PCRun®

by Biogal Galed Labs.

READER MANUAL

Biogal Galed Labs. Acs. Ltd. | www.biogal.com

33 PRD119 1/7/2020

Table of Contents

Unpacking and Assembling

Contents of Box

Fig. 1: Reader

Fig. 2: Power cable

Fig. 3: On/off switch (present only in certain models)

Fig. 4: USB /Micro-USB connector

Fig. 5: Stylus

Fig. 6: USB Portable Memory Stick

Fig. 7: Transformer

⚠ **Attention!**

Before installing the PCRun® Reader please pay attention to the following:

- Do not place the Reader in an area which receives direct light (natural or artificial). During the amplification process light is emitted from the reagents. The generated light is collected, interpreted and transformed to a readable signal of positivity or negativity. Strong external light may cause background noise which may be translated into a false positive signal.

- Do not place the Reader on the same table with apparatus that my cause vibrations (centrifuge, vortex, shakers etc). Vibrations will result in unstable readings.

Assembly of PCRun® Reader

Remove the PCRun® Reader **(Fig. 8)** from the protective packaging and rest on a **solid, level** surface allowing approximately 25 cm of clearance space above the unit for opening. Allow 5 cm distance from any wall or object to allow for proper ventilation. **Make sure that the Reader is not housed in area with strong light.**

▶ **Fig. 8:** Front view

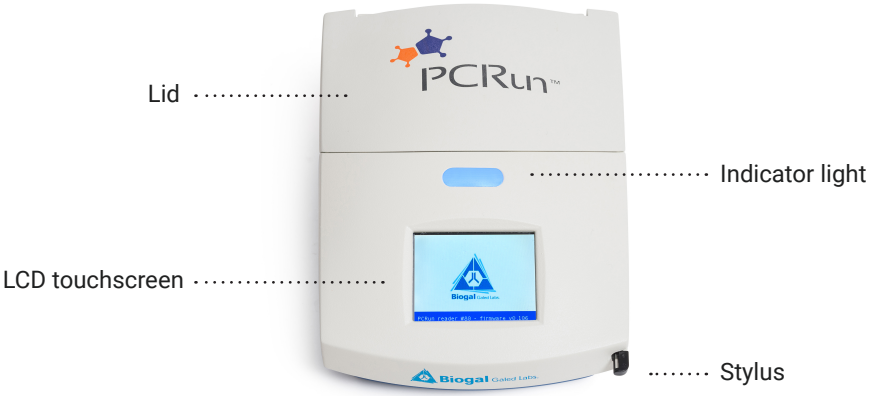


Fig. 9: Back view

Connect the transformer **(Fig. 7)** to the power cable **(Fig. 2)** and then to the back of the PCRun® Reader **(Fig. 9).** If the Reader comes with an external on/ off switch **(Fig. 3)** connect it to both the back of the PCRun® Reader and to the transformer cable. The transformer will adapt the voltage to 220 or 110.

General Feature

The PCRun® Reader is a complete system which contains a heater and luminometer to be used in conjunction with PCRun® reagents designed for the amplification process and analysis of PCRun® molecular reactions. The unit contains a graphical LCD touch panel on which the final results are displayed.

Safety Precautions

- Operate the instrument on a solid dry surface away from a strong light source.
- Ensure the laboratory electrical supply is appropriate and surge protected.
- The PCRun® Reader should be switched off when not in use.
- Do not open the casing of the Reader.
- Maintenance of the unit must be carried out by Biogal personnel only.

User Responsibility

- Users are responsible for familiarizing themselves with the product instructions and limitations.
- External factors such as sample quality and preparation, as well as testing protocols and laboratory techniques, may influence the final results. It is the user's responsibility to select the proper sample material which meets the criteria of the chosen test.
- As with any test method utilized for in vitro diagnostics, the results obtained from use of the PCRun® technology should be interpreted together with the results of other tests.

Operation Guide

Prior to using the PCRun® Reader make sure, that it has been set up according to the “Unpacking and Assembling” instructions.

1. Starting the PCRun® Reader

1.1

Turn on the PCRun® Reader using the on/off switch located on the power cord **(Fig. 10, Model A)** or on the back of the Reader **(Fig.10, Model B).**

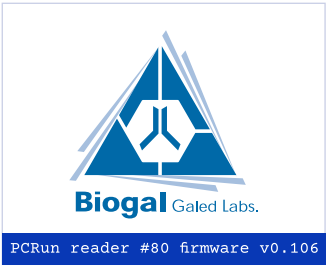
Fig. 10 | Model A

Fig. 10 | Model B

1.2

The following display will appear briefly **(Fig 11).** The PCRun® Code # and the firmware that is installed in the Reader are located on the bottom of the screen.

Fig. 11

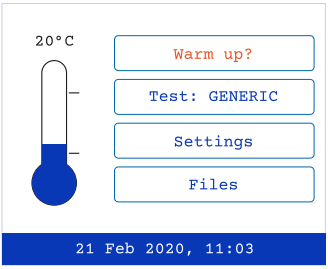


1.3

The main screen **(Fig. 12)** will replace the Logo display. The following details will be displayed:

- Warm up ?
- Test: GENERIC
- Settings
- Files
- Present date and hour
- Thermometer with ambient temperature

Fig. 12

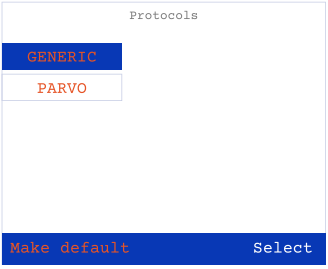


2. Choosing the Default Test Protocol

2.1

The default test protocol setting is **GENERIC** and is suitable for most of the PCRun® reactions. Alternate protocols may be recommended for certain kits. Prior to using the Reader, check the kit instructions to determine which protocol is suitable for your test. In the case that a different protocol is recommended, the following instructions will explain how to change the program temporarily or to define a new default program. Using the stylus, activate the Test: GENERIC tab **(Fig. 12).** The names of the various protocols will appear in the window. Choose the recommended protocol **(Fig. 13).**

Fig. 13



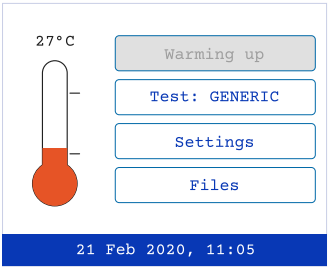
If you will be using the protocol for a single application press **Select** located on the bottom right hand side of the screen. If you choose to make the new protocol the default setting, press **Make default** located on the bottom left side of the screen. Follow by pressing **Select.**

3. Running a PCRun® Reaction

3.1

Using the stylus press **Warm Up? (Fig. 12).** The message on the screen will change to grey and the words **Warming up** will appear. In addition, the indicator light and the thermometer will change to orange **(Fig. 14).**

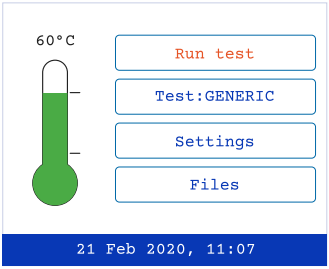
Fig. 14



3.2

Once the temperature of the Reader has reached its target (60°C) the message will change to **Run test.** The indicator light and the thermometer on the touch screen will change to green. The temperature noted above the thermometer will be 60°C **(Fig. 15).**

Fig. 15



3.3

Open the lid of the Reader and load the reaction tubes into the internal wells. Take note of where the tubes are placed **(Fig. 16).**

Fig. 16

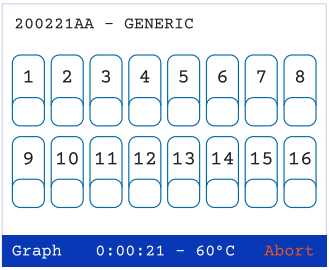
3.4

Close lid completely. **Do not open until completion of the test.**

3.5

Use the stylus to activate the **Run test** tab **(Fig. 15)**. The indicator light will turn red and the screen will change **(Fig 17).** The number on the upper left-hand side of the screen is the “run number”. The number is composed of the date in reverse accompanied by two letters. If more than one run is performed on the same day the number will remain the same and the letters will change. The test protocol is located in the top middle section of the screen. The time period which has passed from initiation of the run can be seen on the bottom middle section of the screen.

Fig. 17



3.6

Sixteen numbered rectangles are located in the middle section of the screen. Each numbered rectangle represents a well in which a reaction can be placed. After approximately 5 min all the numbered rectangles on the touch screen will turn grey, indicating that the amplification process has begun. Most reactions are completed in 60 min. **Do not open the lid of the Reader until the reaction has ended.**

3.7

During the amplification process, the screen can be switched to a histogram plot by pressing **Graph** located on the bottom left hand side of the screen **(Fig 18)**. Using the stylus, press each number on the tab screen, which represents the sample to be viewed. The activated tabs will be accented with a black border. (The graph screen can display only 8 samples at a time). Activate the **Graph** command. The graphical display will appear. A row of color coded numbers can be seen above the graphs **(Fig 19).** The numbers and colors correspond to the activated sample wells. Return to the numbered tab screen by activating **Back** (lower right side of the screen). Positive reactions will be seen on the graph screen as the reaction progresses at any time point of the run. If a reaction is positive, the numbered rectangles on the tab screen will change to red and the time at which the reaction was at its maximum (Time to Peak) will be noted under the positive sign. Different from the positive results, the negative green results will appear only at the end of the run **(Fig 20).**

Fig. 18

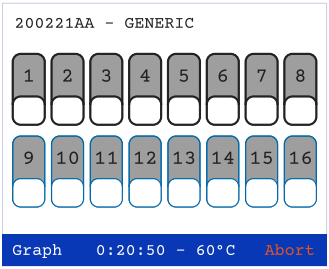
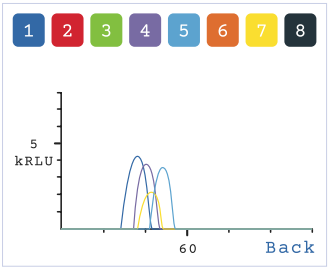


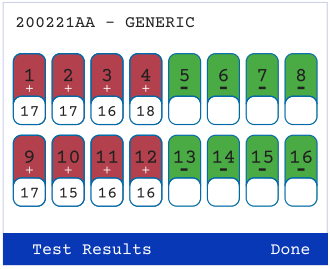
Fig. 19



3.8

Once the reaction is complete activate **Done** on the lower right side of the screen **(Fig. 20).** The heating unit of the Reader will turn off automatically if not in use for 15 minutes.

Fig. 20



4. Analysis of Results

The results can be viewed in two formats, numerical tab **(Fig. 20)** or graphical histogram **(Fig. 19).** It is highly recommended that the user become familiar with the formats and make a point of examining both. It is particularly important to differentiate between background noise and true positive results. Poorly prepared samples containing inhibitors will result in unstable readings and potential false positives or negatives. The selection of graphs presented in **Section 9, page 16** will help in understanding irregular graphs.

®

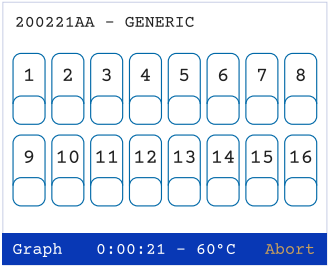
The PCRun® Reader has a reset button that is designed to be used when the program does not respond as expected. It can be found on the lower right side of the Reader **(Fig. 21).** To reset the program, insert the stylus into the small aperture for 2 seconds. Once the stylus is removed, the program will appear. If the problem continues please contact Biogal for assistance.

▶ **Fig. 21**

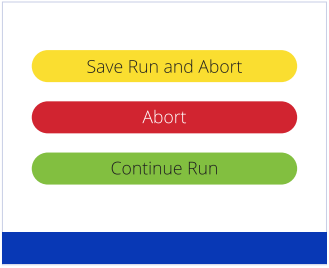
6. Aborting a Run

In cases when a reaction has been initiated and must be ended prior to summation, the run can be aborted by pressing the **Abort** command on the lower right side of the tab screen **(Fig. 22).** Once the command is activated, a new screen display will appear **(Fig. 23).** To save the run activate **Save and Abort.** To end the run without saving the data activate **Abort.** If **Abort** was activated accidently then press **Continue Run.**

▶ **Fig. 22**



▶ **Fig. 23**



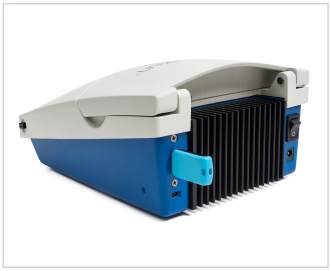
7. Downloading Files from the PCRrun® Reader

One hundred and fifty files can be stored, but only fifteen can be displayed on the screen at a time. The number of runs displayed on the active page and the total number of runs stored in the Reader can be seen on the bottom middle of the screen. The **Files** menu contains 10 pages which can be flipped through by pressing **Next** (right bottom of the screen, **Fig. 26).** To return to the previous pages activate **Back.** The file codes relate to the date in which the test was performed and are the date in reverse (160503AB is the 3rd of May 2016). The first run of the day will receive the suffix **AA** and the second **AB.** This coding will continue for each additional run on that specific day.

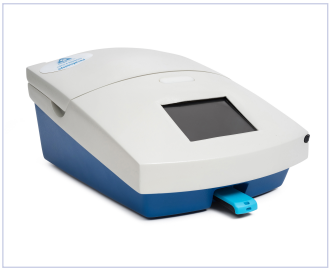
7.1

Place the portable memory stick into the USB port. Depending on the model, the port will either be on the front or back of the Reader **(Fig. 24, 25).**

▶ **Fig. 24**



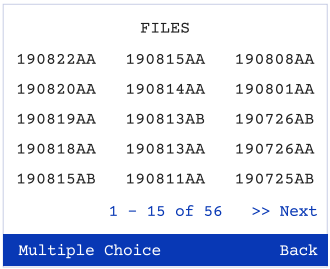
▶ **Fig. 25**



7.2

Open the **Files** menu. A list of the last files will appear **(Fig. 26).** To access the older files activate the **Next** command. A new screen will open containing tests run at an earlier date. Continue activating the **Next** command until the desired files are located.

▶ **Fig. 26**



7.3

Press the **Multiple Choice** command **(Fig. 26)**. A new window will appear **(Fig. 27).** Select the file or files which you wish to transfer to the portable memory stick**.** Press the **USB** command (bottom of screen, **Fig. 28**). The message; File copied to memory stick will appear on the screen.

Fig. 27

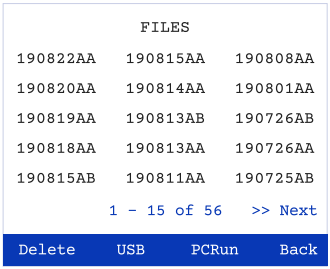
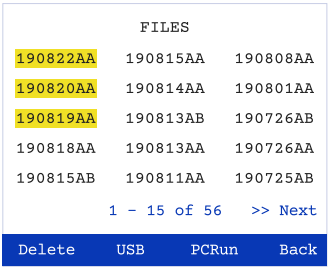


Fig. 28



7.4

Remove the portable memory stick and turn off the Reader. Place the memory stick into the USB port of a computer. Find the file according to the date/code. The file will appear in the format of an Excel sheet which can be analyzed on your personal computer using a **Simulator** found on the portable memory stick received with the Reader. Instructions for employing the **Simulator** are included with this instruction manual in **Section 10, Page 19.**

8. Deleting Files from the PCRun® Reader

The Reader can store one hundred and fifty files. When full, the earliest files will be automatically deleted to make place for the new runs. The files can also be deleted manually using the following instructions:

8.1

Open the **Files** menu **(Fig. 15).** To access the older files activate the **Next** command. Continue activating the **Next** command until the desired files are located.

8.2

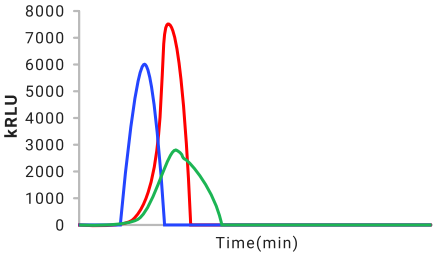
Press the **Multiple Choice** command and then select the file or files which you wish to delete**.** Press the **Delete** command. The **Files** menu will appear and the deleted files will be missing

9. Analyzing PCRun® Graphs

In this section, you will be able to study graphs which may appear on your screen at some stage of your work with the PCRun® Reader. The shape and size of the graph, which appears during a reaction is affected by the quality of the sample used for the test. In addition, the surrounding environment can affect the results. Make sure that the Reader has been placed on a solid table away from any machinery that may cause vibration and in an area where there is no strong or direct light.

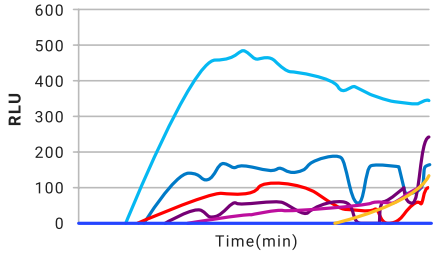
A positive result should have the appearance of a clear histogram shape, as seen in **Fig. 29.**

▶ **Fig. 29**



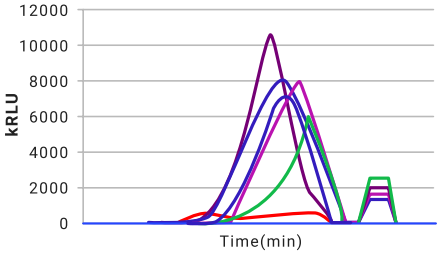
The graph in **Fig. 30** may be observed if the PCRun® Reader has been placed on a surface which receives mild vibrations. At the end of the run the Reader may even interpret some of the peaks as positive if they have a Gaussian shape. The recommendation is to move the Reader to a more suitable area and repeat the test.

▶ **Fig. 30**



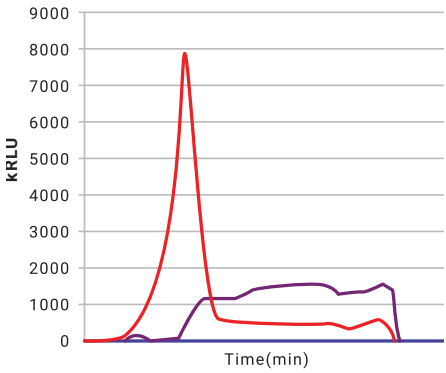
The peaks in **Fig. 31** are clear, but to the right of the curve, low peaks with a flat top are present. This phenomena can occur if the lid of the Reader is disturbed briefly during the run or if there has been a short change in the electrical current. In most cases the internal analysis program can deal with such situations, but if the secondary peaks are higher than the primary peaks the machine may return an inaccurate Time to Peak value and the test should be repeated if necessary.

▶ **Fig. 31**



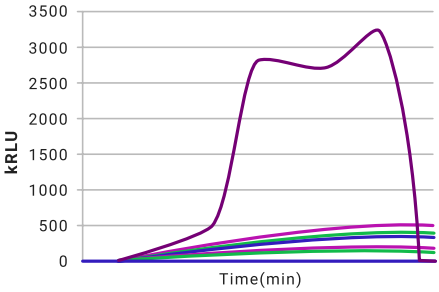
The graph in **Fig. 32** contains a sharp high red peak containing a spread left lower arm and a relatively low flat purple curve. Poorly prepared samples will result in this form of graph which may be difficult for the PCRun® Reader to analyze. The red peak is obviously positive while the purple peak may be questionable. If possible an additional extraction should be performed.

Fig. 32



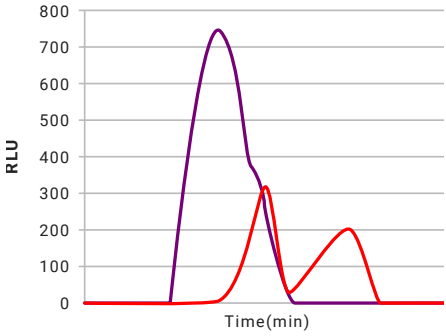
The double peaked graph seen in **Fig. 33** may appear when the reagents have not been allowed to completely dissolve following the addition of the sample or when there are large bubbles within the reaction mix resulting in separation of the fluid into two phases. The PCRun® Reader has been designed to return a Time to Peak of the later and higher peak.

Fig. 33



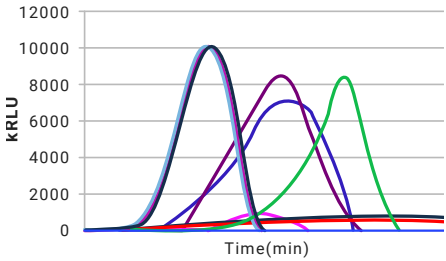
In incidences that the target gene is found in very low concentrations or the extracted sample contains inhibitors the peaks will be very low, in the RLU (Relative Light Unit) range. The PCRun® Reader will usually be able to interpret the negative peaks (red) from the true positive peak (purple) **(Fig. 34).**

Fig. 34



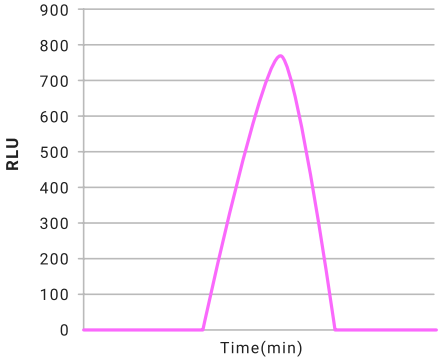
If strong positive tests are run beside a weak positive test (pink peak) the low peak may be hidden by the larger peaks. The PCRun® Reader will detect these peaks and return a positive response on the tab screen **(Fig. 35).**

Fig. 35



In order to visualize the low peaks deactivate all of the tabs relating to the strong reactions.
The y axis will change from kRLU to RLU and the peak will appear as a clear histogram **(Fig. 36).**

Fig. 36



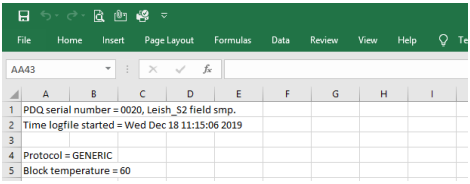
10. Instructions for Use of the PCRun® Reader Simulator

The simulator can be used for analysis of the Excel files produced by the PCRun® Reader.
The first step in the process is to transfer the chosen file to a portable memory stick and copy the file onto your computer. To Download Files from the PCRun® Reader see **Section 7, pages 14-15.** You will receive the PCRun® Simulator on the portable memory stick which is supplied with the Reader. Save the simulator file to your computer. The following instructions describe how to transfer the raw data collected from the PCRun® to the Simulator.

1. Save the file which you downloaded from the Reader to your personal computer.
2. Open the Excel file which you transferred to your computer.
3. Activate the “Select All Button” on the upper left hand side of the sheet **(Fig. 38)**.

▶ Fig. 38

Select All Button ·····



4. The entire worksheet will be selected and shaded light grey.
5. Copy the selected sheet.
6. Open the PCRun® Simulator. The file consists of a workbook containing 4 worksheets.

   You will see the tabs of the 4 worksheets on the bottom of the open worksheet.
7. Activate the “Paste entire.cvs file here” tab. Once open, locate the top of the worksheet (A1).

   Place the cursor on the A1 cell and paste the raw data onto the sheet.
8. If performed properly you will see the graphical and numerical results of your file on the

   “Results and Parameters-60” worksheet.
9. This is a standard Excel workbook and modifications can be made using excel commands.
10. Save the file after completing any changes made.

For assistance please contact Biogal Galed Labs by
Email: info@biogal.com or Tel: +972-4-9898605.