



**TITLE: Operating Manual PR2A
Twin Shot Reader**

SOP Number:

PTK043 version A

Created: 12-12-18

Issued: 02-01-19

Status: Issued Page 1 of 46

TITLE: Operating Manual PR2A Twin Shot Reader

PURPOSE

To provide user direction on the correct use and general maintenance of the Protak scientific PR2A Luminometer.

SCOPE.

- This Operating Manual is structured as follows: The manual covers all manipulations in a workflow order starting from installation via regular operation to maintenance.
- In each section, you are guided through the respective procedures step by step.
- The steps are consecutively numbered in each section.
- Explanations on the individual steps are added in small type font. Explanations on the various types of operations are highlighted specifically.
- For your convenience, illustrations are placed directly next to the respective text.

RESPONSIBILITIES AND AUTHORITIES

The user is responsible for following the operating instructions as specified in this manual for the PR2A.

PROTOCOL

1.	PREFATORY COMMENTS	3
1.1	Explanation of LED's and Beeps	3
1.2	Typographical conventions	3
2.	SAFETY INSTRUCTIONS	4
2.1	Safety Instructions	4
3.	WARRANTY AND TECHNICAL ISSUES	7
3.1	Special spare parts	7
3.2	Warranty statement	7
3.3	Customer Service	8
4.	INTRODUCTION	10
5.	INSTALLATION	11
5.1	Unpacking and Set up	11
5.2	Software Installation	14
5.2.1	Installation of ATHENA operating software	14
6.	ATHENA SOFTWARE	17
6.1	ATHENA Directories and Files	17
6.2	ATHENA User Interface	18
6.2.1	ATHENA default set up	18
7.	OPERATION	21
8.0	MAINTENANCE	27
8.1	Cleaning the Instrument	27
8.1.1	Cleaning the instrument surface	27
8.1.2	Cleaning the inside of the instrument	27
8.2	Priming Tubing	32
8.2.1	Priming before Measurement	32
8.3	Emptying Tubings	35
8.4	Preparations for transport	36
9.0	TROUBLESHOOTING	37
10.0	TECHNICAL DATA	40
11.0	APPENDIX	41
a.	Customer Reply Form	41
a.	Confirmation on Decontamination Form	43
b.	Index	45

1. Prefatory Comments

1.1 Explanation of LED's and Beeps

LED	Instrument status
lights up green	Instrument OK and connection to PC OK
flashes green	Measurement in progress
lights up yellow	Instrument OK, no connection to PC
flashes yellow + 1 short beep	New CAN(Controller Area Network) is installed after power on of instrument
lights up yellow + 1 long beep	CAN correctly installed
lights up red	Shortly after power on of the instrument (during initialization)
flashes red + 2 short beeps	Error after power on of instrument/ CAN module not correctly installed

1.2 Typographical conventions

<**Add formula**>,
<**OK**>, <**Close**>

Buttons are printed inside angular brackets in bold typeface

Menu **File**, **Open** dialogue box

Menu titles and **dialogue boxes** are printed in bold type

File | **Open**,
Options | **Read**

Menu items are also printed in bold type; menu and submenu item is separated by a vertical line.

2. Safety Instructions

2.1 Safety Instructions



Caution! This sign alerts you to important operating procedures with a potential danger of damaging the equipment and endangering your safety on disobeying. Refer to the user and instrument manuals for precautionary instructions.



This operating manual includes information and warnings that have to be observed by the user in order to ensure safe operation of the instruments.



Please do always act according to the following safety instructions, before as well as during operation of the system! Before setting up and operation of the instrument, it is necessary to read the instructions below as neither safe operation of the instrument nor safety of the user are guaranteed otherwise. Failure to follow the instructions may invalidate the warranty.

The instrument has been manufactured in accordance with the safety requirements for electronic and medical measuring systems. If the law lays down regulations on the installation and/or operation of the sample measuring system, then it is the operator's responsibility to adhere to them.

The manufacturer has done everything possible to guarantee that the equipment functions safely, both electrically and mechanically. The user has to make sure that the instrument will be set up and installed properly to guarantee safe operation.

The instruments have been tested by the manufacturer and are supplied in a condition that allows safe and reliable operation.



- This equipment must be installed and used in accordance with the manufacturer's recommendations. Installation must be performed by properly trained and authorized personnel.

- The installation category is II.

- The instrument must not be used in areas with a potentially explosive atmosphere.

- The instrument may only be operated by personnel who have been trained on the use of the system. It is strongly recommended that all users read this manual prior to use.



- Never put parts of your body or other devices into the instrument while the unit is in operation.**

- Remove the transportation lock before switching on the instrument.**

- Use the instrument only for the designated application.

- The instrument is designed for indoor use only.

- The instrument may not be operated at altitudes above 2000 m above sea level.

- The instrument is designed to be operated within a temperature range of 15 to 40 °C.

- The instrument is designed to be operated at a maximum relative humidity of 80 % for temperatures up to 31 °C decreasing linearly to 50 % relative humidity up to 40 °C.
- Protak Scientific assumes no liability for any damages, including those to third parties, caused by improper use or handling of the instrument.
- The user is responsible for connecting the instrument in accordance with the valid regulations for electrical instruments.
- Set the instrument up to ensure easy access to the mains switch.
- The mains supply voltage fluctuations must not exceed +/-10 % of the nominal voltage. Maximum voltage to be applied is 253 VAC.
- The instrument is provided with a 3-pole grounded plug. If your wall outlet does not allow connection of a 3-pole plug, have a suitable wall outlet installed by qualified personnel or use an adapter for safe grounding. Please observe the safety specifications of the grounded plug.
- The instruments are designed according to the IEC 61010-1 or EN 610 10-1 regulations for electrical measuring systems.



- To disconnect the instrument from power the appliance coupler has to be removed from the mains.
- Do not open any instrument doors as long as the instrument is in operation.
- Service and repair work may be carried out by qualified personnel only.
- The operator may only perform the maintenance work described in this user guide.
- There are no exchangeable electrical components in the instrument. In case of malfunction, call authorised service personnel.
- Use only parts described in this manual for servicing.
- Disconnect power supply before opening the instrument.
- Pull the power cord to disconnect instrument from the power supply.
- Turn the instrument off before pulling the power cord.
- Upon removal of the front and top parts of the housing, no safety measures are in effect. Be aware of any moving parts. The interior of the instrument may reach temperatures that can cause burns. Some parts of the instrument may remain hot without visual indication for some time after the power has been turned off.
- The electronic unit of the detector generates a high voltage. Do not touch it during operation!
- If you can see that the instrument has become unsafe to use, switch it off and disconnect it from the power supply.



- If liquid gets inside the instruments, pull the power cord. Clean the unit or have it cleaned by an authorised service centre.
- Protect yourself from electrostatic charge, as discharge could damage sensitive instrument parts, especially sensitive parts of the computer and electronics boards.

- When the lid is opened (e.g. filter change) ESD can no longer be guaranteed. To avoid any damages to the electronic parts it is recommended to take precautions (touching the metal case of a safety grounded object, wearing a grounding strap, etc.).
- The system always has to be primed and washed with solutions recommended by Protak Scientific
- Use only reagents recommended by Protak Scientific
- Use reagents only in accordance with the Protak Scientific instructions.
- Do not use any flammable or explosive solutions or liquids whose mixture is flammable or explosive, other than the supplied wash and rinse solutions supplied by Protak Scientific.
- Waste (when priming/washing the injector tubing) always has to be disposed of properly: if a waste pump is installed, a bottle has to be connected. If no waste pump is present, a suitable prime tube has to be placed below the injectors during priming/washing.
- Injector solutions may be pumped back only if the appropriate reagent bottle is connected.
- Observe all statutory requirements for handling biological waste, reagents and samples.
- The operator is responsible for the use of reagents.**
- The instrument should be shipped in its own case. For transport all transportation locks have to be installed, all tube holders **MUST** be removed.
- For instrument cleaning, please refer to the respective sections in this manual.
- Reliable instrument function can be guaranteed only when original spare parts are used.
- Pollution degree is 2.
- The instrument may only be used in rooms with a max pollution degree of 2.

The tests and service work recommended by the manufacturer has to be performed to make sure that the operator remains safe and that the instrument continues to work correctly. Any service and maintenance work not described in this user guide has to be performed by authorized service personnel. Use the instruments only for the designated application.

3. Warranty and Technical Issues

3.1 Special spare parts

The following spare parts are safety parts: Use the original part from Protak Scientific.

Power supply	XP PLC AED70US24 input 100 - 240 VAC, 1.5 A output 24 VDC, 3.0 A	49986
--------------	--	-------

3.2 Warranty statement

The instrument is sold in accordance with the general conditions of sale of Protak Scientific Limited from the UK and its affiliates and representatives globally.

Protak Scientific warrants this product to be free of defects in material and workmanship for a period of 12 months from the date of delivery, ex works.

Protak Scientific or its authorised representative will repair or replace, at its option and free of charge, any product that under proper and normal use proves to be defective during the warranty period.

Protak Scientific shall in no event be liable or responsible for any incidental or consequential damage, either direct or indirect.

The above warranty shall not apply if:

- a) the product has not been operated in accordance with the operating manual
- b) the product has not been regularly and correctly maintained
- c) the product has not been repaired or modified by a Protak Scientific authorised representative or user
- d) parts other than original Protak Scientific parts are used
- e) the product and parts thereof have been altered without written authorization from Protak Scientific Ltd
- f) the product has not been returned properly packed in the original Protak Scientific packaging

This warranty does not apply to any third-party product involved in the application.

Protak Scientific reserves the right to refuse to accept the return of any product that has been used with radioactive or (micro)biological substances, or any other material that may be deemed hazardous to employees of Protak Scientific. Such products have to be properly decontaminated and marked. Before returning products to Protak Scientific ensure the devices are properly decontaminated and the form “**Confirmation on decontamination**” is properly filled in and will be accompanying the product. (See appendix for a blank form)

Before returning products to Protak Scientific, a returns/repair number (RMA) must be obtained and clearly identified on the packing and documents. Call Protak Scientific to get this number. Retain the original packaging for use if the instrument needs to be returned to Protak Scientific.

3.3 Customer Service

Customer Service be provided in the first instance by the network of Protak Scientific representatives. In the event of any problem experienced with your instrument, the first recourse should be **your local Protak Scientific representative.** For further problems requiring hardware or software expertise, the Technical Support group at Protak Scientific will be available by phone, fax or email to deal with your queries. Here is their address, phone, fax and e-mail:

Technical Support
Protak Scientific
Luminox House
48 Holmethorpe Avenue
Redhill
Surrey
RH1 2NL
United Kingdom

Phone: +44 1737 924 900

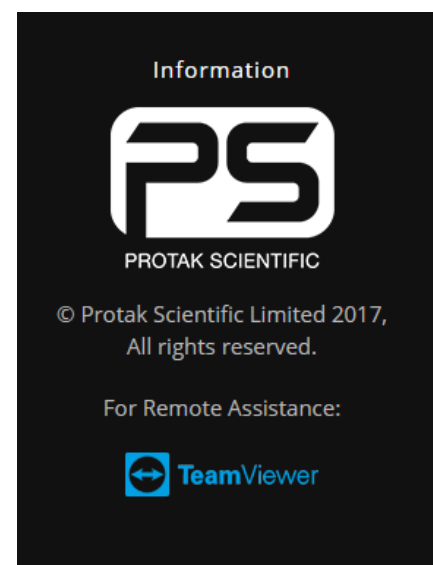
Fax: +44 1737 924 901

Email: service@protakscientific.com

For Software queries, Technical Support is also available through TeamViewer. A link is available to TeamViewer Via the Protak Scientific website, featured at the bottom of the homepage.

- Please download TeamViewer prior to Contacting Protak Scientific to allow for a quick resolution of your query.

<https://www.protakscientific.com/>





**TITLE: Operating Manual PR2A
Twin Shot Reader**

SOP Number:

PTK043 version A

Created: 12-12-18

Issued: 02-01-19

Status: Issued Page 9 of 46

At the end of this manual, you will find a Customer Reply Form (Appendix section). If a problem arises with the instrument which you are not able to resolve, please fill in this form.

This form should then be transmitted to your Protak Scientific representative or to Technical Support at Protak Scientific, where it will receive early attention.

Please also make sure that you have the relevant information available before contacting Protak Scientific.

Helpful information would include:

- serial numbers, part number, revision:
see production label on the instrument
- software and firmware versions
- monitor and log files (refer to the respective manuals)

4. Introduction

The **PR2A** tube luminometer is a bespoke and custom enhanced device for reading thermostable Adenylate Kinase (tAK) for decontamination validation.

Detector sensitivity and stability are the results of decades of experience with photon counters. **True photon counting** has the benefit that no user parameters need to be set, ensuring the same conditions are used for every measurement during the instrument's entire lifetime. The fast photon counting circuitry provides a dynamic range in excess of six orders of magnitude, which complements our tailored reagents.

A proprietary design of the optical and the **tube loading system** enables loading of 2 tubes and eliminates crosstalk and incursion of ambient light. The sample chamber and the sample holder form a single unit. The sample holder contains 2 cavities, each for one sample tube, and sits on the round measurement chamber as a rotating block. It is turned in 180° steps by the integrated software, moving one hole in front of the photomultiplier (measurement position) and the other into the loading position.

The PC based **ATHENA operating software** has been designed as a bespoke and purpose-built decontamination validation performance measuring platform and offers straightforward access to the respective parameter settings. Besides raw data measurements, the user can select Achieved Log Reduction (ALR) and also via setting modify and custom tailor and tune the reading process to specific equipment and processes

The instrument can read **effectively via Protak Supplied Reading Tubes**, the user should not use any other type of test tube as this will invalidate results and performance. The visual characteristics of the Protak tubes are paired with the reading process.

To obtain good and consistent results please **follow these recommendations**:

- Do not expose instrument to direct sunlight
- A delay time of 2 sec before each measurement is recommended when the instrument is used in rooms with bright light as the reflectors may exhibit phosphorescence after exposure to light
- Set up the instrument in dry rooms
- Keep tube cavities free from dirt
- Remove spilt reagents immediately with a damp cloth or optical grade tissue
- Very bright samples may cause saturation of the PMT (indicated by an "Overload" message); let the PMT recover for a few seconds
- Injectors may only be used with Protak tubes

To avoid damages to mechanical and optical components **obey these rules**:

- Load tubes correctly
- Do not fill the tubes above their specified maximum volume
- When using injectors take the additional volume into consideration for calculating the total volume

5. Installation

Read this part completely prior to starting with the first steps and make sure that all prerequisites are met as described below.

5.1 Unpacking and Set up

1. Unpack **PR2A** and **accessories**
2. Put PR2A onto an appropriate laboratory desk
3. External Power supply plug to IEC not Provided



4. Connect IEC to AC/DC Power supply and plug to mains



5. Insert each of the tube holders into the sample positions of the sample rotor. Take care to fit correctly, sitting into the housing FLUSH and SQUARE





Ensure the upper surface of the wider part of the adapter is levelled with the rotor surface by pushing the adapter down

6. Attach the **reagent tubing(s)** to the connector(s) of the injectors.

Ensure a good fit and seal.

DO NOT OVER TIGHTEN.

Ensure Injector lines 1 to ATP Only and 2 to ADP Only.



7. Connect the **USB cable** to USB port of the instrument



USB port

8. Connect the power cord to the respective socket of the instrument



Mains switch

Mains socket

9. Verify the mains switch is in **OFF** position

10. Check whether the power supply is within the permissible range of the operating voltage (**110 – 240 VAC**) of the PR2A
Connect instrument only if it is matching!

11. Put the jack of the external power supply into the wall outlet
12. Connect the USB cable to the USB port of the computer



13. **For the proceeding software installation, the instrument should remain turned off.**

5.2 Software Installation

5.2.1 Installation of ATHENA operating software

Note: The software requires a computer with a Windows operating system (Windows 7, Windows 10). **For installation local administrator level is recommended and may be necessary for some Windows versions.**

Note: The following instructions for installation are described for an English Windows 10 operating system. Screens may be different when using other operating systems.

Note: As the software requires some additional resources for proper operation the setup wizard will check for the presence of these resources (**.NET Framework 4.5** and **Crystal Reports for .NET Framework**) on the computer. If the resources are found the installation of **ATHENA** software is started.

In case these resources are not available on the computer the setup wizard will start with the installation of these resources.

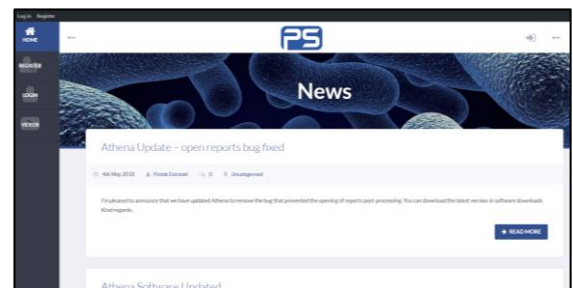
1. Close all Windows applications before you start installing the software
2. **Download ATHENA** latest installation program from

<https://extranet.protakscientific.com/software-download/>

New users must first register to gain access and will need the serial number of PR2A

3. Click **<Run>** when the Security Warning dialogue appears

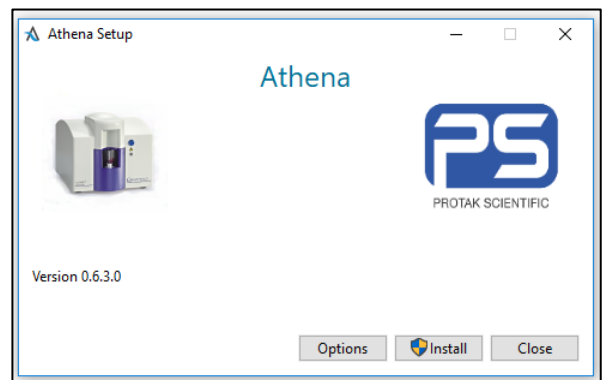
This or similar dialogues may appear during consecutive steps of the installation due to Windows security settings. Always confirm the messages to continue the installation.



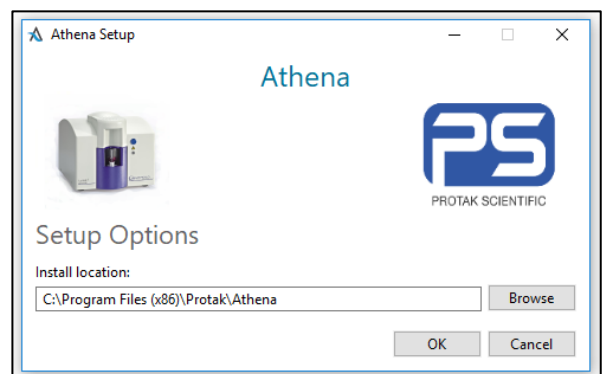
4. Choose a **language**
5. Click **<OK>**



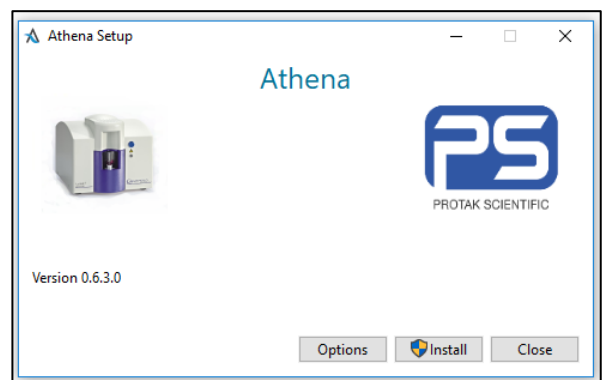
6. InstallShield will configure itself
7. Click **<Next>** to start installation procedure



8. You may modify the **installation directory**
Due to support issues, it is recommended to use the defaulted one
9. Click **<OK>**



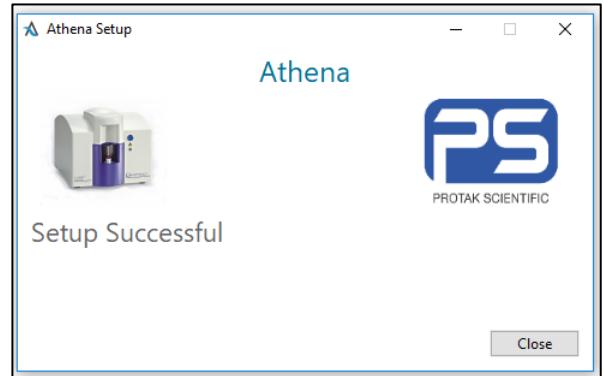
10. Click **<Install>**



11. The installation procedure will be executed automatically

Click **<Accept>** or **<Run>** should any warning messages appear

12. Click **<Close>**



13. After a successful installation, an **ATHENA icon** will be visible on the desktop

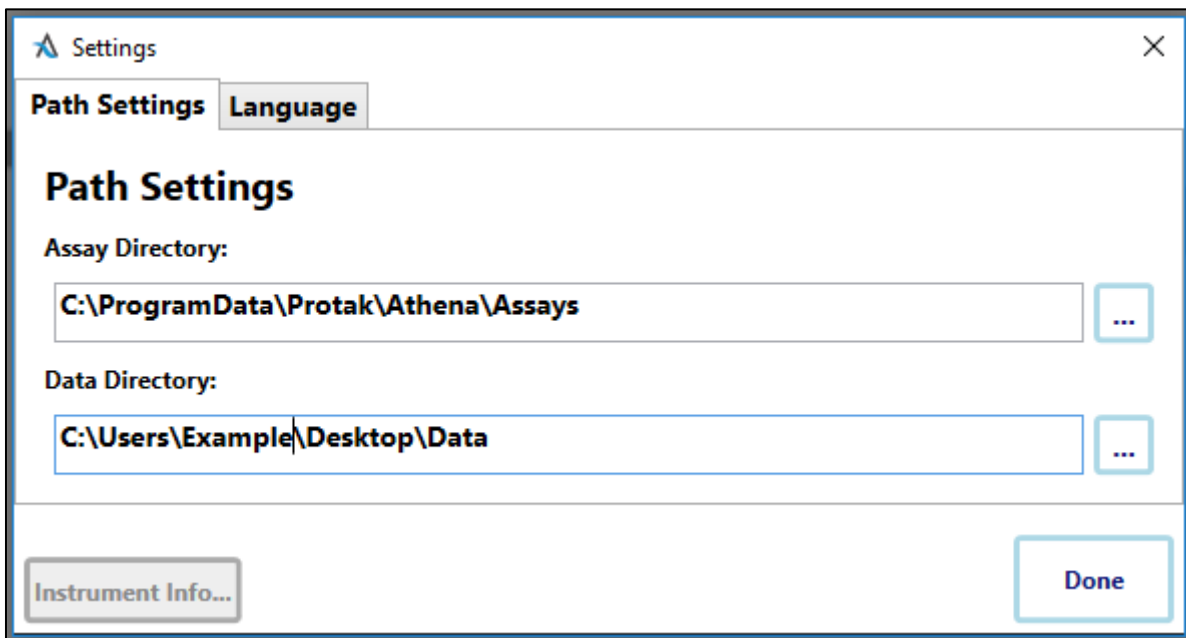


6. ATHENA Software

6.1 ATHENA Directories and Files

The directories for data and parameter files default as described below. Any accessible directory on the computer and the local network can be selected when saving data and parameter files using the “**Save ... File As...**” command.

Default directories



File Names

There is no limitation in naming data and protocol files other than the Windows conventions.

Data file names are to be defined prior to measurement start. Renaming is possible using the “**Save Data File As...**” command producing a copy of the data file with a new name.

Protocol file names are to be defined at the end of creating a protocol. Renaming is possible using the “**Save Protocol File As...**” command producing a copy of the protocol file with a new name.

File Types

ATHENA works with 3 file types indicated by the respective file name extensions.

- Protocol files have the extension. prp
- Data files have the extension. prg

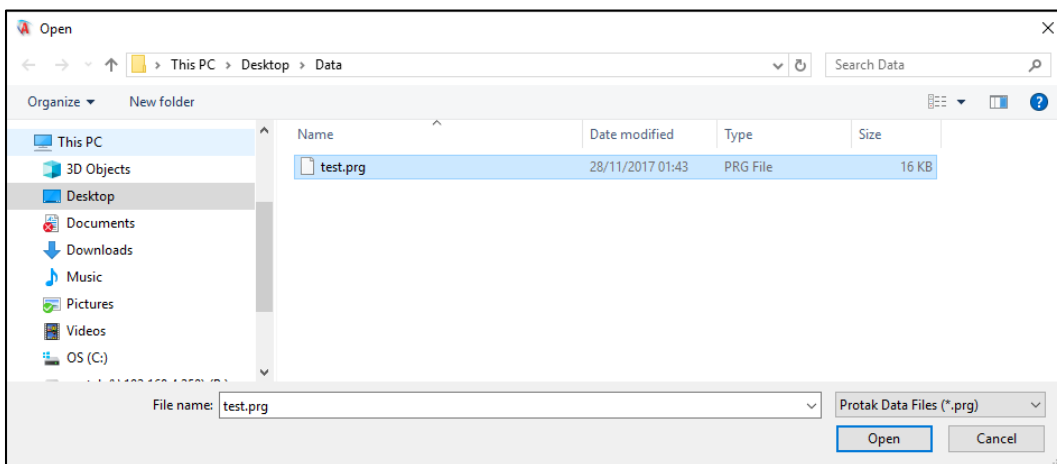
6.2 ATHENA User Interface

6.2.1 ATHENA default set up

The next figure shows the default start-up screen of Athena.



Athena in offline mode can open previously created data files and report but all machine functionality is disabled.



In Order to use the function of Athena software, it is necessary to connect a registered product to the PC.

Now the full functionality of the software is available.





PROTAK SCIENTIFIC

**TITLE: Operating Manual PR2A
Twin Shot Reader**

SOP Number:

PTK043 version A

Created: 12-12-18

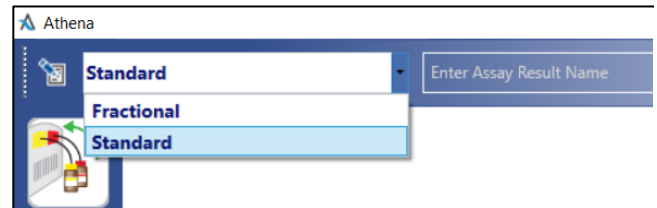
Issued: 02-01-19

Status: Issued Page 20 of 46

7. Operation

Standard Cycle Set-up and Operational Process

1. Check that "Standard" Cycle is selected.



2. Enter a **File Name** of your choice.

Press the GREEN Play ICON.

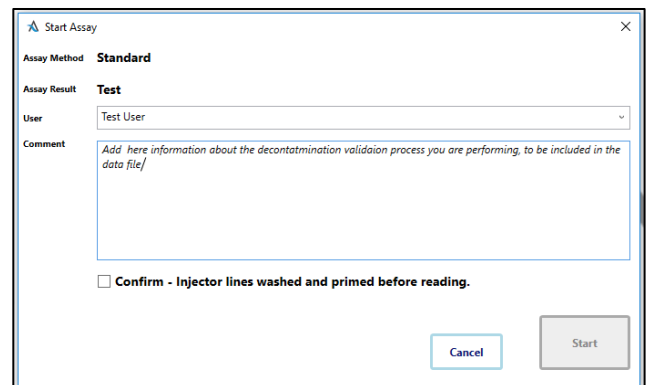


3. Cycle Detail splash screen.

Enter User Name or Select from Dropdown

Enter any comments you would like to save to data file here.

Confirm that the Injector Lines are Washed and Primed. (See Section 7)
Select Start.



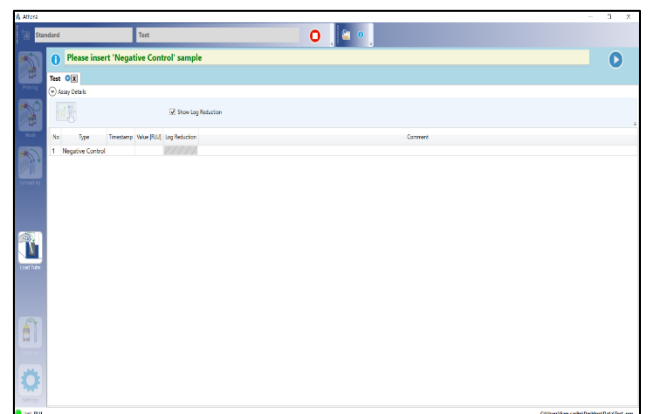
4. Reading Process. Negative Control.

The first step will be the read of reagents only to perform a Negative Control process to ensure reagents are within manufacturers working efficacy.

Insert an Empty Tube and Either Press the Blue Button on the Reader or the BLUE Icon "Play" on the software.

The program will automatically perform the reading process. It takes 60 seconds to perform.

The first injection of ATP after 3 seconds. 60 seconds hydration of the test strip if present to



maximize the accuracy of the reading process, then injection of ADP and reading performed.

This Read Cycle is the same for every “standard” read process.

The Negative Control Must be within the expected range.

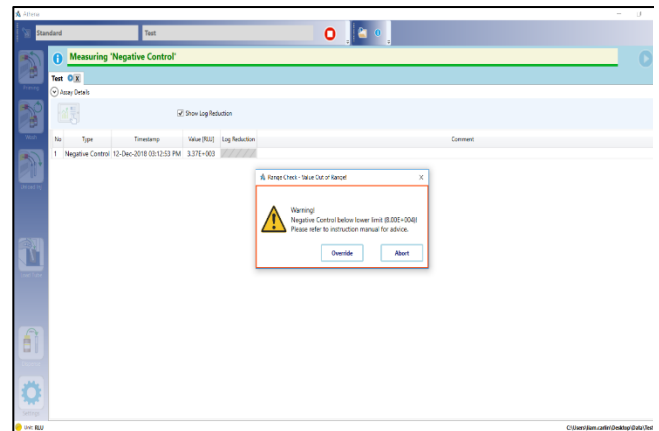
Negative Control

Lower Limit. 8.00E+004

Upper Limit. 3.40E+005

It is possible to override the Negative Control, but this will be reported on the data set.

See fault finding for possible reasons for Out of Range, Negative Control.



5. Reading Process. Positive Control.

The second step will be the read of reagents and an **unexposed Positive Control test strip**. The strip should be from the same packet as strips used in the validation process.

Insert a test tube with the test strip presented correctly to the reader.

Presentation of the test strip is important and should always be to the following:

Test Face Always Pointed into the Reader aligned with the machined slot in the tube holder. At the back of the tube. See Reading Exposed Strips for more information.

The program will automatically perform the reading process. It takes 60 seconds to perform.

The first injection of ATP after 3 seconds. 60 seconds hydration of the test strip if present to maximize the accuracy of the reading process, then injection of ADP and reading performed.

This Read Cycle is the same for every “standard” read process.

The Positive Control Must be within the expected range.

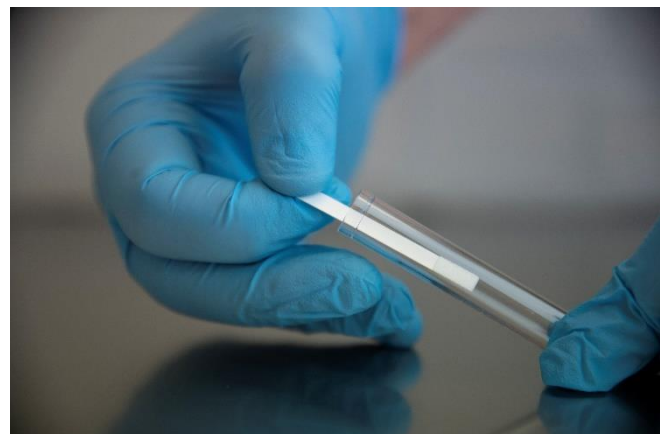
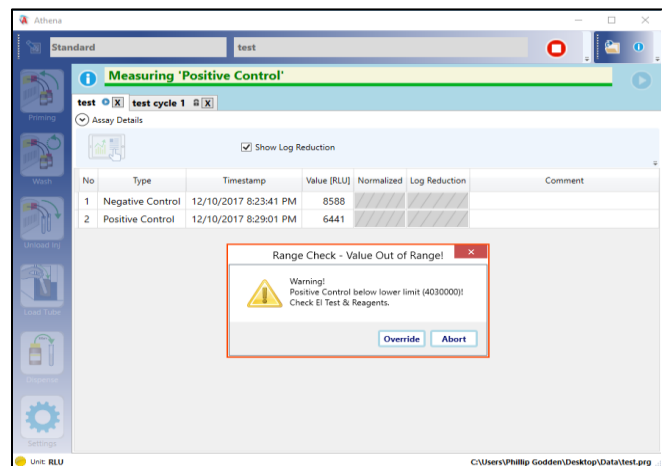
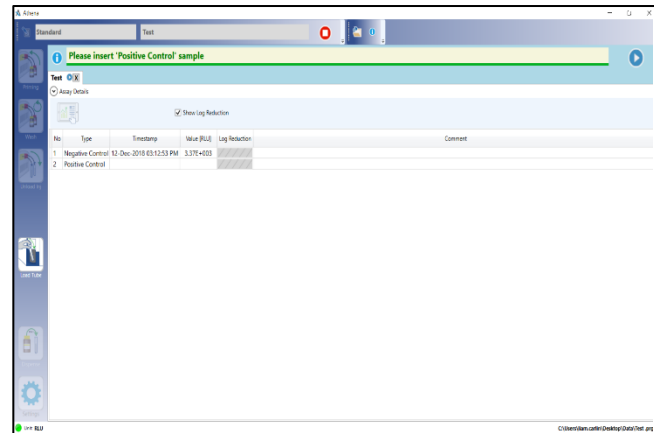
Positive Control.

Lower Limit. 6.00E+007

Upper Limit. 1.64E+008

It is possible to override the Positive Control, but this will be reported on the data set.

See fault finding for possible reasons for Out of Range, Positive Control.



6. Standard Protocol. Reading Process, Reading Exposed Strips.

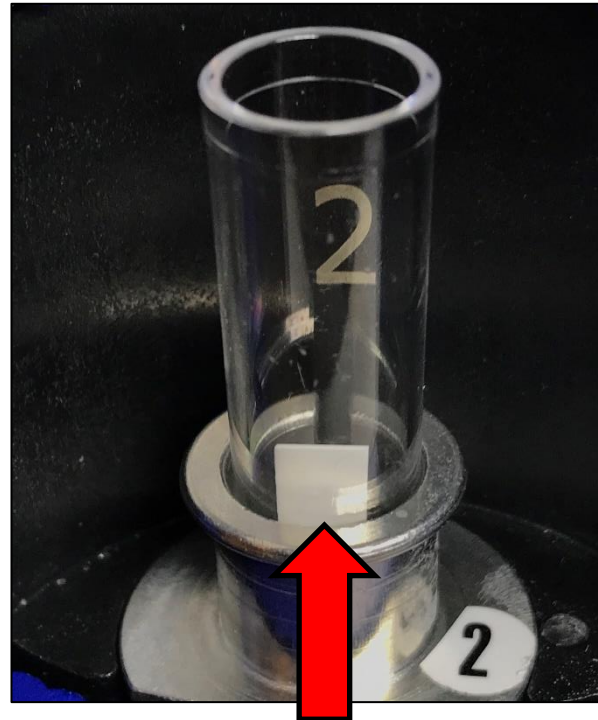
Strip Presentation is important. The strip should always be presented with the tAK bonding mesh facing into the reader, through the machined “reading slot”.

The test should be sat at the back of the test tube, exactly as shown. This presentation allows for full saturation and the best refractory light reading possible.

The strip “tAK mesh” must face into the slot of the reader.

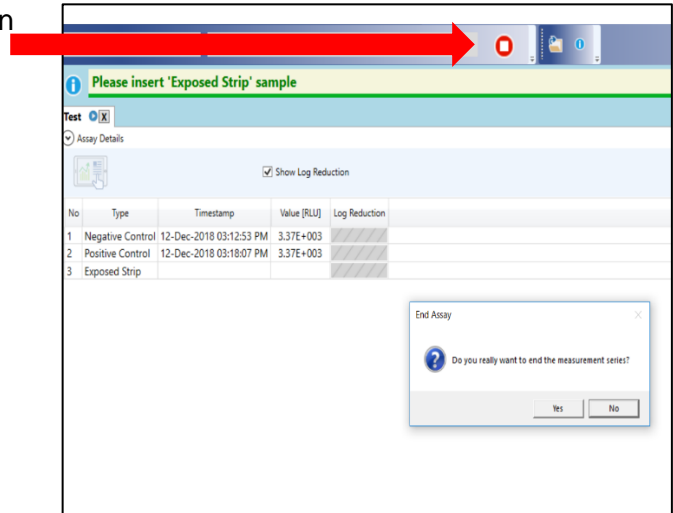
You can see that the mesh presentation is actually facing into the refractory lens with this presentation. Allowing for maximum reading performance.

Once the strip is presented properly the reading operation can be performed by pressing the blue button of the reader or the blue “play” button on the software.



7. When all exposed strips have been read then simply end measurement by pressing the RED Stop Button.

Confirm when prompted **Yes**



8. If selected in “Settings” then the user can manually enter any selected cycle information into the data and end user report.

Please provide the following information

Please enter Cycle Information below

Temperature Optional Entry °C **Humidity** Optional Entry %

H2O2Conc Optional Entry % Conc. **H2O2Volume** Optional Entry ml

Decontamination Equipment:
Please enter description of equipment here...

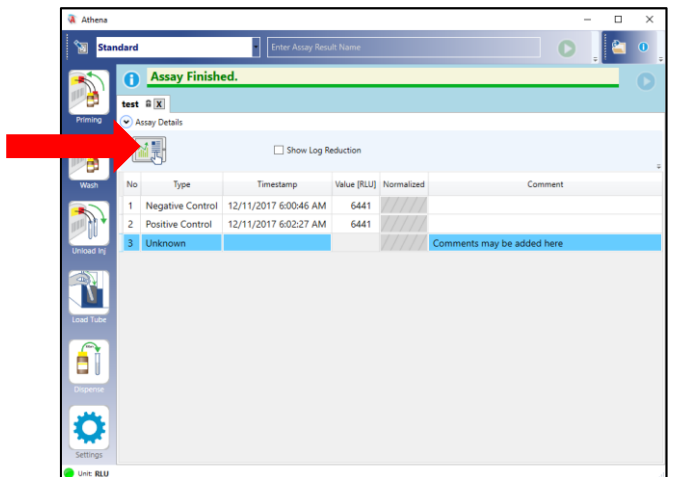
Notes:
Here you can leave notes on the cycle...

Done

9. Reporting and Assay Details

The Assay Information may be reviewed by clicking on the drop-down menu.

The Reporting of the data file may be accessed by pressing the **Report icon**





**TITLE: Operating Manual PR2A
Twin Shot Reader**

SOP Number:

PTK043 version A

Created: 12-12-18

Issued: 02-01-19

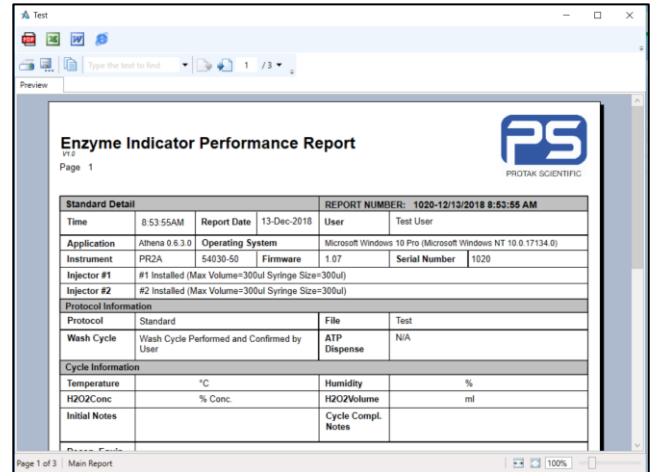
Status: Issued Page 26 of 46

10. Reporting.

The main report can be provided in

- .pdf
- Excel
- Word

Formats for user review.



For information on Fractional cycle Set-up please contact Protak Scientific to learn about the recommended operating procedure.

8.0 Maintenance

8.1 Cleaning the Instrument

8.1.1 Cleaning the instrument surface

The **surface** of the instrument is protected by a washable finish. Dirty or dusty surfaces should be cleaned using a damp cloth or optical grade tissue. If necessary, use a mild detergent or diluted EtOH.

Do not use a scouring agent!

8.1.2 Cleaning the inside of the instrument

Only Trained Service users should open the Reader.

The inside of the instrument does not need to be cleaned regularly. Only in the case of liquid spillage, it may be necessary to clean the inside.

Before opening the instrument, turn it off and disconnect it from power supply!

Open the screws on the instrument cover to clean the instrument inside. Then detach the cover by moving or lifting it carefully.

Always keep the sample holders and the entire inside of the instrument clean. Wipe off any dirt using a damp cloth or optical grade tissue. Use cotton buds for corners. Remove dirt quickly so it does not get dry and may not have any adverse effect on moving parts.

Injector tubing has to be washed

- before starting work
- at the end of each work session before turning off the instrument
- after long periods of inactivity

Other recommended cleaning reagents are

- deionised water
- diluted alcohol: 70 % Ethanol, Propanol

Some of these reagents may be hazardous. Please refer to the respective safety instructions (e.g. R and S codes) of the supplier.

It is recommended to use this solution at least once a week to ensure a long lifetime of the injectors!

Injector lines have to be primed

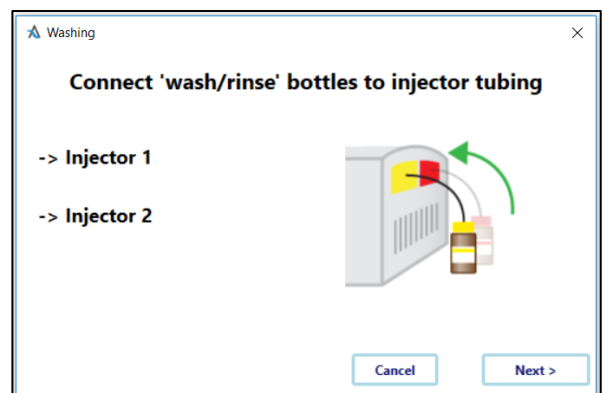
- prior to each assay/ reagent change using the respective reagents.

Click **Wash** in the **Instrument** menu



1. Ensure the correct Wash Solution is connected to **both injectors 1 and 2**

Click **next**

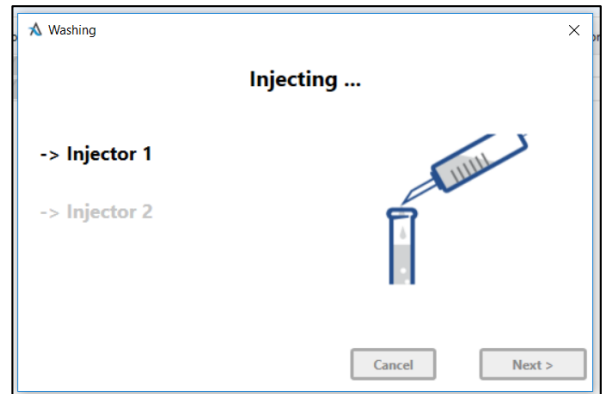
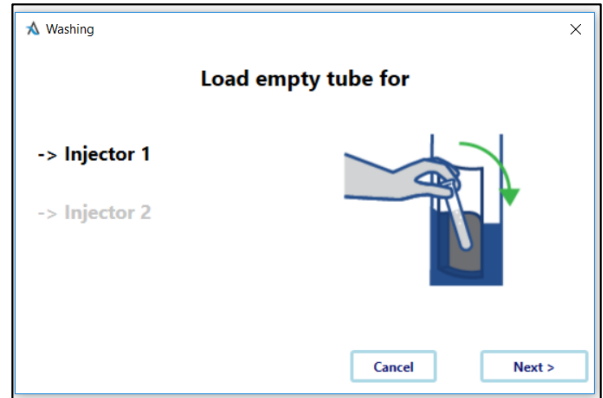


2. Load an **empty tube** (for injector 1)
3. Click **<Next>**

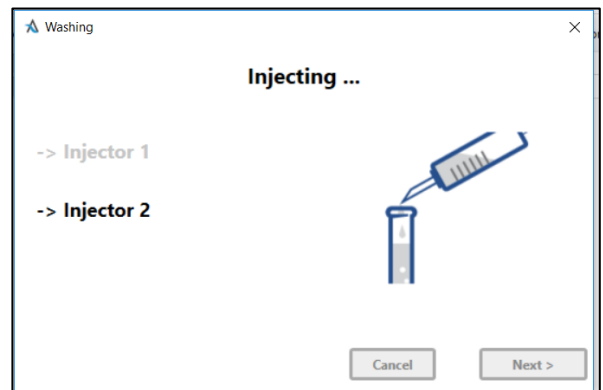
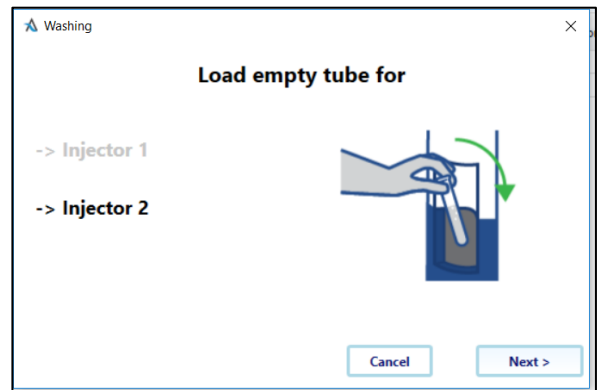
4. Wait for the Wash procedure to be finished for injector 1

5. Load an **empty tube** (for injector 2)
6. Click **<Next>**

7. Wait for the Wash procedure to be finished for injector 2
8. Repeat steps 1-6 for Rinse Cycle with Distilled water.

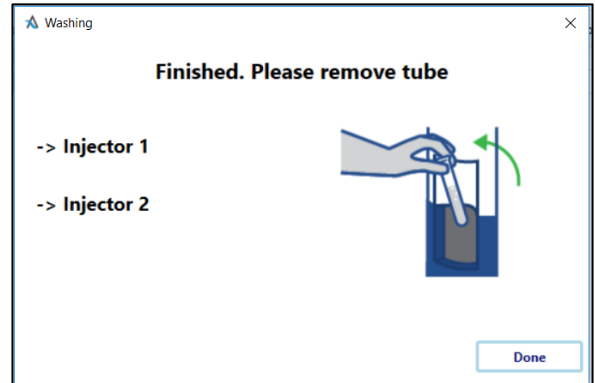


2



9. Do **Not** forget to remove filled tubes from the wash cycle!

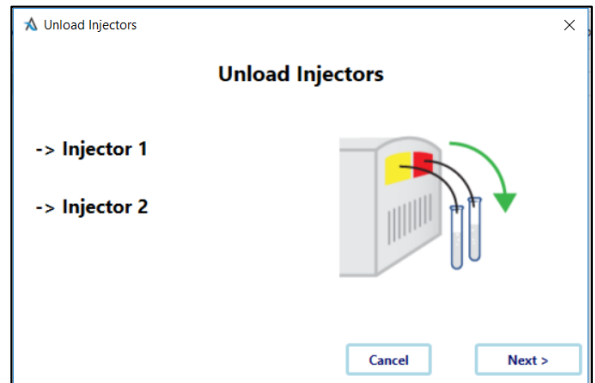
Protak will not be held responsible for OVERFILL



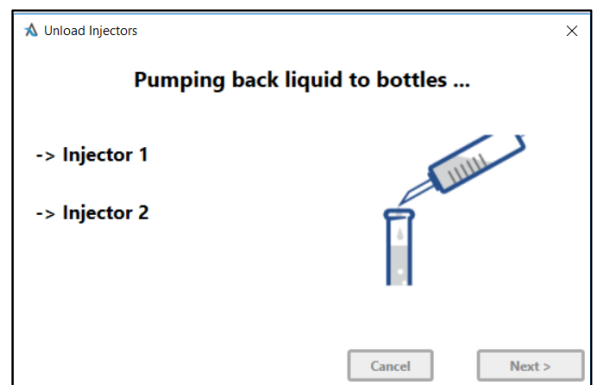
When Finished with Wash Process you must UNLOAD INJECTORS – to empty the wash or rinse solution from the lines. Unload Reagents into clean test Tubes and discard.



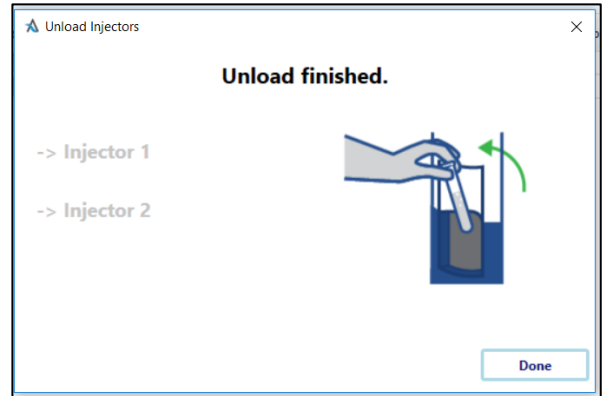
1. Press **Next** to unload injectors back into the containers. The process will be performed for both injector lines at the same time



2. The process will be performed for both injector lines at the same time



3. When finished remove Wash or Rinse solution containers and ensure the reader is free from filled test tubes.
4. You may use the BLUE function button to rotate the reader position if needed.



The Wash and Rinse Cycles MUST be performed in sequence.

Wash both lines first. Unload Lines.

Rinse both lines.

Unload before Priming with reagents.

The reader is now ready for priming if performing reading function or storage if at the end of the reading process.

8.2 Priming Tubing

8.2.1 Priming before Measurement

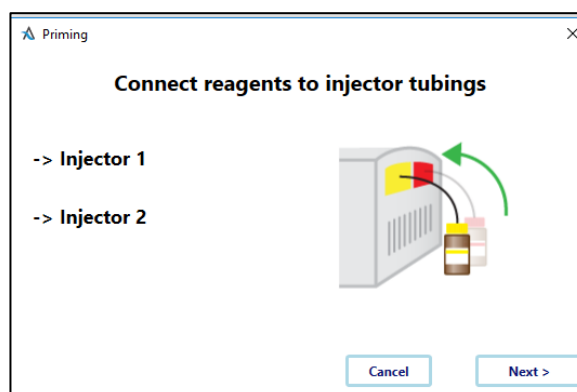
Injection lines have to be primed (filled) prior to measurements which require the use of injectors for reagent addition.

Note: Ensure that both lines are washed, rinsed and unloaded before priming reagents.

1. Click **Prime** in the **Instrument** menu



2. Click **<Next>**

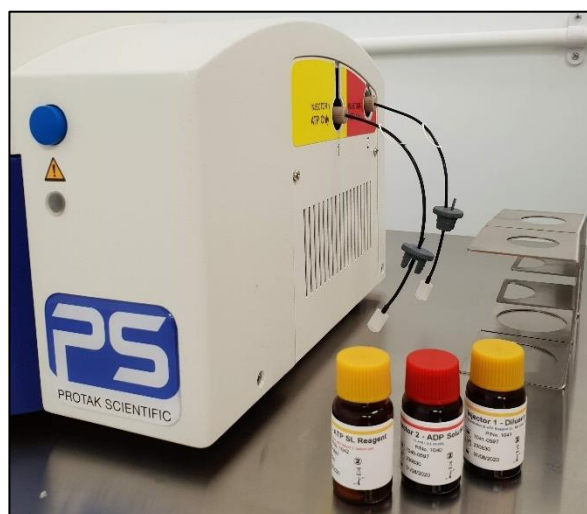


3. Attach the bottle(s) containing the appropriate **Assay Reagents**
4. Click **<Next>**

Important! Reagents must be at room temperature before use and the ATP must be rehydrated.

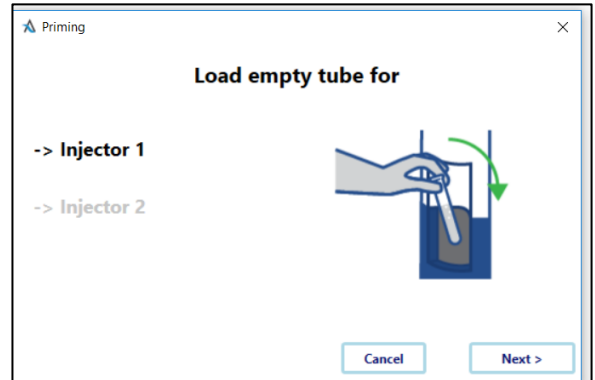
Use 1 full bottle of Diluent C to hydrate ATP reagent. Use **VERY GENTLE** motion to mix ATP and Diluent C to avoid air bubbles.

Allow to stand at room temperature for 60 minutes before use.

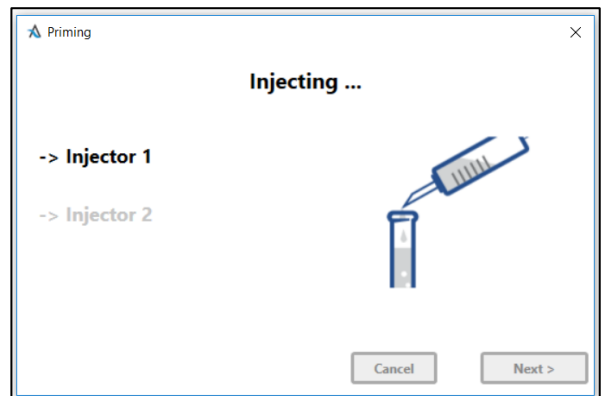


5. Load an **empty tube** (for injector 1)

6. Click **<Next>**

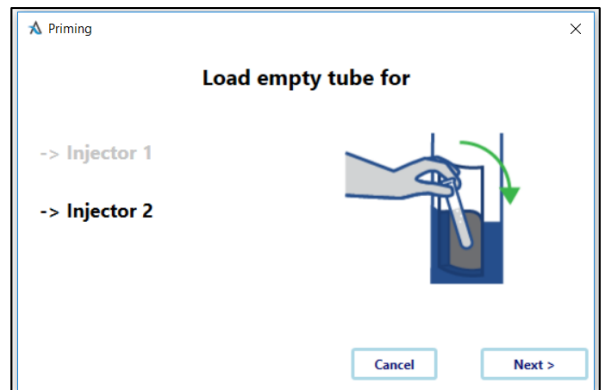


7. Wait for the Prime procedure to be finished for one injector

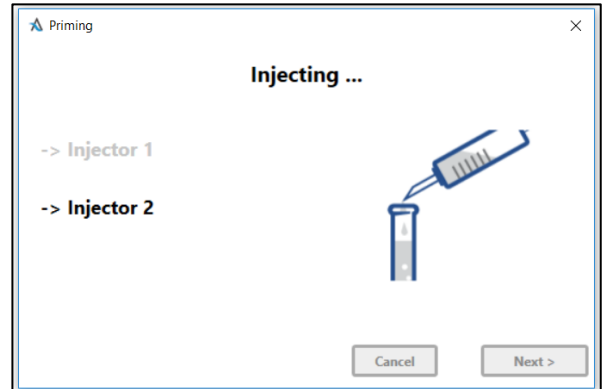


8. Load an **empty tube** (for injector 2)

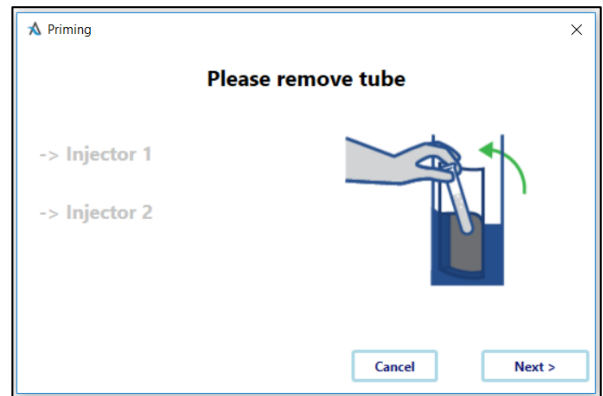
9. Click **<Next>**



10. Remove the **used tube**
11. Wait for the Prime procedure to be finished



12. **Remove tube**
13. Click **<Done>**



14. The instrument is now ready for use

Each Reagent Set will provide up to 24 test reads. This provides double the volume of reagents needed for the reading process! It is fine to use the same reagent set for different packets of tests.

Reagent Storage and Use.

Reagents should be stored at 2-8 C.

Reagents should be used at room temperature. Allow 60 minutes to stabilize.

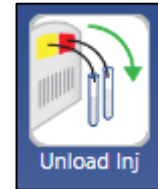
tAK Assay should be performed at a room temperature between 22 and 25 °C

If not used fully reagents should be returned to cold storage ASAP

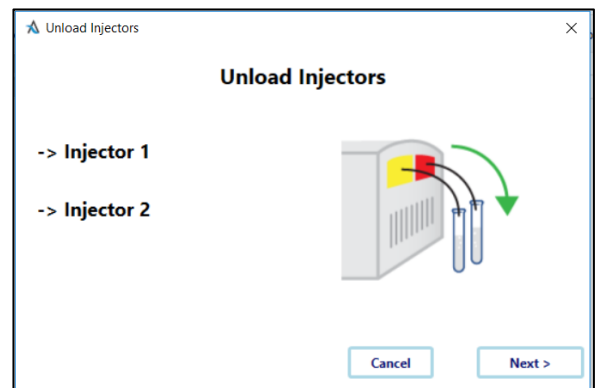
Once Hydrated ATP and Reagent Set Should be used within 5 days.

8.3 Emptying Tubings

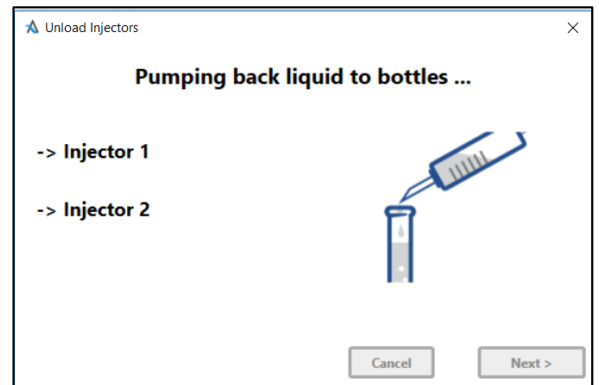
1. Click **Unload Injector** in the **Instrument** menu



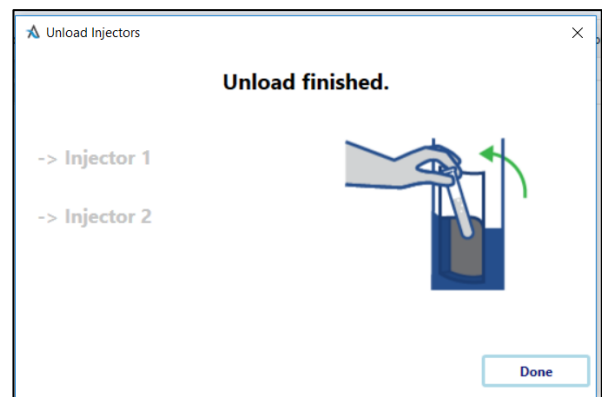
2. Click **<Next>**



3. Wait for the unload operation to be finished



4. Click **<Done>**



This operation can be used to empty the injection lines after the assay has taken place.

For storage of the luminometer follow the instructions given in 8.2 Cleaning Injector Lines.

When storing make sure the injector lines have been unloaded to reduce the risk of Biofilms Forming.

8.4 Preparations for transport

The following safety provisions have to be taken to transport or ship the instrument:

- Turn instrument off and **disconnect it from mains**



- Remove both sample tube holders



- For shipping, you **must** use the **original transportation case**
- Encase the instrument with the Styrofoam parts
- **Tape shipping carton tightly**
- Have a filled in **Declaration of Decontamination** accompany the instrument when shipping back to Protak Scientific or one of its representatives

9.0 Troubleshooting

Symptom	Possible cause	Solution
LED flashes red accompanied by 2 beeps	CAN module not correctly installed	1) switch instrument off and on again 2) call service
LED stays orange	The cable between instrument and computer is not connected The wrong COM assigned	1) attach cable properly 2) use service software and run "Scan COM ports" command
The instrument does not respond to software commands (status "Timeout Error")	The cable between instrument and computer is not connected The wrong COM assigned	1) attach cable properly 2) use service software and run "Scan COM ports" command
LED stays dark	The instrument is not switched on Mains not plugged in mains supply deactivated mains plug defective	1) switch instrument on 2) plug into mains 3) check with local house electrician 4) call service
Lower signal than expected	Pipetting/preparation error Reagents consumed Injector lines clogged	1) verify by checking replicate and other samples/controls/standards and prepare faulty sample again 2) attach new reagents 3) thoroughly wash injector lines, esp. reagent filters 4) replace reagent filters 5) call service to replace injector tubings
Signal not above background readings	No sample No reagents injected Injector lines not properly filled	1) check sample preparation 2) attach reagents 3) prime properly
No signal at all	Faulty PMT	Call service

Rotating tube chamber does not move	Tube not correctly inserted	remove tube
High background signal	Reagents not prepared properly Reagents intermixed Injector lines contaminated Reagents contaminated Tube compartment contaminated	1) prepare reagents properly 2) attach reagents to the right injector 3) thoroughly clean injector lines 4) prepare fresh reagents 5) smoothly clean with cotton buds 6) call service
The instrument does not inject	Wrong sample tube	Use 12 x 75 mm Lumi tubes
Excel Files cannot be opened	Excel is not installed	Install Excel
Adobe PDF files cannot be opened	Adobe Acrobat Reader is not installed	Install Adobe Acrobat
The instrument USB driver is not installed correctly and automatically		Perform manual installation : 1) Launch the Control Panel of the computer 2) Launch the Device Manager 3) Expand the section Universal Serial Bus controllers You'll be able to locate an entry called Protak Scientific Lumat3 or FTDI which will show an exclamation mark sign, alternatively, you may find an entry in section Other Devices called Protak Scientific PR2A which labelled with an exclamation mark sign 4) Double click onto it 5) Select Update Driver in the main tab or select the Driver tab 6) Click Install Driver



**TITLE: Operating Manual PR2A
Twin Shot Reader**

SOP Number:
PTK043 version A

Created: 12-12-18
Issued: 02-01-19
Status: Issued Page 39 of 46

		<ul style="list-style-type: none">7) Select Browse my computer for driver software8) Browse to the USB drive (with the PR2A) and select the Athena installation .exe9) Click <Next>10) Select Install this driver anyway in case a warning message appears11) The installation may take a few minutes12) Follow the prompts
--	--	---

10.0 Technical Data

Mains Supply	100 – 240 VAC Fluctuations must not exceed $\pm 10\%$; max. voltage 253 VAC 50 / 60 Hz
Operating voltage	24 VDC
Power consumption	30 VA
Certifications	CE, UL, CSA
Safety standards	EN 61010-1, EN 61326-1, EN 61000-3-2, EN 61000-3-3
Installation category	II
Machine Temperature range	storage: 0° - 40°C operation: 15° - 35°C
Humidity	10 – 80%, not condensing maximum relative humidity of 80 % for temperatures up to 31 °C decreasing linearly to 50 % relative humidity up to 40 °C
Altitude	< 2000 m (above sea level)
Pollution degree	2
Dimensions	240 x 280 x 220 mm (W x D x H)
Weight	4 Kg
Tube formats	Lumi tubes (12 x 75 mm, 12 x 55 mm)
Measurement technology	Luminescence
Operation Modes	Standard or Fractional EI Developed Cycles
Detector	Photomultiplier operated in single photon counting technology
Sensitivity	TSH: < 0.001 mIU / L ATP: ~ 1 amol Firefly: ~ 1 zmol
Dynamic Range	6 orders of magnitude
Injection system	Up to 2 injectors (variable volume: 25 – 300 μ L or 10 – 100 μ L each) JET injection technology; precision: >98%; accuracy: >98%
Interface(s)	USB
Operating system	Windows 7 and Windows 10
PC requirements	Pentium, 500 MHz (or better), CD ROM drive, USB port, EXCEL 2007 (or more recent)
Software	Athena V0.6.3.0+



**TITLE: Operating Manual PR2A
Twin Shot Reader**

SOP Number:

PTK043 version A

Created: 12-12-18

Issued: 02-01-19

Status: Issued Page 41 of 46

11.0 Appendix

a. Customer Reply Form

Send Customer Reply Form to:

Technical Support
Protak Scientific
Luminox House
48 Holmethorpe Avenue
Redhill
Surrey
RH1 2NL
United Kingdom

Phone: +44 1737 924 900

Fax: +44 1737 924 901

Email: service@protakscientific.com

or **your local representative.**

A blank Customer Reply Form can be found overleaf.



TITLE: Operating Manual PR2A
Twin Shot Reader

SOP Number:

PTK043 version A

Created: 12-12-18

Issued: 02-01-19

Status: Issued Page 42 of 46

Customer Reply Form

Date: _____ Customer no.: _____

Name: _____

Company: _____

Department: _____

Address: _____

Address: _____

Phone: _____ Fax: _____

Email: _____

Instrument: _____

ID no.: _____

Serial no.: _____

Embedded software version: _____

Instrument driver software version: _____

Accessory instruments:

PC Software: _____ PC software version: _____

Windows version: _____

Computer type: _____ CPU type: _____

Other installed software:

Time when problem occurred (Windows clock):

Error message(s):

Description of the problem:



**TITLE: Operating Manual PR2A
Twin Shot Reader**

SOP Number:

PTK043 version A

Created: 12-12-18

Issued: 02-01-19

Status: Issued Page 43 of 46

a. Confirmation on Decontamination Form

Confirmation on Decontamination

If you return an instrument to Protak Scientific for servicing purposes which is not properly decontaminated, there will be a health risk for Protak Scientific employees. We therefore, need your confirmation that the instrument was decontaminated and cleaned properly before shipping. If the form below is not filled in accordingly and completely, we are forced to reject the instrument. Please understand that this is intended to protect our employees from any hazards.

Please put one copy into the shipping box and a duplicate into an envelope attached to the outside.

(Please use capital letters!)

instrument / component: _____	serial no.: _____
instrument or component has come into contact with:	
<input type="checkbox"/> radioactive substances Isotope(s): _____	means of decontamination applied: _____
<input type="checkbox"/> chemical reagents specify: _____ R and S rules: _____	means of decontamination applied: _____
<input type="checkbox"/> biological material specify: _____	means of decontamination applied: _____
<input type="checkbox"/> contagious agents specify: _____	means of decontamination applied: _____
indicate security level of the laboratory the instrument has been used in <input type="checkbox"/> S1 <input type="checkbox"/> S2 <input type="checkbox"/> S3 <input type="checkbox"/> S4	
<input type="checkbox"/> I hereby confirm that the instrument or component specified above was not contaminated with any of the above mentioned substances / reagents / agents	
<input type="checkbox"/> I hereby confirm that the instrument or component specified above was decontaminated / cleansed using the appropriate method	
date: _____	signature: _____
name: _____	address: _____
title: _____	_____
phone: _____	_____
fax: _____	_____

7-40.12 – 31531/03

b. Index

.NET Framework	14	Preparations for transport	33
Cleaning the instrument	25	Prime	29
Cleaning tubings	25	Safety instructions	6
Confirmation on Decontamination	9, 40	Set up	12
Crystal Reports	14	Software installation	14
Customer Reply Form	38	Special Spare Parts	9
Customer Service	100	start-up screen	18
Directories	17	System Overview	11
Dos & Don'ts	11	Technical data	37
Emptying tubings	32	Timeout Error	34
Filename	17	Trouble shooting	34
File type	17	Typographical conventions	5
Filling tubings	29	Unload Injector	32
ICE software installation	14	Unpacking	12
Installation	12	USB cable	13
LED	5	USB instrument driver manual	
LED flashes red	34	installation	35
LED orange	34	USB port	13
LED unlit	34	User interface	18
Mains switch	13	Warranty Statement	9
Maintenance	25	Wash	25, 26
Measurement Delay	11	Wash Solutions	25
no injection	35	Windows OS	14
Operating manual	5		
Phosphorescence	11		
Power supply	12		
Power Supply	9		
Power supply assembly	12		



TITLE: Operating Manual PR2A Twin Shot Reader	SOP Number: PTK043 version A Created: 12-12-18 Issued: 02-01-19 Status: Issued Page 46 of 46
--	--

Document History:

Version	Date	Description of changes
A	18-12-2018	Initial Version

Review and Approval:

	Name	Title	Signature	Date
Author	Liam Carlin	Technical Sales Specialist		02-01-18
Reviewer	Owain Virgin	Quality Manager		02-01-18
Authoriser	Phillip Godden	CEO		02-01-18