

AmpliFire[®]

User's Manual





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AmpliFire Safety



WARNING

Read and understand equipment operator's manual before operating or performing maintenance. Failure to do so could result in serious injury or death.

Overview

AmpliFire® performs isothermal nucleic acid amplification in minutes. Instrument is equipped with data storage, touch screen interface, and two USB ports for data retrieval and keyboard connection.

Instrument is not intended for use with standard PCR chemistry or for use as a denaturing instrument for sample preparation.

Mass:

FR1407: 2.2kgs (4.9lbs)

FR1604: 2.3kgs (5.0lbs)

General Safety

Before starting instrument each time:

- Ensure compartment lid is in working order.
- Ensure instrument is in operating condition.

To shutdown instrument, turn power switch to off.

Storage

- Transport only by carrying handle.
- Pack securely for long term transportation/ shipping paying particular attention to protecting touch screen.
- Store in dry location between -20 °F and 140 °F (- 29 °C and 60 °C).
- Disconnect battery if stored for over one month.

Before Starting Instrument

- Do not operate instrument unless you have been

trained to do so.

- Do not operate instrument until you read and understand operating instructions. Thoroughly familiarize yourself with instrument and its controls.
- Always wear safety glasses and any other required safety equipment as required by your company's Personal Protective Equipment (PPE) policy.
- Never remove warnings displayed on instrument. Replace any worn or damaged labels. Contact Agdia for replacement labels.

Operating

- Only authorized personnel should operate this instrument.
- Never operate an instrument with compartment lid removed.

Operation environment temperature:

FR1407: 39°F to 104 °F (4 °C to 40 °C)

FR1604: 39°F to 91 °F (4 °C to 33 °C)

Supported reaction temperature:

FR1407: 113°F to 162 °F (45 °C to 72 °C)

FR1604: 102°F to 162 °F (39 °C to 72 °C)

- Instrument is not designed to support weight of a person. Do not step on any part of instrument.
- Process only materials identified in sample and assay protocols with this instrument.
- Avoid use of FR1604 in dusty environments, or on surfaces with small loose particles such as sand or gravel. These conditions may result in degraded optical performance.

General Maintenance Safety

- Annual instrument cleaning and calibration is recommended for both FR1407 and FR1604. Contact Agdia for details.
- Always contact Agdia before performing any repairs or maintenance on instrument.
- Do not operate faulty or damaged equipment. Always perform proper service and maintenance procedures.
- Do not service an instrument without thorough qualifications. Ensure familiarity with necessary service

tasks.

- Never open covers that house electrical components.

Cleaning Safety

- Use caution while using toxic or flammable solvents to clean instrument.
- Always wear safety glasses and any other required safety equipment as required by your company's Personal Protective Equipment (PPE) policy.

Heat Safety

- Do not touch heated surfaces.

Chemical Safety

- Follow all SDS chemical sheet recommendations.
- Do not touch, ingest, or inhale samples.

Battery Safety



WARNING

Failure to read and follow instructions may result in fire, personal injury and damage to property if charged or used improperly.



WARNING

Use only AmpliFire unit to charge battery. Do not use a NiMH or NiCd charger. Failure to do so may cause a fire, which may result in personal injury and property damage.

- Keep Li-Ion battery pack away from children.
- Li-Ion battery & packs may explode and cause fire if misused or defective.
- Lithium batteries have a cycle life. Replace old battery with new when it reaches its service life or when it is two years old, whichever comes first.
- Use caution to avoid puncture of cells. Puncture of cells may cause fire.
- Never drop batteries.

- Do not expose battery pack to direct sunlight/ heat for extended periods.

Charging Process

- Follow instructions exactly to control charging and discharging current.
- Never charge batteries unattended. Always monitor charging process to assure batteries are being charged properly. Failure to do so may result in fire.
- Charge battery with AmpliFire charger only.
- Let battery cool down to ambient temperature before charging.
- Only charge battery when in AmpliFire unit.
- Never store or charge battery pack inside car during extreme temperatures. Extreme temperature could cause fire.
- If battery starts to balloon, swell up, smoke or gets hot, discontinue charging process immediately. This may cause battery to leak and reaction with air may cause chemicals to ignite. Disconnect battery and observe in a safe place for approximately 15 minutes.
- Charge battery every two months when not in use.

Operating/Charging Temperature:

32 °F to 113 °F (0 °C to 45 °C)

Discharge:

32 °F to 140 °F (0°C to 60 °C)

During discharge and handling of batteries, do not exceed 160 °F (71 °C).

Complete Battery Discharge Recovery.

For Serial number 201411DA0136 and previous:

1. Turn off instrument (on/off switch should be set to "0").
2. Plug instrument in for 10 minutes.
3. Turn instrument on, battery charge level should read a value (not "!%").
4. After confirming charge level plug instrument in for approximately 4 hours to fully charge.

Note: If charge level reads "!%", deplete battery and repeat steps 1-4. If issue persists contact Agdia.

For Serial number 201411DA0137 and later:

1. Plug charger into instrument.

Note: If instrument is left on and plugged in, upon initial power up battery charge level will show “!%” and instrument will display “Battery failure please contact service”. Instrument will display “!%” because battery charge level is between 0 and 1%.

2. Allow instrument to charge, after 10 minutes battery charge level will begin to increase and “Battery failure please contact service” will disappear.
3. If battery charge level does not increase, unplug instrument from charger. Leave instrument on to deplete battery.
4. Turn off instrument (on/off switch should be set to “0”).
5. Plug in instrument for 10 minutes.
6. Turn instrument on, battery charge level should read a value (not “!%”).
7. After confirming charge level plug instrument in for approximately 4 hours to fully charge.

Note: If charge level reads “!%”, deplete battery and repeat steps 4-7. If issue persists contact Agdia.

Note: If instrument is turned off and plugged in, upon power up battery status will show correct charge level. If “!%” is displayed follow steps 4-7 to recharge depleted battery. If issue persists contact Agdia.

Life:

Batteries that lose 20% of their capacity must be removed from service and disposed of in accordance with national regulations. Discharge battery making sure output wires are insulated, then wrap battery in bag for disposal.

NOTICE

Disposal of battery must be in accordance with national regulations.

Recognizing Safety Precautions

NOTICE

If any safety stickers are damaged or missing, contact Agdia for replacements.

Warning Safety Precautions



Warning - Read Owner's Manual Before Operation

Caution Safety Precautions



Caution - Burn Hazard

AmpliFire

Component Identification FR1407

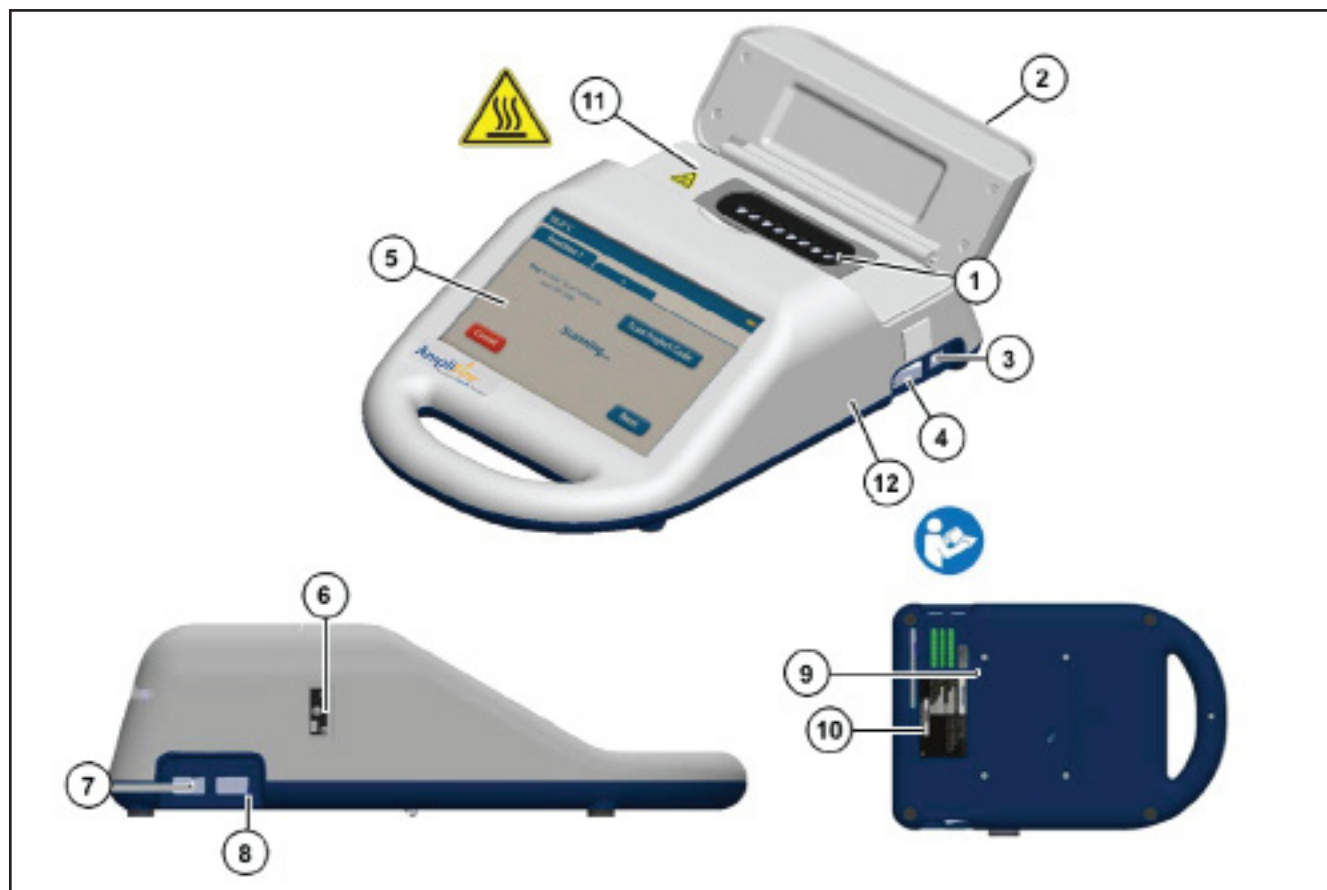


Figure 1

REF #	DESCRIPTION	REF #	DESCRIPTION
1	Sample Station	7	USB Port
2	Sample Station Cover	8	USB Port
3	Power Input Jack	9	Battery Compartment (lithium ion rechargeable battery included)
4	On/Off Switch	10	Serial Number Plate
5	Touch Screen	11	Caution: Burn Hazard Decal
6	Bar Code Camera	12	Read Owners Manual Before Operating Decal

AmpliFire

Component Identification FR1604

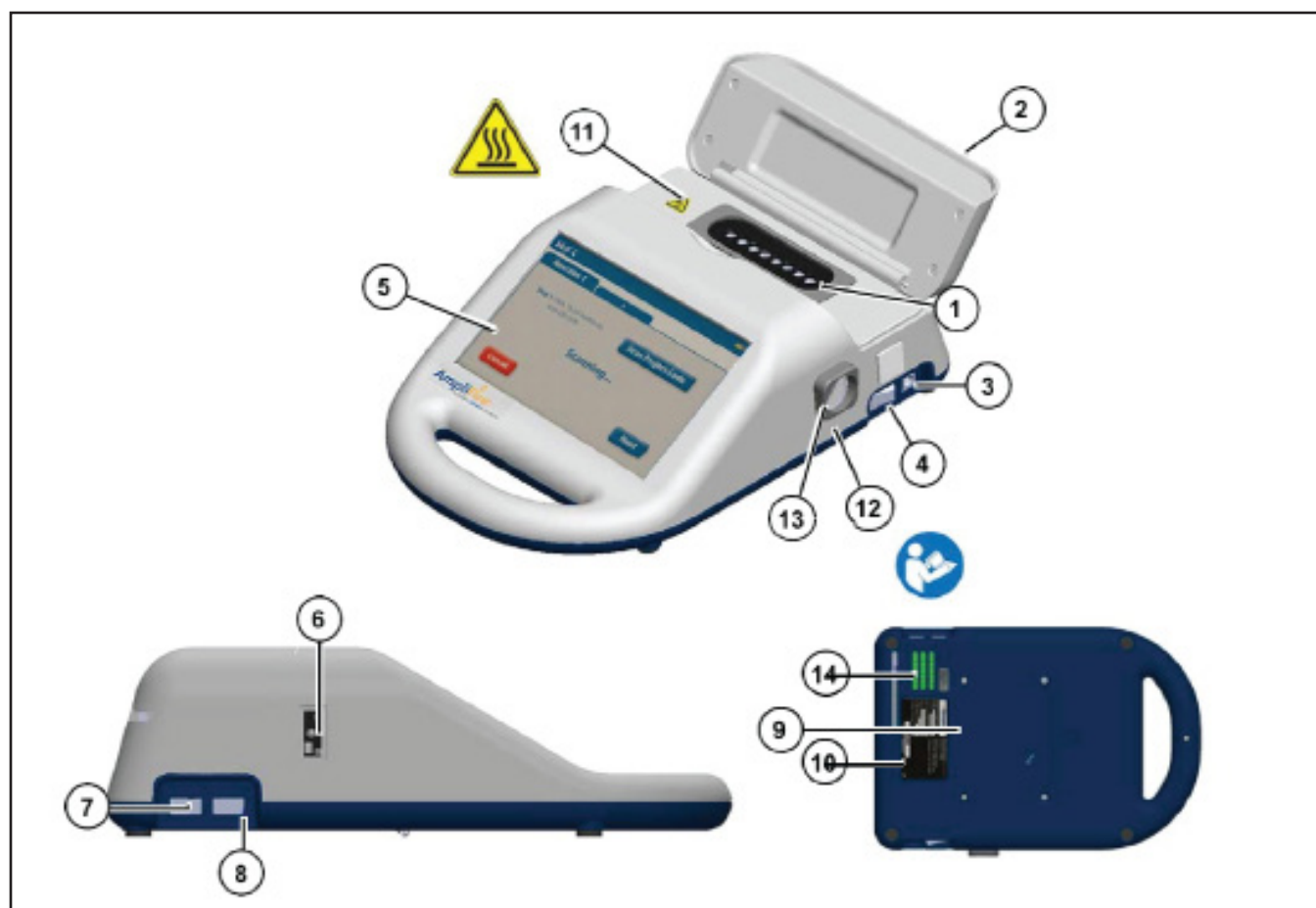


Figure 2

REF #	DESCRIPTION	REF #	DESCRIPTION
1	Sample Station	8	USB Port
2	Sample Station Cover	9	Battery Compartment (lithium ion rechargeable battery included)
3	Power Input Jack	10	Serial Number Plate
4	On/Off Switch	11	Caution: Burn Hazard Decal
5	Touch Screen	12	Read Owners Manual Before Operating Decal
6	Bar Code Camera	13	Exhaust Fan
7	USB Port	14	Air Intake

Operation

1. Turn on AmpliFire using On/Off switch (4) (Figures 1 & 2).

Note: Unit will warm to reaction set point temperature (39°C to 72°C).

2. Prepare sample according to directions.

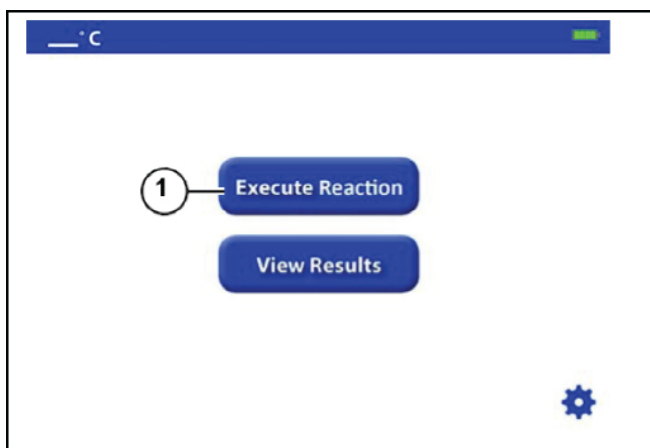


Figure 3

3. Press "Execute Reaction" (1) (Figure 3).

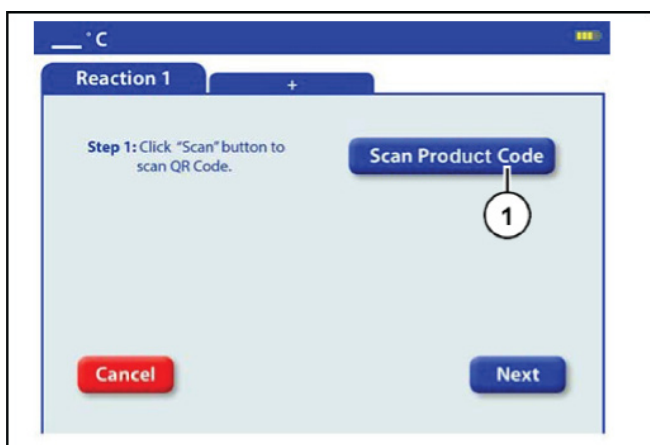


Figure 4

4. Press "Scan Product Code" (1) (Figure 4).

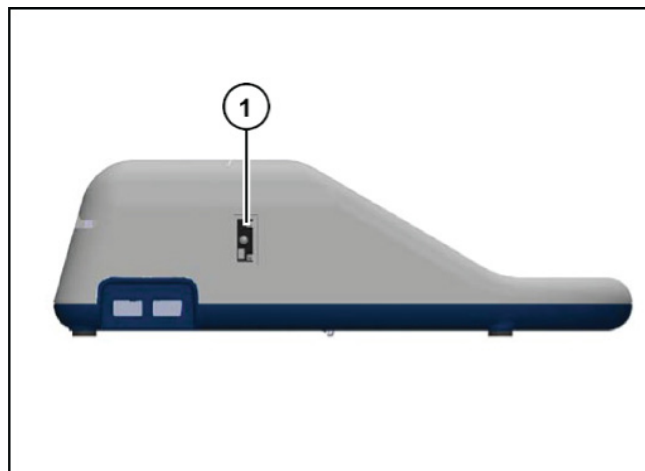


Figure 5

5. Scan assay bar code with bar code camera (1) (Figure 5)

Note: Hold bar code approximately 6" from camera to scan. Unit will beep once when scan is complete.

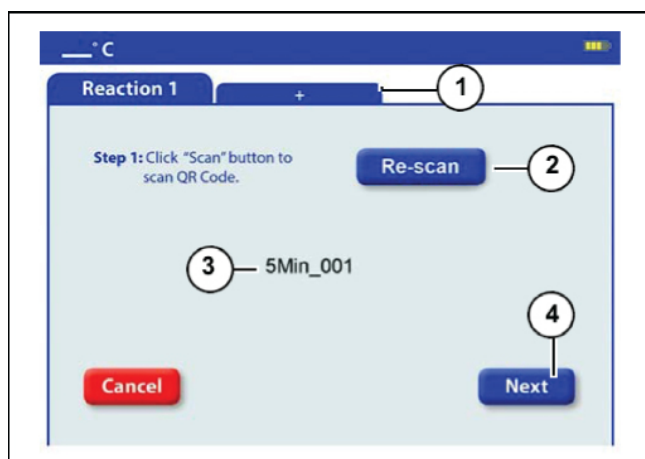


Figure 6

6. Once scan is complete, protocol name will be displayed (3). Press "Next" (4). (Figure 6)

Note: Press "+" (1) (Figure 6) to add another reaction and scan next bar code (if desired).

Note: Press "Re-scan" (2) (Figure 6) to rescan code if necessary.

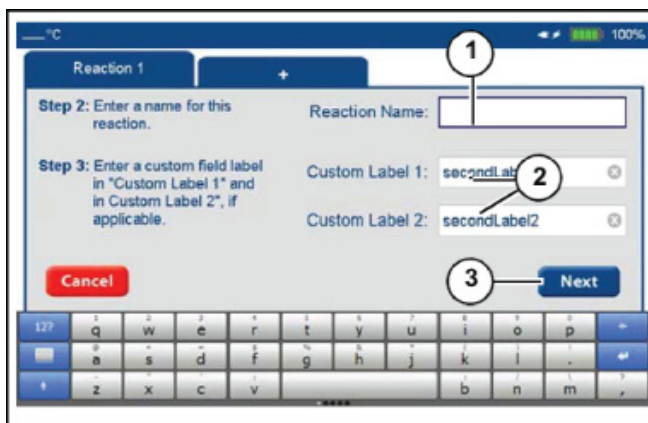


Figure 7

7. Enter a "Reaction Name" (1) (Figure 7).
8. Enter custom label name in "Custom Label 1" and in "Custom Label 2" if applicable. (Figure 7)

Note: Use custom labels to further identify sample information if necessary. (Ex. sample location)

9. Press "Next" (3) (Figure 7).

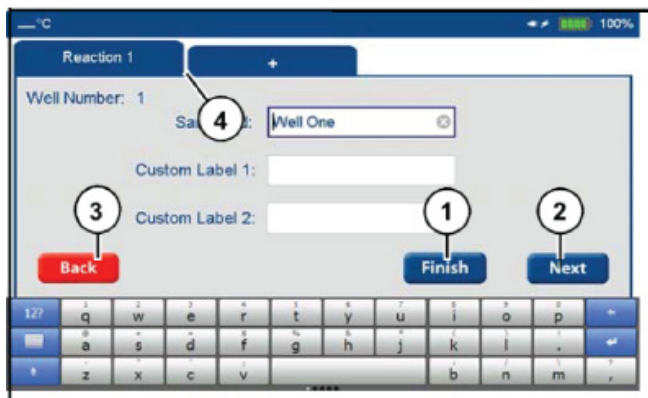


Figure 8

10. Press "Next" (2) (Figure 8) to advance to next well and identify custom labels if applicable.
11. Press "Finish" (1) to proceed, press "Back" (3) to return to main menu. (Figure 8)

Note: If setting up more than one test, click on Reaction 1 (4) (Figure 8) to be taken to start test menu. Only one test will be allowed to run at a time.



Figure 9

12. Press "Start" (1) (Figure 9).



Figure 10

13. Open sample station cover (1) and insert tubes (2) into sample station (3). (Figure 10)
14. Close sample station cover (1) (Figure 10).



NOTICE

Place AmpliFire on flat surface. Do not open lid, move unit or remove tubes during test.

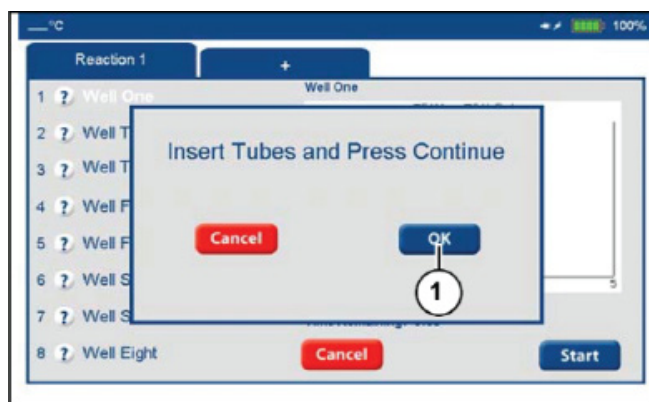


Figure 11

15. Press "OK" (1) (Figure 11)

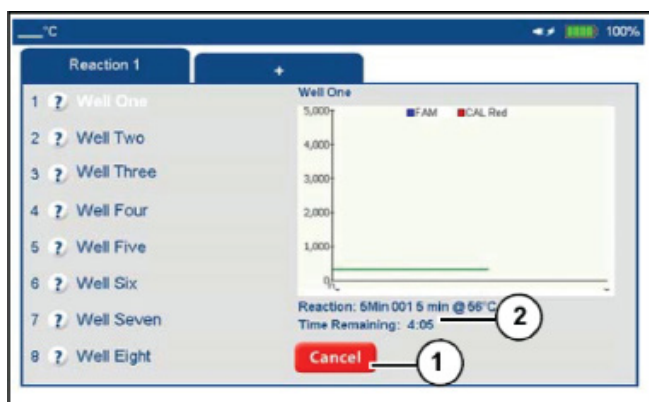


Figure 12

Note: Sample test will start to run. Press "Cancel" (1) to stop test. Time Remaining (2) will count down. (Figure 12)

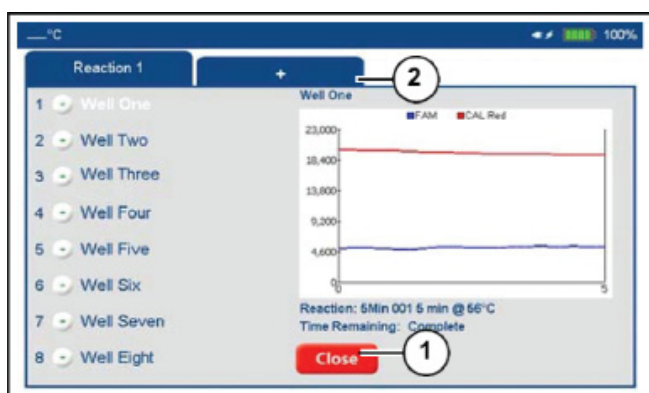


Figure 13

16. Press "Close" (1) or "+" (2) to add/view multiple test results. (Figure 13)

Viewing Results

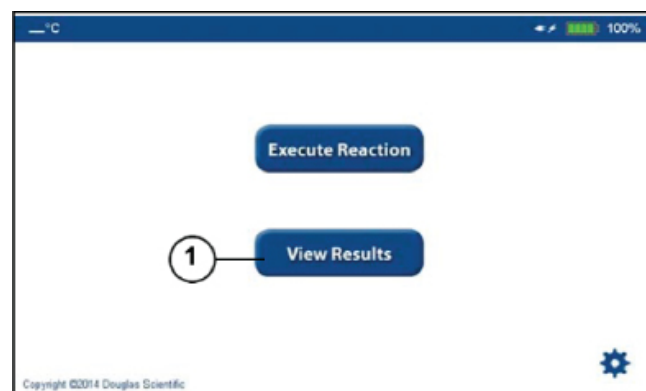


Figure 14

1. Press "View Results" (1) (Figure 14).

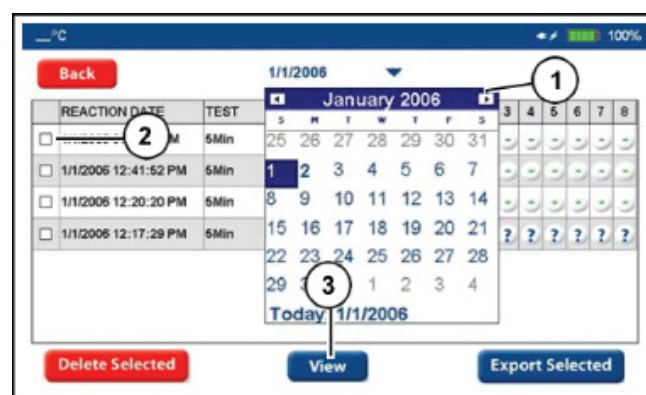


Figure 15

2. Select desired reaction date (1) (Figure 15) from drop down menu.
3. Select reaction file (2) (Figure 15) to view.
4. Press "View" (3) (Figure 15) to view selected reaction.

Exporting / Deleting Test Results

Exporting Test Results

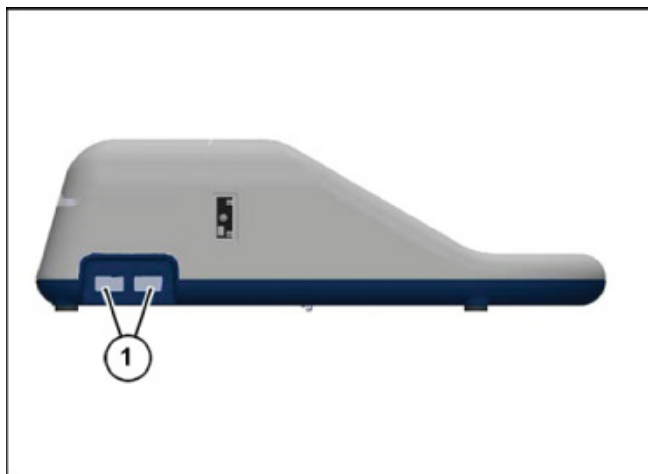


Figure 16

1. Insert USB into either USB port (1) (Figure 16).



Figure 17

2. Select desired reaction date (1) (Figure 17) from drop down menu.
3. Select reaction file(s) (2) (Figure 17) to export by checking box next to reaction(s).
4. Press "Export Selected" (3) (Figure 17).



Figure 18

5. Press "OK" (1) (Figure 18).

Note: Files will be exported to USB in .CSV format.

6. Press "Back" (2) (Figure 18) to exit to main screen.

Note: Checking "Remove from device" (3) (Figure 18) will export and remove test data from device.

Deleting Test Results

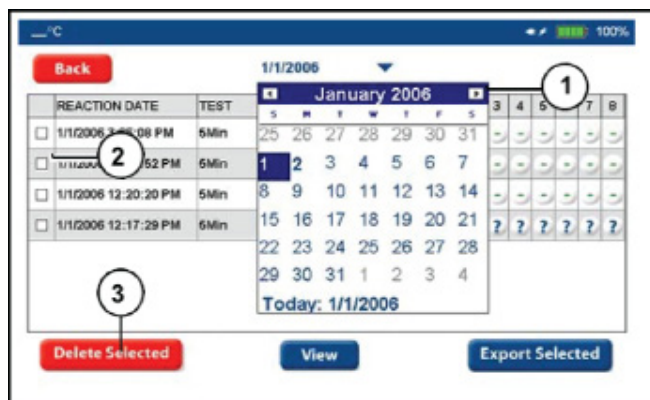


Figure 19

1. Select desired reaction date (1) (Figure 19) from drop down menu.
2. Select reaction file (2) (Figure 19) to delete by checking box next to reaction.
3. Press “Delete Selected” (3) (Figure 19).



Figure 20

1. Press “OK” (1) (Figure 20).



NOTICE

Over moistening q-tip may result in liquid entering instrument which may result in damage.

Weekly cleaning instruction.

- Swab all areas of sample station with a cotton swab moistened with a 10% bleach to water solution (or 70% Isopropyl Alcohol/30% water solution).
- Swab all areas of sample station using a cotton swab moistened with water.

Note: Instrument use in dirty/dusty conditions may need more frequent cleaning.

Trouble Shooting

Problem	Solution
Bar Code Won't Scan	Clean bar code camera window with soft cloth. Do not use solvents!
Inconsistent test results	Clean sample station with canned air.
Warm up failed	<ol style="list-style-type: none"> 1. Turn unit off and back on. 2. If error message is displayed a second time after cycling power and battery is displaying two bars or less, charge battery. 3. If error message continues with battery charged to maximum level or with unit connected to power source contact technical support.

Technical Support Department

Telephone	574-264-2615
Product Support	info@agdia.com
Address	Agdia, Inc. 52642 County Road 1 Elkhart, IN 46514
Website	www.agdia.com

Appendix

Initial Instrument Set-Up

1. Turn on AmpliFire using On/Off switch (4) (Figures 1 & 2).



Figure 21

2. Press settings button (1) (Figure 21).



Figure 22

1. Refer to Figure 22.
2. Enter instrument name (1) by pressing gray box and entering with popup keypad.
3. Enter date (2) using drop down arrow.
4. Enter time (3) using drop down arrow.
5. Press "Save" (4).
6. Press "Back" (5) to return to main menu.

Note: "Delete Data" (6) will clear all reactions from device.

Warranty

Warranty Term

All new AmpliFire® products manufactured and supplied by Agdia are warranted to be free from defects in materials and workmanship when used in accordance with Agdia's published guidelines for a period of one (1) year from the date instrument is shipped from our facility.

Warranty Qualification

To qualify for this warranty, the product must be purchased directly from Agdia or from an Agdia authorized distributor.

Warranty Coverage

Agdia will be responsible for the repair, replacement, or refund of instruments that are, in its sole determination, defective and covered by warranty. This responsibility includes handling and non-expedited shipping charges to return an instrument to the customer, but excludes all applicable duties, taxes and inspection fees. Repaired or replaced product will assume the remaining warranty period of the original product.

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Warranty Service Support

Agdia can be contacted for warranty service through telephone or internet. Claims must be submitted within 30 days of the alleged product failure and, in any event, prior to the expiration of the AmpliFire product warranty. Agdia will pay standard shipping charges for returned AmpliFire product, if shipping is required.

To make a warranty claim: (a) submit claim information through Customer Support at amplifiresupport@agdia.com; or (b) call telephone service Monday through Friday 8am to 4pm CST at +1(574)264-2014. Once a notice has been submitted, follow instructions given to you from the Agdia service representative.

Your Responsibilities

Before receiving warranty service, Agdia may require that you furnish product serial number ID, respond to questions designed to assist with diagnosing potential issues, and follow Agdia's instructions for obtaining warranty service. This may include your responsibility to ensure product has been properly decontaminated. Before submitting your AmpliFire for warranty service you should maintain a separate backup copy of the contents of its storage media. Do not store sensitive information within your AmpliFire product as it is uncontrolled and does not contain security measures to deter instrument access.

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Declaration of Conformity

2014/30/EU EMC Directive
2011/65/EU RoHS Directive

Name of manufacturer or supplier

Agdia, Inc.

Full postal address including country of origin

52642 County Road 1
Elkhart, IN 46514 USA

Name and address of the Responsible Person, established within the community, authorised to compile the Technical File (if different from above)

TUV SUD UK, Belasis Business Centre, Coxwold Way, Billingham, Teesside, TS23 4EA UK

This company will accept enquiries from National Authorities requiring relevant information regarding this Product and will supply either as an electronic or hard copy, as required

Description of product

Amplifier & Detection

Name, type or model, batch or serial number

AmpliFire unit FR1407 & FR1604

12 VDC

Serial Number: _____

Standards used, including number, title, issue date and other relative documents

EN55011 +A1, EN60204-1:2006/AC: 2010, EN61010-1: 2010, EN61000-3-2: 2014, EN61000-3-3: 2013 and EN61326-1: 2013

Place of issue

Elkhart, IN USA

Declaration

I declare that as the authorised representative, the above information in relation to the supply / manufacture of this product, is in conformity with the stated EN Standards and other related documents following the provisions of the above Directives and their amendments.

Name:

Signature:

Position held:

Date of Signature:



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Nplot: AmpliCode™ Desktop

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Open Source QRCode Library

(ThoughtWorks.QRCode): AmpliCode

Desktop

<http://www.codeproject.com/Articles/20574/Open-Source-QRCode-Library>

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OpenNETCF: AmpliFire

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Protobuf-net: AmpliFire, AmpliCode Desktop

The core Protocol Buffers technology is provided courtesy of Google.

At the time of writing, this is released under the BSD license.

Full details can be found here: <http://code.google.com/p/protobuf/>

This .NET implementation is Copyright 2008 Marc Gravell

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