartridge. Once removed, the analyzer door will close automatically.

13. The Results screen will appear for the user to review and confirm.

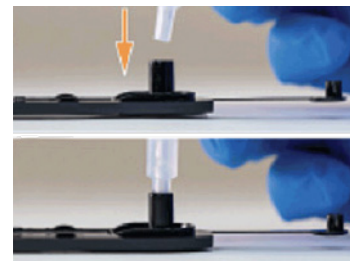


#### 4.3.4 Running a Fecal Sample

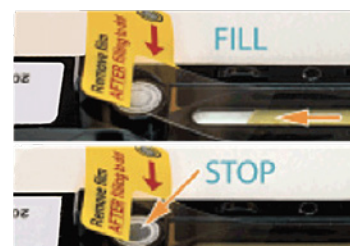
1. To add a new patient, touch  on Pending Tests screen and Add New Test window will appear.
2. Enter information into the teal colored required fields and any other information the user deems appropriate.
3. Choose Quick Scan or Full Scan profile.
4. Touch  to save to the Worklist or  to run the sample.
5. Open the Element AIM cartridge pouch and label cartridge tab with patient information.
6. Perform a fecal floatation as described in Section 4.2.4, Preparation Procedure for Fecal Samples.



7. Load the Element AIM cartridge as described below:
  - 1) Connect the fecal prep device to the port on the Element AIM cartridge.



- 2) Twist the cap of the fecal preparation device to inject ~0.5 mL of your fecal float sample into the Element AIM cartridge, filling until the window is full of sample and the filter is discolored.

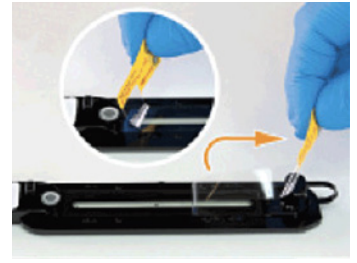


- 3) Remove fecal preparation device and cap the port securely.

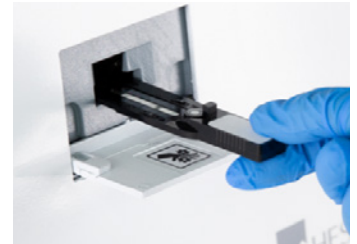




4) Remove protective plastic film from the cartridge.

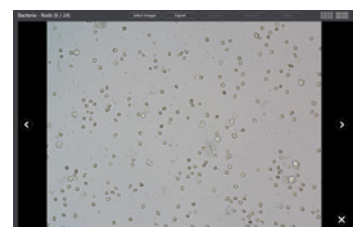
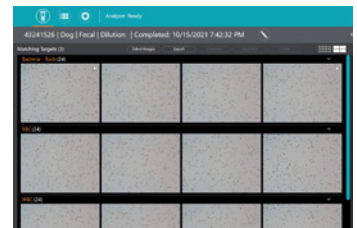




8. Touch **OPEN ANALYZER DOOR** and insert the cartridge into the analyzer once the door has opened.
9. Once the cartridge has been detected, the cartridge will be pulled into the analyzer and the door will close automatically.
10. As images are acquired, they will be displayed on the monitor.
11. Once the scan is complete, the user will be alerted to remove the cartridge from the analyzer. Touch **EJECT CARTRIDGE** and the analyzer door will open automatically.
12. Remove the Element AIM cartridge. Once removed, the analyzer door will close automatically.
13. The Results screen will appear for the user to review and confirm.

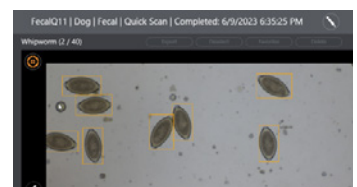
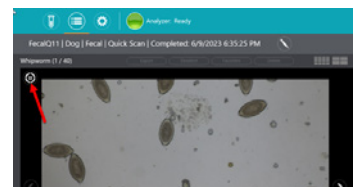


#### 4.4 Confirming and Reviewing Results

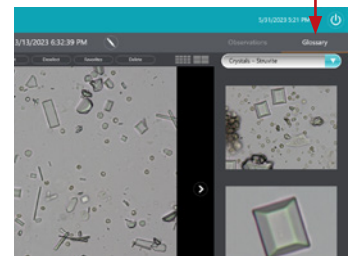
1. Images containing objects of interest will be sorted into categories (*i.e.*, RBCs, WBCs, bacteria, *etc.*).
2. To examine images closer, double click on the images of interest.  
The user can then zoom in/out further using their fingers to examine the image. To toggle through images within the category, use **<** or **>**. Touch **X** to return to the main the results screen.



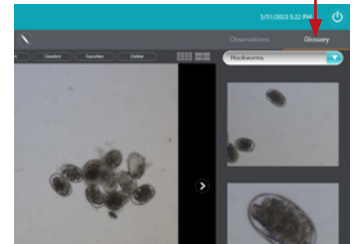
Click the Target  in the upper left corner of the image. It will turn orange when it is on  and displaying the orange Bounding Box surrounding the object.



Click Glossary to access a reference glossary with example images for each object.



Urine






Fecal

- Objects of Interest identified by artificial intelligence will be automatically displayed on the result panel located on the right side of the screen. The objects found by the software will have a vertical orange bar to the left while all other will have a vertical teal bar.

**NOTE:** To change the Operator, use the drop down menu and select "Create New" to add a new Operator.

**NOTE:** The user has the ability to export to USB or email, up to 5 images with each test. See Section 4.5 Exporting Images for more information.

- The operator can change the quantities of objects observed by selecting from a drop down under each object of interest. Touch the object name of interest and then touch  to select the quantity seen. Touch  to save changes.
- To remove an item from the results panel, touch .
- To add an item to the results panel, click on the object of interest.
- For bacteria, casts and crystals, the user can select the specific type using the drop down menus.



8. For any additional finding, a classification of Other may be used. The user can then type in their findings.

Manual Findings: [Close]

- Color: Yellow
- Appearance: Clear
- USG: 1.022
- pH: 6.8
- Leukocytes: Not Yet Selected
- Blood: Not Yet Selected
- Protein: Not Yet Selected
- Glucose: Not Yet Selected
- Ketones: Not Yet Selected
- Bilirubin: Not Yet Selected
- Nitrite: Not Yet Selected
- Urobilinogen: Not Yet Selected

[Save] [Reset All]

9. At any point the user can manually enter USG and urine chemistry (dipstick) values into the report by touching **ENTER USG AND DIPSTICK INFO**.

When entering optional urine chemistry results, the user can choose preferred result format of semi-quantitative (+, ++, +++), Imperial, or SI method of measurement in the Settings ► Required Fields tab. The default format will be set to semi-quantitative.

Settings ► Required Fields

Display Mode: Semi-Quantitative (+/+/+)

Quantitative Imperial

Semi-Quantitative (+/+/+)

Quantitative SI

Settings ► Required Fields

Manual Findings: [Close]

- Color: Yellow
- Appearance: Clear
- USG: 1.022
- pH: 6.8
- Leukocytes: +
- Blood: Negative
- Protein: Trace
- Glucose: +
- Ketones: Not Yet Selected

[Reset All]

Semi-quantitative

Manual Findings: [Close]

- Color: Yellow
- Appearance: Clear
- USG: 1.022
- pH: 6.8
- Leukocytes: 70 Leu/uL
- Blood: Negative
- Protein: 15 mg/dL
- Glucose: 250 mg/dL
- Ketones: Not Yet Selected

[Reset All]

Imperial

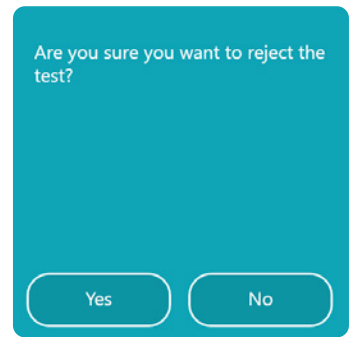
Manual Findings: [Close]

- Color: Yellow
- Appearance: Clear
- USG: 1.022
- pH: 6.8
- Leukocytes: 70 Leu/uL
- Blood: Negative
- Protein: 0.15 g/L
- Glucose: 15 mmol/L
- Ketones: Not Yet Selected

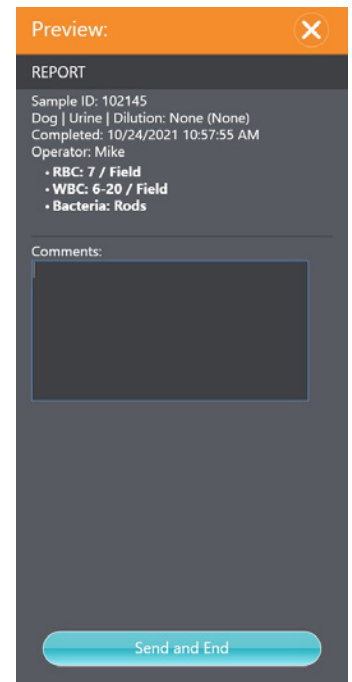
[Reset All]

SI

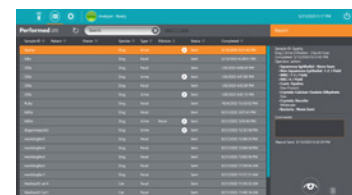
- To reject the report, touch **REJECT AND END** and then **YES** to confirm.  
To accept the report, touch **ACCEPT AND END** and a report preview will be displayed.  
Additional comments can be added to the comments section as needed.



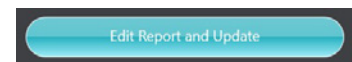
- Touch **SEND AND END**, then **DONE** to finalize the report.



- Finalized reports can be reviewed in the Performed tab and can be viewed by touching .  
Tests performed using Quick Scan Profile are indicated with a lightning bolt .

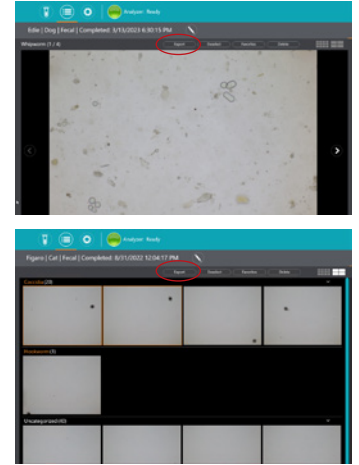


- To review or edit a previously run report. Click and then either double click the patient's name, or touch the patient name once and then touch .
- To save any edits that have been made, touch **EDIT REPORT AND UPDATE** and then touch **SEND AND END** and the **DONE** to finalize the report.



## 4.5 Exporting Images

User has the ability to send images via e-mail or export to USB drive.



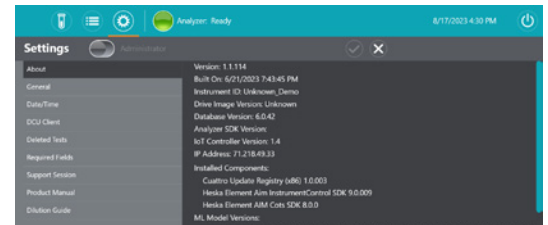
## 4.6 Settings

### 4.6.1 General Settings

To access Settings, click .

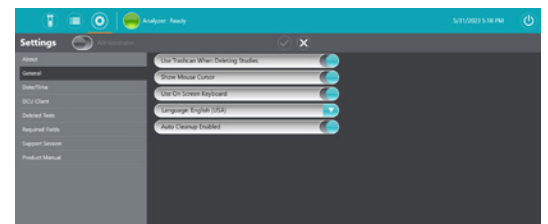
About

- View current version of software.



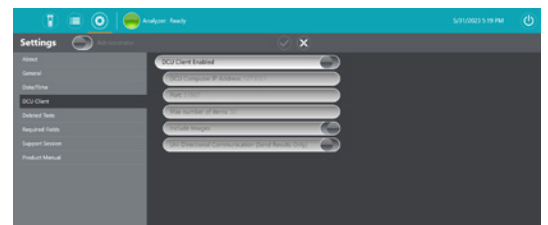
General

- Manage deleted studies.
- Enable/disable keyboard and mouse use.
- Change default language settings.
- Enable/disable auto-cleanup of performed tests.



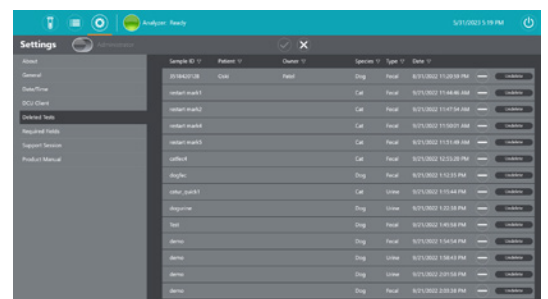
Data Capture Utility (DCU)

- Enable/disable DCU client.
- Update IP address.
- Manage report structure.
- Enable unidirectional or bidirectional communication.



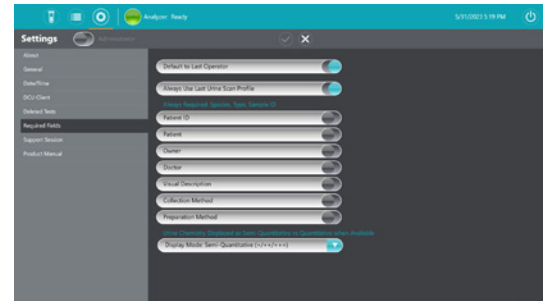
Deleted tests

- View deleted reports.
- Undelete reports returning to Performed Results tab.
- Permanently delete reports.



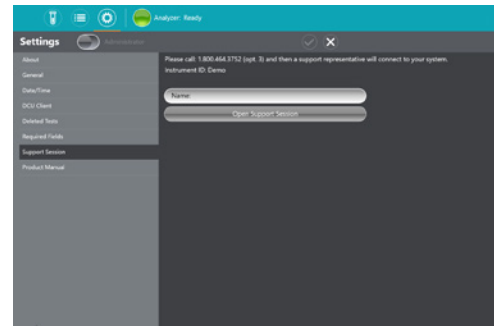
## Required fields

- Manage preferences for default operator, urine scan profile, required fields, and unit of measurement for urine dipstick parameters.



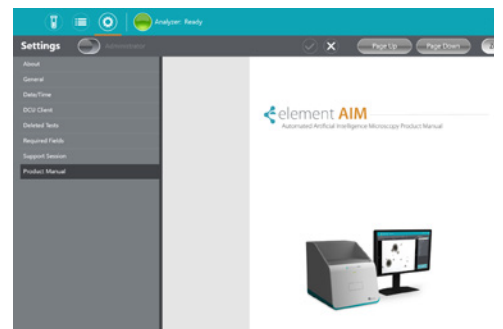
## Support session

- Get a support session started.



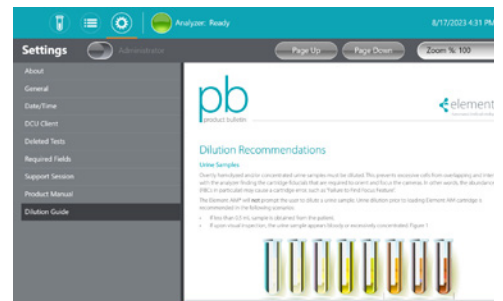
## Product manual

- View product manual.



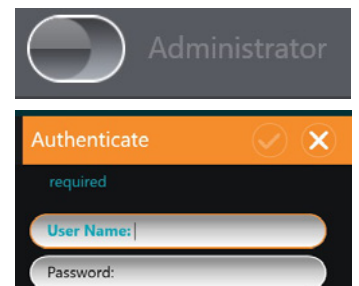
## Dilutions Guide

- View dilutions guide.



## 4.6.2 Administrator Setting

To access locked Administrator Settings, touch **ADMINISTRATOR** icon and enter administrator user name and password.



## Analyzer management

- Manage Image uploads.
- Update display settings.
- Initiate cleaning procedures for optics. See *Subsection 5.2.2*.

## Users and logins

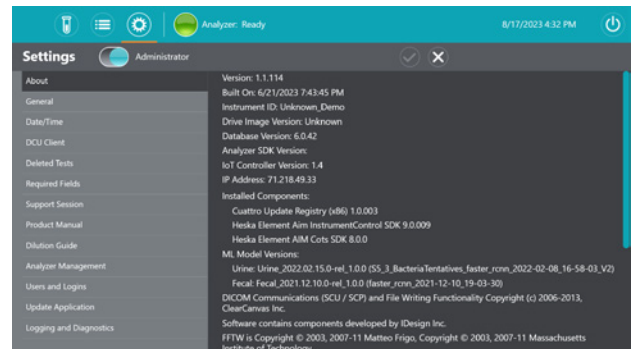
- Add new operators and administrators.
- Inactivate users.
- Manage requirement for passwords.

## Update application

- Enable/disable auto update.
- Check system for updates.
- Initiate updates.

## Logging and diagnostics

- Contact Heska's Technical Support Services at 800.464.3752, option 3 for assistance.



 **WARNING**

The analyzer contains no user servicing or maintenance that requires removal of the covers. Removal of the covers exposes the user to the possibility of electric shock and/or mechanical injury. Unauthorized removal of the covers will void the analyzer warranty.

## 5.1 Cleaning Outside Surfaces

The following cleaning fluid formulations are approved to use for periodic cleaning of the outer surfaces of the analyzer. Carefully wipe outer surfaces as necessary, minimizing expose of the cleaning formulation to less than 15 minutes:

- Isopropyl alcohol, 70%
- Ethanol alcohol, 70%
- Bleach solution, 10%, in water

Before using any cleaning or decontamination methods except those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment.

## 5.2 Cleaning Optics

 **WARNING**

### Risk of eye injury


The optics cleaning process involves the use of compressed air. Ensure eye protection is worn to avoid risk of accidental eye injury from foreign particles.

It is recommended that the following optics maintenance procedure be performed Heska's Field Support team every 12 months to prevent dust build up and ensure image quality and analyzer performance.

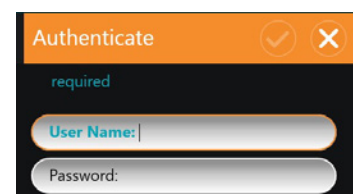
### 5.2.1 Equipment

- Personal Protective Equipment (PPE)– PPE eye protection
- Optics cleaning cartridge
- Compressed air cannister/duster with straw

### 5.2.2 Cleaning Procedure for Optics

1. Select the option for cleaning optics from the software.
2. Touch  to open the Settings menu.
3. Touch **ADMINISTRATOR** icon and enter Admin user name and password.
4. Touch **START MAINTENANCE** to initiate cleaning process. The indicator light on the analyzer turn purple and the analyzer door will open.
5. When door opens, insert optics cleaning cartridge until it clicks into the detent.
6. Secure straw in air cannister outlet and administer 3 shorts blasts of compressed air to remove answer moisture or debris from within the straw.

**NOTE:** Do not invert cannister as this may lead to the introduction of moisture into the analyzer.





7. Insert straw into left port and administer three short (1 second) blasts of compressed air.
8. Insert straw into right port and administer three short (1 second) blasts of compressed air.  
**NOTE:** Do not invert cannister as this may lead to the introduction of moisture into the analyzer.
9. Remove optics cleaning cartridge from the analyzer.
10. Touch **STOP MAINTENANCE** to end cleaning. The door to the analyzer will close and the cleaning procedure is complete.

### 6.1 Troubleshooting and Error Handling

Error Description	Possible Cause	Possible Solution
No Connection to SCP	PC is unable to connect to the instrument.	Check instrument power, check USB connection and retry initializing.
Connection to SCP Lost	PC lost connection to the instrument.	Restart software to reconnect. If problem persists contact Heska's Technical Support Services.
CCP Lost Connection to SCP	USB-C cable Issue.	Unplug the USB cable at the back of the Element AIM analyzer and wait 1 minute. Reconnect USB and re-initialize Element AIM. If problem persists contact Heska's Technical Support Services.
Illumination Error	Very thick/dark sample. Bubbles present within cartridge.	Prepare a new cartridge, ensuring sample dilution is correct and bubbles aren't present within the cartridge.
Accept Cartridge Error	Cartridge not fully inserted. Magnetic door has become detached. Door sensor obstructed or missing.	Remove cartridge. Replace magnetic door if detached. Re-initialize instrument and try again ensuring fully insert cartridge. If problem persists contact Heska's Technical Support Services.
Eject Cartridge Error	System error during eject cartridge script.	Check magnetic door is attached correctly. Re-initialize instrument and try again ensuring cartridge is removed once ejected. If problem persists, power cycle the instrument.
Focus Error Failed to Find Focus Feature	The focus features on the cartridge could not be detected.	Follow on-screen prompts. If problem persists contact Heska's Technical Support Services.
Execute Script Error	Windows Driver was updated in the background. Error communicating with the cameras.	Power off the PC tower. Unplug the USB cable connection at the instrument and wait 5 minutes before reconnecting. Once reconnected, wait 1 more minute and re-initialize. If problem persists, contact Heska's Technical Support Services.
Door Did Not Open	Door did not open for instrument maintenance.	Check magnetic door is attached correctly and retry. If problem persists contact Heska's Technical Support Services.
Door Did Not Close	Door did not close after stopping instrument maintenance.	Check magnetic door is attached correctly and retry. If problem persists contact Heska's Technical Support Services.
Camera Not Detected	The camera was not detected by the software.	Unplug the USB cable connection at the instrument and wait 1 minute before reconnecting. Once reconnected, wait 1 more minute and re-initialize. If problem persists, contact Heska's Technical Support Services.
Instrument Not Detected	The instrument was not detected by the software.	Ensure the instrument is on and/or power cycle the instrument then re-initialize the software. If problem persists, contact Heska's Technical Support Services.
Cartridge Not Fully Inserted	Cartridge sensors indicate that the cartridge slot is partially inserted or empty.	Re-initialize and retry ensuring cartridge fully inserted.
Eject Cartridge Not Retrieved	Cartridge was not retrieved by the user during eject.	Ensure cartridge is removed and re-initialize.
Cartridge Slot Not Empty	Cartridge sensors indicate that the cartridge slot is partially inserted or empty.	Remove the optics maintenance cartridge and re-initialize the instrument.

Error Description	Possible Cause	Possible Solution
No Signal/No HDMI Connection	AIM Monitor is not connecting with the Element AIM computer tower.	Verify the HDMI cable is connected securely to both the monitor and the tower. Verify the HDMI cable is connected to the correct HDMI port at the bottom of the computer tower. Verify the computer is powered on. Power cycle the computer. If problem persists, contact Heska's Technical Support Services.



For further assistance, please call Heska's Customer Support Services

US 800 464 3752  
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