hygiena™



Innovate System Customer Guide

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About

Contributing to Your Success

We want to help your company increase productivity and improve profitability. Our system help you save time and money by providing actionable information fast. Our systems contribute to streamlined compliance with USDA/FDA regulations and help you ensure the safety of your products so you can get them to your customers sooner.

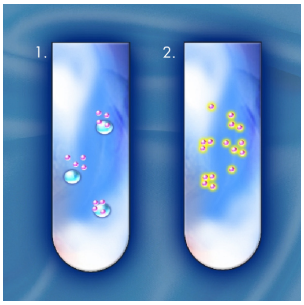
Real, Quantifiable Value

Most companies implementing for a single plant realize a return on investment in just 6–9 months and enjoy a 5-year net present value (NPV) in excess of $500,000. offers a free tool, our Value Creation Model, to help you quantify the financial value of implementing a rapid detection system at one or more of your plants or upgrading an existing system. Developed for a global customer in conjunction with international management consulting firm Arthur D. Little, the model uses readily available manufacturing, quality assurance and financial data from your company to calculate the payback period and the 5-year NPV of adopting asystem. Calculations are specific to your company and confidential, and can be modeled for single and multiple plants.

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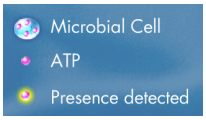
ATP Bioluminescence Technology from

ATP bioluminescence – ATP bioluminescence is a commonly accepted method for the microbial screening of dairy products. It can be used to detect contamination in as little as 24-48 hours, not 4-14 days like traditional methods.



All living organisms contain the compound ATP as a vital part of their energy metabolism. It is this ATP that is released and detected by a standard bioluminescence test. ATP rapidly reacts (in the presence of the luciferase enzyme) with luciferin and oxygen to give a yellow-green light:

$$\text{ATP} + O_2 + \text{Luciferin} \xrightarrow{\textit{luciferase}} \text{AMP} + CO_2 + \text{oxyluciferin} + \text{pyrophosphate} + \text{LIGHT}$$



A luminometer automatically adds the required reagents to a sample and detects the emitted light with great sensitivity. The RapiScreen™ Dairy Kit contains all the necessary reagents that are specifically designed to use ATP bioluminescence for the rapid detection of microbial contamination.

- ATX is added to deplete free ATP. Most dairy products naturally contain sources of free ATP. Sources of free ATP include somatic and/or microbial cells killed during the UHT process
- CellSolver is added to release microbial ATP
- Sensilux is added and ATP is measured

The RapiScreen™ Dairy Reagents

The following reagents are used in the RapiScreen™ Dairy kit:

- **ATX:** Apyrase enzyme in a freeze-dried form.
- **Dilutor DA:** Dilution buffer for reconstitution of ATX
- **CellSolver:** Extractant for releasing microbial ATP from the cell
- **Sensilux :** Luciferin / Luciferase enzyme in a freeze-dried form
- **Dilutor DS:** Dilution buffer for reconstitution of Sensilux

The RapiScreen™ Dairy Kit must be stored refrigerated at 2-8°C. Once reconstituted, the stability of the reagents is 5 days in the cooling unit.

Customer Support & Ordering Information

For assistance or to place an order, please contact :

When placing an order, please include:

- Catalog number, product description and quantity
- Ship to address, phone number, fax, e-mail and contact person
- Billing address, phone number, fax, e-mail and contact person

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- Purchase order number

*All orders are subject to approval and availability of inventory.

Supplies Available from

Item	Catalog #
RapiScreen™ Dairy Kit 1000 Assay	KIT4000 (82010)
RapiScreen™ Dairy Kit 5000 Assay	KIT4001 (82050)
Maintenance and Cleaning Kit	KIT4012 (1290500)
ATP Positive Control	KIT4014 (1291483)
Innovate Injector Test Fluid	MIS4077 (321744000)
5-50µl Pipettor	MIS4087 (91200)
20-200µl Pipettor	MIS4085 (91184)
200µl ATP-Free Pipette Tips (960 / case)	MIS4091 (93679)

Quotes
Upon request, prices are quoted in writing. Quotes are only valid for a specified period of time as indicated on the quote. Please reference the quote number when ordering to avoid pricing or shipping errors.

International Shipments
Shipments are made “freight collect” by the forwarding agent of your choice. Please provide the name, address, telephone number and contact name of the importing broker, as well as special shipment instructions, if any. If requiring shipment via courier (Federal Express or DHL), please provide courier account number and account name.

All shipments are Ex-Works shipping point (Camarillo, California USA or Watford, Hertfordshire, UK). All shipping, handling, storage, customs duties, taxes and import fees must be paid by the client.

Permanent import licenses should be in place before shipment of instruments, dry goods and reagents. International reagent orders that have been approved and confirmed are shipped only on Monday and Tuesday before noon (unless otherwise agreed upon) to allow goods to reach the destination in the same week.

Prices
Prices are subject to change without notice. Please contact to verify pricing.

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Payment
We offer the following options:

1. **Purchase Order**
2. **Wire transfer:** Please contact Customer Service for additional information on wire transfers.
3. **Credit card:** American Express, Visa or Master Card. Please notify Customer Service if you wish to use this option.

Standing Orders
Standing Orders are available for all disposable products (e.g., test kits, cuvettes, etc.) and must be approved by . A firm, non-cancelable purchase order must be issued for six (6) or twelve (12) months. The order must specify monthly shipment schedules. Please contact Customer Service to set up a standing order.

Warranties
All products are 100% QC before shipping. We strongly recommend refrigeration of reagents (2-8º C) at all times during transit and customs. The insulated shipping carton is not designed for prolonged use, even with external refrigeration. No warranty will be given for defects in shipped products (reagents and accessories) due to improper handling or storage, including delays in transit and in customs.

In no event shall be liable for any loss, damage, cost of repair or consequential damages of any kind in connection with the design, installation, use, performance, repair or replacement of the products supplied and/or installed by or its distributors.

Damaged Product
The delivering carrier is responsible for damage in shipment. Packaging material should be kept if damage occurs. Immediately contact the delivering carrier for inspection of damage and claim filing. Damaged items cannot be returned without authorization.

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System Operation – Reference Guide

RapiScreen™ Dairy Assay on Innovate

This Overview is for reference only and does not supersede any company-specific Standard Operating Procedures (SOPs) established by your company. If your company has SOPs for the operation of this system, please refer to them for guidance in system operation.

DAY 1



Sample Prep

- Incubate the sample in its original package at 30°C (or other validated temperature) for a minimum of 48 hours.

DAY 3



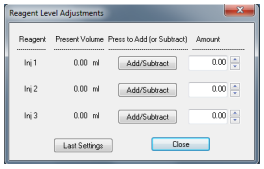
Reconstitute Reagents

- Remove reagents from the refrigerator.

  RapiScreen Dairy 1000
  - **Sensilux** (yellow label) – Carefully open a vial of **Sensilux** and a vial of **Dilutor DS** (yellow label). Pour the contents of the **Dilutor DS** into the **Sensilux** vial, swirling gently to mix and pour the total contents into the 50ml PP-vial.
  - **Cellsolver DE** (green label) – **Cellsolver DE** is ready for use.
  - **ATX** (red label) – Carefully open a vial of **ATX** and a vial of **Dilutor DA** (red label). Pour contents of the **Dilutor DA** into the **ATX** vial, swirl gently to mix and pour the total contents into the 50ml PP-vial.

  RapiScreen Dairy 5000
  - **Sensilux** (yellow label) – Dispense 12ml of Dilutor DS (yellow label) into the Sensilux vial, swirling gently to mix and pour it into the 50ml PP-vial. Dispense the second 12ml Dilutor DS directly into the 50ml PP-vial.
  - **Cellsolver DE** (green label) – Cellsolver DE is ready for use.
  - **ATX** (red label) – Dispense 9ml of Dilutor DA (red label) into the ATX vial, swirl gently to mix and pour total contents into the 50ml PP-vial.

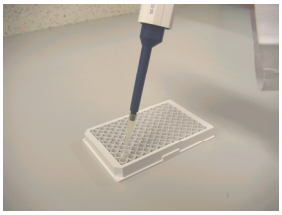
- Swirl gently, place the reagents in the Innovate reagent holder and leave for 15 minutes before use.



Injector Startup

- **Washing**
  - First turn on the instrument and then open the **Innovate.im** software.
  - Select **User** as username and enter the password **User**.
  - Select **Instrument/Wash** on the menu bar.
  - Wash injectors 1 and 3 with Microwash by following the on-screen instructions.
  - Click on **Instrument/Reagent levels** to enter the reagent volumes. Select Last Settings in case reagents are left from the previous day.
  - Connect the reagents. **ATX** to injector 1 and **Sensilux** to injector 3. **Cellsolver** is already connected to Injector 2.
  - Click on **Instrument/Prime** to fill the three injectors with reagents. Select all three injectors and follow the on-screen instructions.
- Please refer to the Innovate Operator Manual for more details.

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Daily Control

- It is important to perform daily controls prior to using the system to screen samples. Follow the steps below to perform your daily controls:
  - Leave two wells empty in the microtiterplate for the **InsBlank** measurement.
    - *Results must be < 50 RLU before proceeding*
  - Leave two wells empty in the microtiterplate for the **Reagent Blank** measurement.
    - *Results must be < 70 RLU before proceeding*
  - Pipette 50 µl of ATP into two wells for the **ATP Positive Control** measurement.
    - *Results must be > 40,000 RLU before proceeding*
- Daily controls can be measured using the **Controls** protocol

Samples

Pipette 50 µl of each sample into the wells (column wise). It is important to pipette the sample into the bottom of the well and to avoid splashes against the wall.

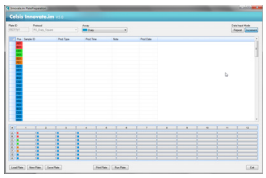
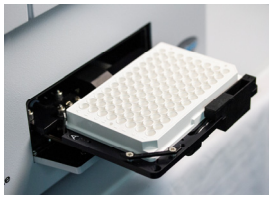


Plate Preparation in Innovate.im

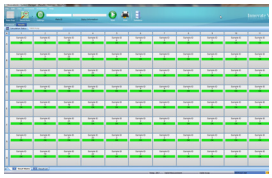
- Protocol selection
  - Click on **PlatePrep** icon.
  - Enter Plate name followed by enter.
  - Select Assay **Dairy_Linear** or **Dairy_Square** to measure the products.
  - Select **Dairy** with the arrow near the Product Box and in the bottom screen, select the wells containing the product.
- Sample Identification
  - Enter the sample information into the cells in the upper screen.
- Click on **Run Plate** to measure the plate. The file name will be saved after confirmation.
- Click on **Save Plate** if you want to define the next microplate before measurement.



Start Measurement

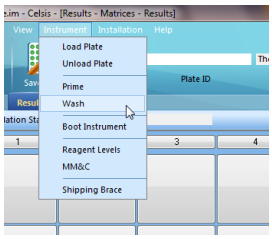
- Click **Start** to start the measurement.
- The Innovate will automatically unload the previous plate outside the instrument.
- Load plate and click on **OK**. The measurement will automatically start.
- In case of insufficient reagents, you will be automatically prompted to add more reagents. Follow the instructions on the screen.
- Measurement results are automatically saved (C: Program Files/Innovate/Data) and transferred to the **Innovate.im** database.

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Interpretation

- The system automatically interprets and displays the results based on the criteria established during installations. Typically any sample result greater than 2-3 times the RLU value of non-contaminated sample is positive.



Cleaning the instrument

Injector system needs to be cleaned at the end of the working day, following the measurement of all samples.

- Connect Microwash to Injector 1 and 3.
- Wash Injector 1 and Injector 3 by selecting **Instrument/**Wash. Follow the on-screen instructions.
- Please refer to the Innovate Operator Manual for more detail.
- Unload the last plate by the **Instrument/Unload Plate** command.
- Close the Innovate.im software.
- Leave the reagent is the Innovate reagent holder
- Turn off the instrument. Make sure the cooling unit of the reagent holder is not switched off.

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Preventive Maintenance

The Innovate system has redefined what microbial screening should be: great instruments designed around customer needs, highly sensitive enzyme reagents and world-class technical support. The recommended preventative maintenance procedures and schedule below will help you optimize the performance of your instrument.

Daily	• Clean pipettor daily with alcohol • Wash injector lines at start-up and shut-down with Microwash solution. • Check waste container and empty contents if more than 2/3 full. • Perform instrument controls to confirm the system is operating within specification before testing any samples: – Instrument Blank Control (InsBlank). Negative Control to check instrument interior for light leakages or reagent spillage. – Reagent Blank Control (ReaBlank). Negative Control to ensure there is no contamination of injector lines or reagents. – ATP Positive Control (ATP). Positive Control to ensure that the Sensilux reagent is fully active.
Weekly	• Inspect instrument interior for spillage and/or splashed reagents with considerable attention to the plate mask and plate carrier. Clean the interior with Microwash solution and a lint-free towel as appropriate • Perform a visual inspection of injector tips to ensure tip ends are open and clean • Inspect external injector tubing for kinks and ensure that all connections are tight. • Perform a visual (qualitative) injector volume check using ATP Free Red Dilutor • Clean/dust reagent holder and cooling block
Monthly	• Clean injector system with the **Maintenance and Cleaning Kit** (see kit insert for instructions). • Perform the (quantitative) **Injector Volume Check** to ensure that volumes are within +/- 5% of specification.
Annually	• Schedule a preventative maintenance visit by a Certified Service Representative to perform a full instrument service.

Certified Service Program

If an instrument requires service or repair, please contact Customer Service and describe problem. Service for all systems can be performed on site or at by an authorized service engineer. Instruments cannot be accepted without proper authorization by . Upon system arrival, the Service Department will determine the extent of the repair and fax the customer with details and an estimated cost of repair. A purchase order must be provided with a signed copy of the repair estimate before work will begin.

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Troubleshooting

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If your issue is not listed above, please contact Technical Support

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Innovate Technical Support Quick Reference Guide

Assay Control	A	B	C	D
Instrument Blank	OK	TOO HIGH	OK	OK
Reagent Blank (Reagent Control)	OK	OK	TOO HIGH	OK
ATP Positive Control	OK	OK	OK	TOO LOW

A All controls are within recommended specifications

- **Instrument Blank** = <50 RLU
- **Reagent Blank** = <70 RLU
- **ATP Positive Control** = >40,000 RLU

B Instrument Blank too high. Possible causes include:

- **Elevated PMT temperature**
- **Increased background noise PMT**
- Go to Customer Guide for detailed troubleshooting steps.

C Reagent Blank too high. Possible causes include:

- **Reagent contamination** – Open fresh reagents including wash solution and run 2-3 wash cycles
- **Dispenser contamination –** Autoclave bottle top dispenser if using bulk dilutor with 5000 assay kit
- **Injector contamination** – Clean the injector system using the monthly maintenance and cleaning kit
- Go to Customer Guide for detailed troubleshooting steps.

D ATP Positive Control too low. Possible causes include:

- **Expired reagents and/or ATP positive control** - Open fresh reagents/ATP
- **Improper storage/usage of reagents** - Ensure that reagents/ATP have been stored according to instructions in kit insert
- **Injector volume outside of recommended specifications** - Perform injector volume checks for all injectors used. Check that pipettor is delivering proper volume of ATP
- Go to Customer Guide for detailed troubleshooting steps.

Contact Technical Support if these steps do not resolve the issue.

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Instrument Control Solutions

High Instrument Blank

High instrument (INS) blank readings using the Innovate can be caused by a number of factors. The following steps should be performed to determine the cause:

Step 1: Check for crosstalk

- Perform cross-talk check by pipetting 50µl ATP positive control and 100µl Sensilux into one well in the center of the micro titer plate (e.g. E7). Perform Ins Blank measurements in eight surrounding wells (e.g. D6, E6, F6, D7, F7, D8, E8, F8). If the cone is sealing properly, the wells surrounding the center ATP well (E7) will be <50 RLU indicating no crosstalk (proceed to Step 2). If the surrounding wells have high background readings then the plate mask must be cleaned.
- After cleaning the plate mask system run Ins Blank Assay. Results can be high due to PMT exposure to light.
- Wait 15-30 minutes and re-run Ins Blank Assay. Results should be lower than when previously run.
- Wait additional time until Ins Blank results are <50 RLU
- Re-run Cross Talk check
- If OK, stop. If still high proceed to Step 2

Step 2: Check for spraying

- Exit Innovate.im software and power down instrument
- Open lid and inspect plate mask for dry/wet liquid. Clean as needed with micro wash
- Power on instrument and start Innovate.im software
- Wash instrument three times with micro wash and prime reagents
- After cleaning plate mask system run Ins Blank Assay. Results can be high due to PMT exposure to light.
- Wait 15-30 minutes and re-run Ins Blank Assay. Results should be lower than when previously run
- Wait additional time until Ins Blank results are <50 RLU
- If Ins Blank results do not decrease, proceed to Step 2

Step 3: Check for static

- Pipette 50 µl of liquid into each well of the microplate and run Ins Blank measurements in the Controls Assay. If the original high Ins Blank readings were caused by static, all RLU values should be <50. If still high, proceed to Step 3.
- Alternatively, wipe the bottom of the microplate with a moist (not wet) towel and run Ins Blank measurements in the Controls Assay. If the original high INS Blank readings were caused by static, all RLU values should be <50. If still high proceed to Step 3.

Contact Technical Support if these steps do not resolve the issue.

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Instrument Control Solutions

High Reagent Blank

High Reagent (Rea) Blank readings on the Innovate can be caused by a number of factors. Perform the following steps to determine root cause:

Step 1: Run Instrument Blank and if too high suspect wet plate mask.

Step 2: Wash ONLY Injector 3 with Microwash

Step 3: Inspect plate mask

- Exit Innovate.im software, power off instrument
- Open lid and visually inspect plate mask for evidence of sprayed/splashed reagent/wash residue
- Clean as needed with Microwash
- Close lid and power on instrument, start Innovate.im software
- Wash instrument 4X with Microwash, prime reagents
- Allow sufficient time (~15-30 min) for Instrument (INS) Blank values to return to normal (will run high after PMT exposure to light)
- Run Rea Blank Assays. If OK, stop. If still high proceed to Step 5

Step 4: Check for contaminated reagent injection system

- Manually pipette CellSolver (50 µl) and Sensilux (100 µl) into two wells.
- Run Ins Blank assay. If results <70 RLU proceed to Step 8. If results >70 RLU proceed to Step 6

Step 5: Prepare new reagents

- Set aside ALL in-use reagents, including bulk dilutor solutions if used with 5000 assay kit
- Wash instrument 4X with Micro wash
- Prepare new reagents in new vials. Use sterile 10 ml pipettes to dispense bulk dilutor solutions – do not use bottle top dispenser until contamination has been ruled out
- Prime new reagents
- Run Rea Blank Assays. If OK the contamination is in a buffer or reagent solution set aside - discard reserved reagents and proceed to Step 7 to decontaminate the dispenser unit. If Rea Blank Assay is still high proceed to Step 8

Step 6: Clean Dispenser Unit (for 5000 assay kits only)

- Empty dispenser contents into basin
  Fill a suitable container with ethanol
- Clean the dispenser by flushing with ethanol making sure that the dispenser is set at its maximum volume
- Allow the dispenser to air dry
- Place dispenser in fresh Dilutor DS reagent

Step 7: Check for contaminated instrument injection system

- Run Maintenance and Cleaning kit
- Run Rea Blank Assays. If OK, stop. If still high contact Technical Support.

Contact Technical Support if these steps do not resolve the issue.

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Instrument Control Solutions

Low ATP Pos Control

Low ATP positive control readings on the Innovate can be caused by a number of factors. Perform the following steps to determine root cause:

Step 1: Test for low ATP activity.
- Remove a new vial of ATP positive control from the freezer
- Repeat ATP positive control assay using fresh ATP
- If OK stop, If still too low proceed to step 2

Step 2: Test for low Sensilux activity
- Set aside Sensilux reagent currently in use
- Perform wash sequence on injector 3 two times using micro wash solution
- Prepare new Sensilux reagent
- Load new Sensilux reagent on instrument and prime injector 3
- Repeat ATP positive control assay using fresh Sensilux reagent
- If OK, Stop, If still too low proceed to step 3

Step 3: Check volume of injector 3
- Perform injector volume check for injector 3 following instructions provided in the Appendix.
- Volumes should be 95-105% of specification. If the volumes are out of specification proceed to step 4. If volumes are within specification contact technical support

Step 4: Check for source of restricted flow (should be performed by trained personnel only)
- Verify in-line filter for injector line 3 is not blocked (remove and visually inspect, see instructions provided in troubleshooting guide)
- Verify all tubing connections are tight. Steel to filter, filter to line, line to injector port
- Verify tip of injector 3 is not blocked with dried reagent

Contact Technical Support if these steps do not resolve the issue.

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Installation Driver Window – Innovate.im Software Communication Error

Solution Number: SLN - 00038

An “Installation Driver” window may appear after trying to open the Innovate.im software for several reasons. In order to properly troubleshoot, the user should exit the software.

Note: To properly exit the software, select “cancel” on the “Installation Driver” window. A “Program Activation” window will appear, select “cancel”. The Innovate.im software will successfully shut-down after canceling both windows.

Step 1: Check internal connection
An “Installation Driver” window will appear if the instrument is not turned on, or if the software is started before the instrument is turned on. The proper sequence is to turn the instrument on before starting the software.

- Exit the “Installation Driver” window as instructed above
- Turn on the instrument followed by the software. The LED light should light up green or orange. If “Installation Driver” window still appears proceed to Step 2

Step 2: Check for physical connection
An “Installation Driver” window will appear if the computer is not connected to the instrument by a serial cable.

- Check to make sure that the serial cable is properly connected to the computer and the instrument.
- If properly connected and window still appears go to Step 3

Step 3: Check the MIKROTEK.INI file (not applicable to Innovate.im v5 and higher)
An “Installation Driver” window will appear if the user has pasted or entered the Program ID Code into the Activation Code which is needed for standalone activation. By doing this the user has deactivated the program.

- Open the MIKROTEK.INI file located in the WINT folder for Windows 2000 or the Windows folder for Windows XP
- Look for ProtActiCode and if a code is present delete it.
- Save MIKROTEK.INI file
- Program should be reactivated. If not proceed to Step 4
- See below for example

Incorrect:
ProtProgCode=38684AE83A38684A08C237451AE8CE
ProtDeviCode=
ProtActiCode=38684AE83A38684A08C237451AE8CE

Correct
ProtProgCode=38684AE83A38684A08C237451AE8CE
ProtDeviCode=
ProtActiCode=

Contact Technical Support if these steps do not resolve the issue.

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Continuous Shaking of Samples Beyond Set Time

Solution Number: SLN - 00040

The user may experience the Innovate shaking beyond the set time period (e.g. 10 min). The user will see the time countdown to negative numbers on the software computer screen.

Note: Shaking will continue indefinitely without user intervention. Please follow directions to avoid potential damage to electronics.

This is caused by the interface cable being loose (not disconnected) between the Instrument and PC. The loose connection is not allowing proper communication between the instrument and the PC. The result in this case is that the shaking period is not being transmitted to the PC so the instrument continues to count down to a negative figure.

Step 1: Switch off instrument and shut down Innovate.im software

Step 2: Connect cable

Step 3: Turn on instrument followed by Innovate.im software

Step 4: Re-run new samples on a fresh plate

Contact Technical Support if these steps do not resolve the issue.

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Liquid Injected Outside of Wells

Solution Number: SLN - 00198

During normal operation of the Instrument the plate carrier transport lock screw must be in the released position. If the lock screw is in the locked down position it will prevent full range of movement of the plate carrier during an assay.

If the lock is in the locked down position the far right side of the plate (columns 11-12) will be out of alignment, causing liquid to be injected between wells.

To correct this, follow these steps:

Step 1: Close Innovate.im software and turn instrument off

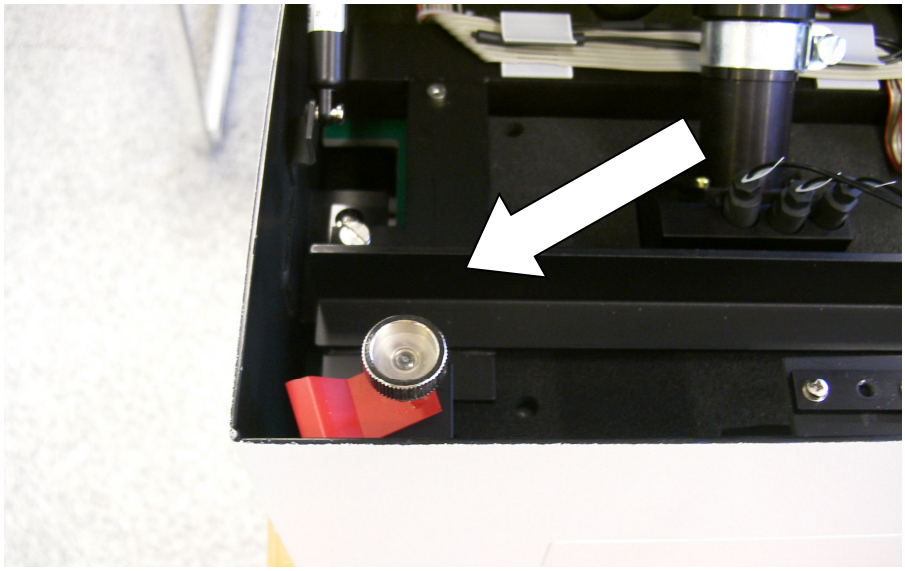
Step 2: Open lid and release transport lock by turning screw illustrated below. Transport lock is a spring loaded screw and will spring up when unlocked. Close lid.

Step 3: Turn instrument on and start Innovate.im

Step 4: Perform a qualitative injector volume check with red Dilutor M596 to ensure that the liquid is being injected correctly

If the transport lock is not engaged, the spraying may be caused by a clogged injector system. Perform several wash cycles with Microwash solution to clean injector system.

Contact Technical Support if these steps do not resolve the issue.



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Software Freezes During Assay

Solution Number: SLN - 00121

Innovate.im requires bilateral communication with the Innovate Luminometer during an assay. If this communication is interrupted, the Innovate.im software may fail to complete an assay and/or appear to freeze.

Step 1: Verify instrument and PC are both plugged into a surge protector. Power surges can interrupt communication between instrument and PC.

Step 2: Determine which COM port the Innovate Luminometer is installed on

- Close Innovate.im software
- Launch Service.exe program found in below directory depending on operating system and IM version.
  - Innovate.im v3 or v4
    - Windows XP = C:\ProgramFiles\InnovateIm\CellScan\Service.exe
  - Innovate.im v5
    - Windows XP = C:\Documents and Settings\All Users\Application Data\InnovateV5\CellScan
    - Windows 7 = C:\ProgramData\InnovateV5\CellScan
- Select "Instrument" and then "Scan COM Ports"
- The Com Port that the instrument is connected to will be displayed
- The default com port is Com1

Step 3: Verify that no other Windows devices are using the same COM port as the instrument and that the COM port is correctly configured (Device Settings in Windows Control Panel).

Step 4: Check the Power Options in Windows and verify that the “Turn Off Hard Drive” option is set to "Never" and that the System Standby option is also set to "Never".

Step 5: Turn off screen saver or set the delay time to a minimum of 1 hour. This will allow adequate time for a 96 well assay to complete without screen saver activating in the middle of the assay.

Contact Technical Support if these steps do not resolve the issue.

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Start Button not Visible (not applicable to Innovate.im v5)

Solution Number: SLN - 00102

After setting up assays and entering sample ID info in the plate prep window the user presses the "Run Plate" button. The "Start" button, however, is not visible to initiate the assay.

Root Cause:
"Start" button is part of the read toolbar. If the toolbar is closed, the "Start" button will not be visible.

Solution:
Click either the "Read" button or "Read" in the main menu to display the toolbar containing the "Start" button.

Contact Technical Support if these steps do not resolve the issue.

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Verifying ATX Reagent Activity

Solution Number: SLN - 00223

The ATX reagent in the RSD1000 **KIT4000** (82010) and RSD5000 **KIT4001** (82050) kits is used to deplete background or free ATP which is present in dairy samples.

If this reagent is old or not prepared properly it may not fully deplete the background ATP signal prompting questions about false positive results and/or variable results. If correct injection volume of this reagent has already been ruled out as a cause of high/un-repeatable results the following ‘assay’ can be run to verify activity of the ATX reagent. (Note: the normal Rea Blank assay used in the Innovate.im Controls.par file does not inject ATX.)

Step 1: Add 50 µl of ATP Pos Control Solution to four (empty) wells on a microtiter plate

Step 2: Manually pipette 25 µl of ATX reagent into the last two wells

Step 3: Allow 60 seconds for the ATX and ATP to react

Step 4: Assay the four wells using the Controls.par/ATP POS assay. This will inject Sensilux reagent and measure the light output.

The first two wells (ATP only) should give a normal positive control response of >40,000 RLU.

The second two wells (ATP + ATX) should give a RLU <1000 which verifies that the ATX reagent is fully active and is able to deplete free ATP. If there is little or no change in RLU values between the two sets of wells then the ATX reagent in use should be replaced and the procedure repeated with newly prepared ATX.

Contact Technical Support if these steps do not resolve the issue.

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Innovate LED Indicator Light

Solution Number: SLN - 00384

The front panel of the Innovate system features a multicolor LED indictor light to convey critical information about the instrument's status. When the power is turned on, the LED will change color from red to orange to green. This indicates normal function.

LED Color	Status	Action
Green	System operating normally	Begin testing after running daily system controls
Orange	No communication between instrument and computer	Turn off instrument and computer. Ensure proper connection of instrument cable to computer. Reboot computer. Turn on power to the Innovate system
Red	Critical system failure	Immediately turn off instrument and contact Technical Support

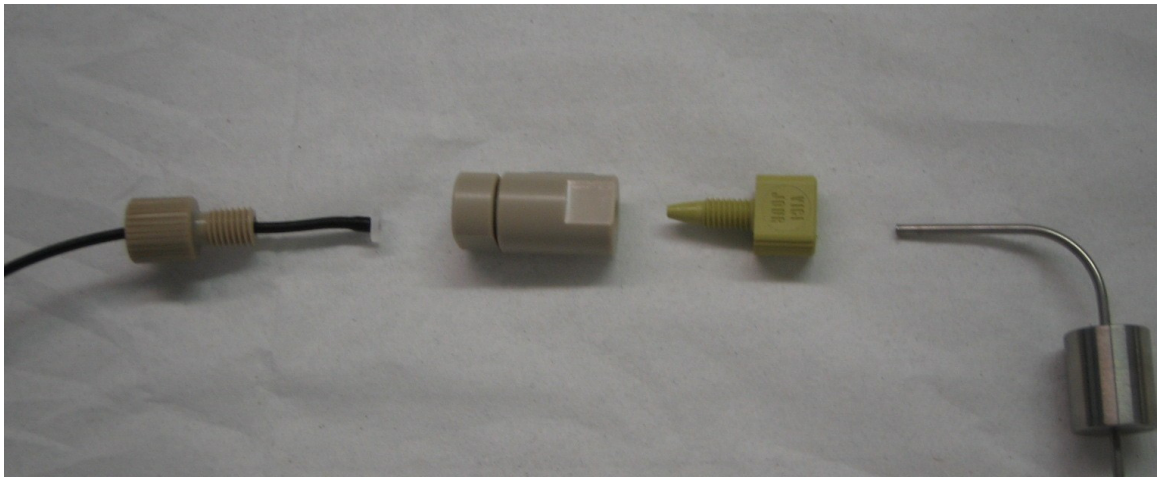
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Inspecting/Changing the In-Line Filters

Note: This operation should only be performed by specially trained personnel.
Note: Always use powder free gloves when working with in-line filters.

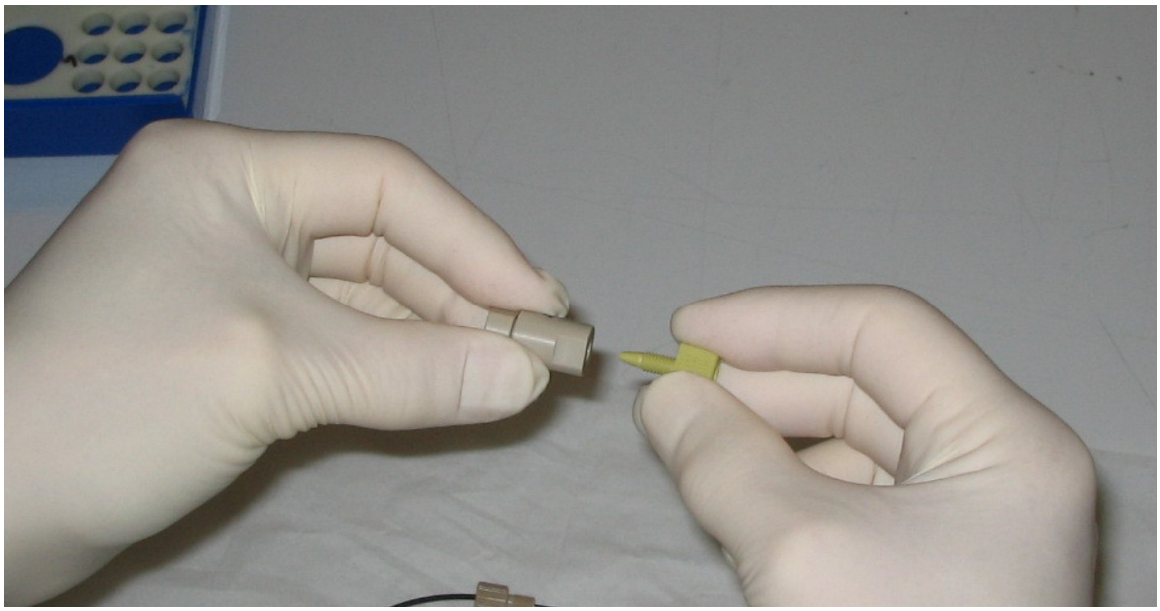
To check and/or change the in-line filters on the Innovate perform the following steps:

Step 1: Unscrew the filter assembly



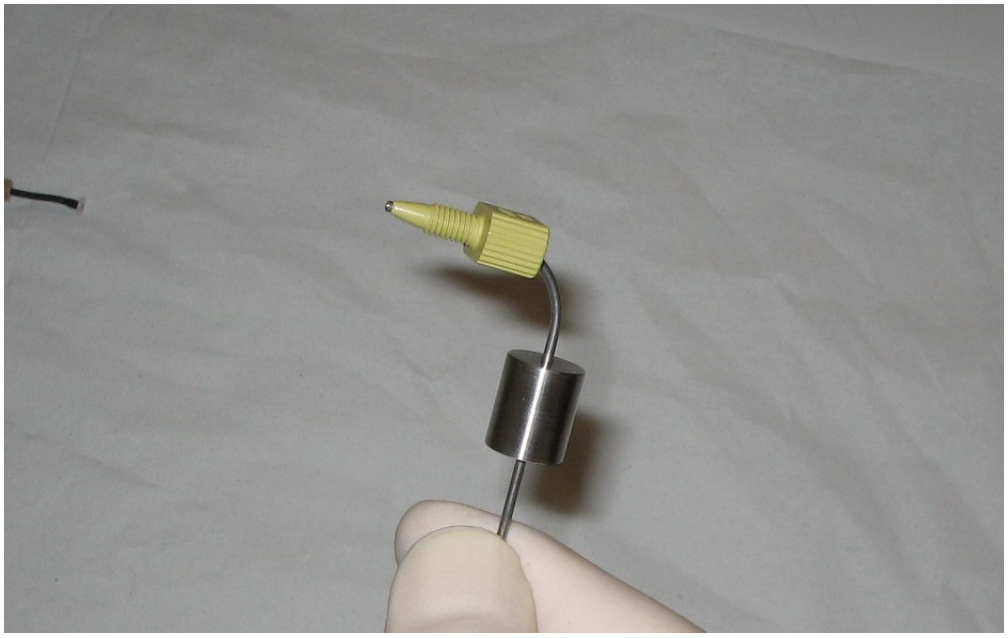
Step 2: Check the filter by holding it up to the light. In a clean unclogged filter, the mesh grid of the filter will be visible.

Step 3: Screw the colored steel connector into the new unclogged in-line filter **until finger tight.**

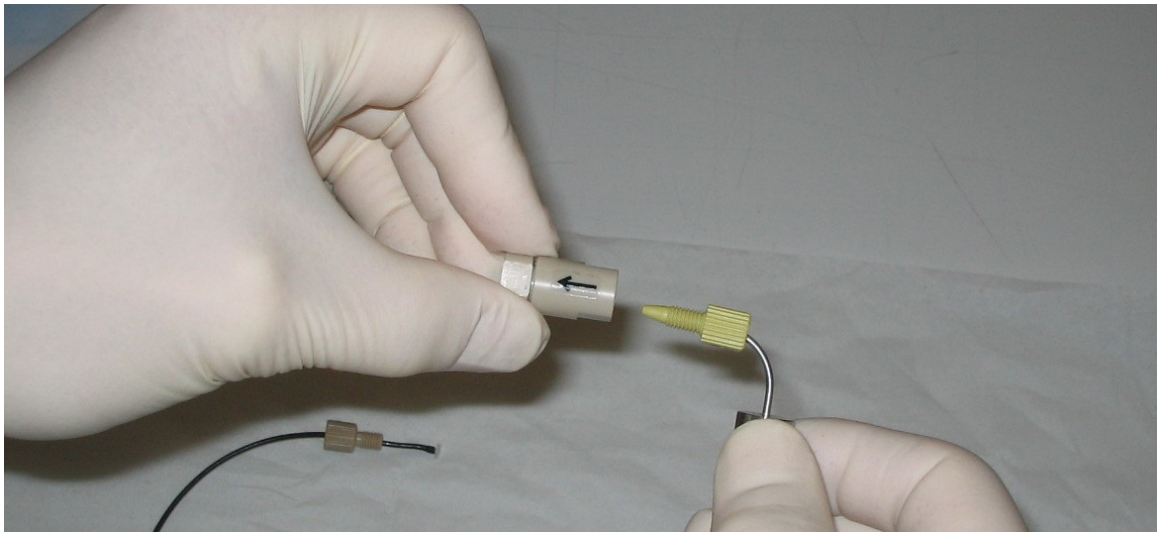


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Step 4: Unscrew colored steel connector from in-line filter and place on the steel end as shown. Connector must stay fixed on the steel end.

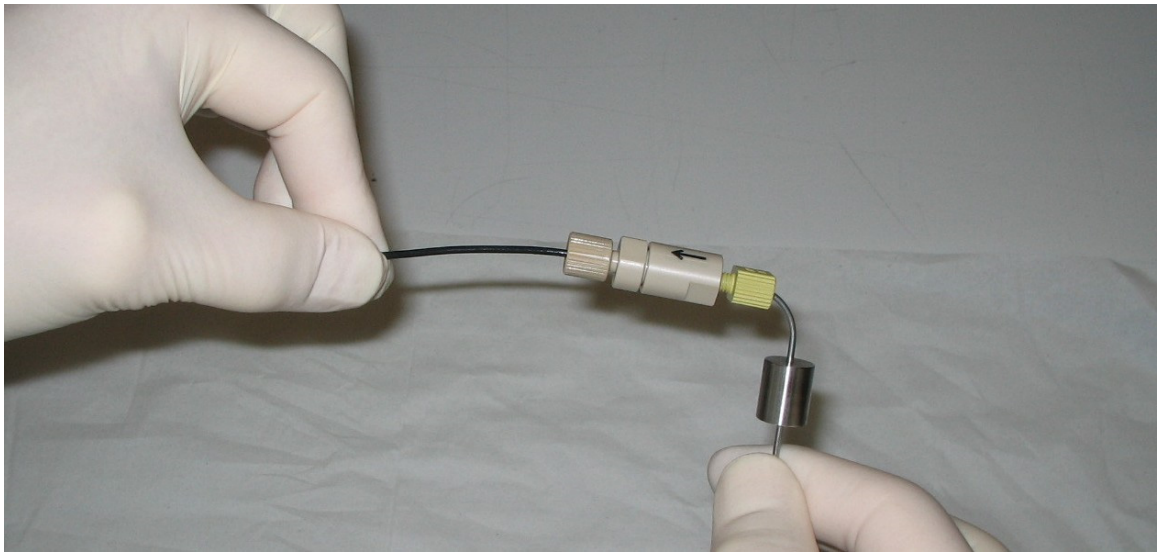


Step 5: Screw the new in-line filter onto the colored steel connector by holding the steel connector stationary while turning the in-line filter until tight.



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Step 6: Place tubing end into filter end. Screw tubing connector into in-line filter



Important: Upon completion, perform injector volume check for all three injectors. If injector volume check is outside of specification, there may be a bad connection. Repeat above procedure to ensure that all connections are tight.

Contact Technical Support if these steps do not resolve the issue.

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Changing Innovate Injector Tips

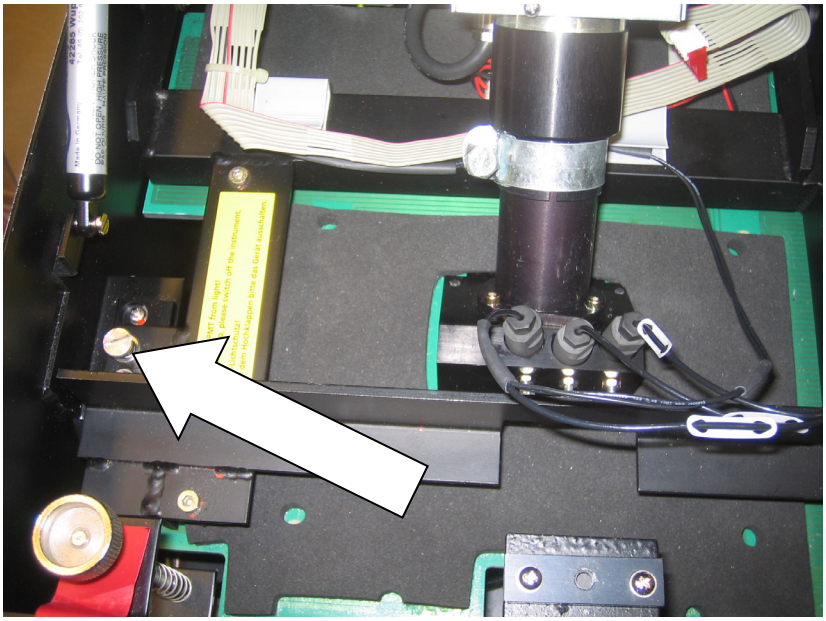
Note: This operation should only be performed by specially trained personnel.

Step 1: Shut down Innovate.im software and turn off the instrument

Step 2: Remove plastic cap on instrument lid and use ball-nose driver (supplied) to loosen lid-lock

Step 3: Raise instrument lid to open position

Step 4: Loosen set-screw securing detector head platform



Step 5: Raise detector head platform until it locks in place in the raised position

Step 6: Using fingers, unscrew injector tip.

Step 7: Grasp connector at terminus of reagent line and pull tip(s) out being careful not to damage the tip end(s)

Step 8: Gently remove old tip and push new tip into place.

Step 9: Insert tip back into detector head block being careful not to damage the end of the tip.

IMPORTANT: Always turn connector keeping plastic nut and reagent line from twisting. Twisting the reagent line may cause a constriction and restrict flow of reagent.

Step 1: Secure tips in place by hand tightening

Step 10: Lift the platform until it locks into position and check the position of the injector tips as they pass through the tip housing in the bottom of the detector head block.

Note: Injector tips (particularly tip number 3) are ex-centric, not positioned in the exact middle of the housing.

Step 11: Check injector tip ends to ensure they do not protrude beyond the outside surface of the tip housing. Tips should be oriented ½ mm back from opening.

Step 12: Lower detector head platform by releasing locking latch to left of photomultiplier tube. Take care to support platform prior to releasing latch.

Step 13: Close instrument lid, secure with lid-lock mechanism, replace plastic cap

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Step 14: Power on Instrument

Step 15: Launch Innovate.im software

Step 16: Prime all three injectors with ATP Free Red Dilutor and perform qualitative injector tests to check quality of injection stream

Contact Technical Support if these steps do not resolve the issue.

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Plate Jammed in Innovate

Solution Number: SLN - 00379

If the plate carrier with sample plate becomes jammed perform the following steps:

1. Turn off Innovate
2. Open lid with ball nose screwdriver
3. Unscrew and lift detector head platform
4. Remove plate from plate carrier, clean the system in case samples are spilled into the instrument and lower detector head platform back into place
5. Secure platform with screw
6. Lower instrument lid and screw back down with ball nose screwdriver
7. Reboot computer and turn on instrument.
8. Run instrument blank, reagent blank and ATP positive control to verify operation within specifications. If all controls are within spec, stop. If Instrument blank is high, proceed to step 9.
9. If instrument blank is high, PMT may have been overexposed or plate carrier may be out of alignment.
10. Check for plate carrier alignment as follows:
    a. Add 100ul ATP and 100ul Sensilux to well E6
    b. Measure INS blank in D5, E5, F5, D6, E6, F6, D7, E7, F7.
    c. E6 must be high the rest should be at instrument blank level.
    d. If crosstalk is observed, plate carrier needs realignment (contact Technical Support)
11. If no crosstalk, allow PMT to rest and then test again.

Contact Technical Support if these steps do not resolve the issue.

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Error Message: “Measurement Interrupted by User”

Solution Number: 00000022

Using the Innovate, an assay measurement is interrupted by the user pop-up window: "Measurement Interrupted by User" although the “STOP” button was not selected by the user.

This window message normally appears when the “Stop” button has been selected after a measurement is started. However, if this message appears and the user did not intend to stop the run it is likely because the user double clicked to start the measurement when only a single click is necessary. The Innovate.im software sees the first click as a start and keeps the second one in "memory" and interprets this as a “Stop” signal.

To avoid this error message, use only a single (one) click or just “Enter” to start measurement.

Contact Technical Support if these steps do not resolve the issue.

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Error Message: “Plate ID Already Exists…”

Solution Number: SLN - 00200

The error message "Plate ID File Already Exists. Do you want to reload the file?" appears if the user tries to create a new plate layout with a previously used filename.

Answering "Yes" to the above filename will load the previous plate layout with the used positions grayed out. Answering "No" will open the plate layout window with the previously used filename loaded in the PlateID field.

This window should be closed and a new plate layout created with a NEW filename. If the user attempts to create a plate layout with the previously used filename they will receive the error message, "Plate ID file already exists. Do you want to replace the file?"

The correct response to this message is "No". If the user responds "Yes" the write protected PlateID will be loaded. Pressing the “Start” button will generate the following error message "File is write protected. Save operation not possible using this filename."

Contact Technical Support if these steps do not resolve the issue.

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Error Message: “Please enter a filename before starting a measurement” (not applicable to Innovate.im v5)

Solution Number: 00000013

This error message is seen with Innovate.im when a user does not follow the proper sequence of running a plate. The proper sequence to begin a run is to recall the plate ID of the saved plate followed by clicking the "Start" button. If "Start" is single clicked before a plate ID is loaded the file name error message will occur.

Contact Technical Support if these steps do not resolve the issue.

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Appendix

Because documents continually undergo change as needed, the following kit inserts and Safety Data Sheets are provided for reference use only. To make sure you have the most current copy, please call either Customer Service or your Technical Support Representative.

- **RapiScreen Dairy Fact Sheets**
- **RapiScreen Dairy Kit Inserts**
- **Safety Data Sheets (SDS)**
- **Injector Volume Check Worksheet**

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