

Royal Biotech GmbH – VIAL LAB *ADVANCED SYSTEM*

RVLM *USER MANUAL*





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1 INTRODUCTION

Dear User, thank you for purchasing the **Royal Biotech GmbH – VIAL LAB**, an innovative rapid colorimetric system to perform microbiological analyses on food, water and surfaces, developed in collaboration with Roma Tre University.

The analysis is based on the observation of the color change of the suspension within the analysis vial that occurs after the addition of the test sample. The suspension changes color in the presence of microorganisms: the greater the amount of microorganisms, the faster the color change.

The main features of the **Royal Biotech GmbH – VIAL LAB** are:

- **Speed:** the analysis time, from set-up to achievement of results, is reduced from 2 to 5 times compared to traditional methods;
- **Ease of use:** anyone, anywhere can perform the analysis without the need for other reagents or special equipment;
- **Sensitivity:** the lower limit of detection is of 1 colony forming unit (CFU);
- **Selectivity:** it can detect the microorganisms of interest while inhibiting the growth of other microorganisms with an experimental limit of 99.999%;
- **Cost:** the cost of each analysis turns out to be 2 to 4 times cheaper than traditional methods.

The MBS method has been validated according to ISO 16140:2003 "Microbiology of food and animal feeding stuffs - Protocol for the validation of alternative methods".



Specific reagents for the selective detection of the following microorganisms are available:

1. Total Viable Count – CBT-A01;
2. Coliforms (Total and *E. coli*) – CO-A02;
3. Thermotolerant Coliform – CO-A02
4. Escherichia Coli – CO-A02
5. *Enterobacteriaceae* – EB-A03;
6. *Staphylococcus aureus* – SP-A04;
7. *Pseudomonas aeruginosa* – PAO-A05;
8. *Salmonella* spp. – SL-A06;
9. *Listeria* spp. – LY-A07;
10. *Enterococcus faecalis* – EF-A09;
11. Yeasts (*Saccharomyces* spp.) – SC-A11.

The **Royal Biotech GmbH – VIAL LAB** tests can be performed using the **RVLM**. This device automates the analysis process detecting the color change of the vials and allowing the execution of multiple tests. At the end of the analysis a printable customizable report is available. The report generated by the RVLM provides the time for color change, the microbial concentration found in the analyzed sample and all the conditions of the test.

2 IN THE BOX

- RVLM;
- Power supply 230 V – 50 Hz (secondary 12 V, 5 A);
- USB cable;
- CD-ROM with installation Drivers and Managing Software.

3 INSTALLATION

3.1 Connection of the RVLM device to computer

- Connect the power supply to the network power plug (be sure the voltage is ok: 230V – 50 Hz);
- Connect the output power supply plug to the RVLM power connector (fig. 1), **without turning on the device;**
- Plug the supplied USB cable into the USB port on your computer and connect the other end to the USB connector of the RVLM (Fig. 1).



Fig. 1. RVLM – Front panel: (1) Power connector, (2) USB Connector, (3) Power switch

3.2 RVLM software installation

3.2.1 Preliminary operations

- Install on your pc the free software “Java Run Time” (download available at: <http://www.java.com/it/download/index.jsp>). **Note:** Make sure it's the latest version or at least the version 1.7.
- Install on your pc the free software “Adobe Reader” (download available at: <http://get.adobe.com/reader>).

3.2.2 Installation of the RVLM managing software (Operating System: XP, Vista, Windows 7, 8, 32/64 bit)

- Insert the “RVLM Software” CD-ROM into the pc CD ROM slot and open it;
- Double click on the executable file “RVLMsetup.exe” and press the “Next” button to begin installation; choose the destination folder for the installation of the RVLM software and press “Install”;
- Click “Finish” to close the wizard; the RVLM software is now installed on your computer and a “RVLM” link has been created on desktop.

The RVLM is now installed on your computer and ready for use.

3.3 Configuration of the managing software

3.3.1 Choice of the communication port

- Turn on the RVLM using the power switch (fig.1);
- Double click on the “RVLM” link on the desktop. The main user interface of the RVLM will appear (fig.2).

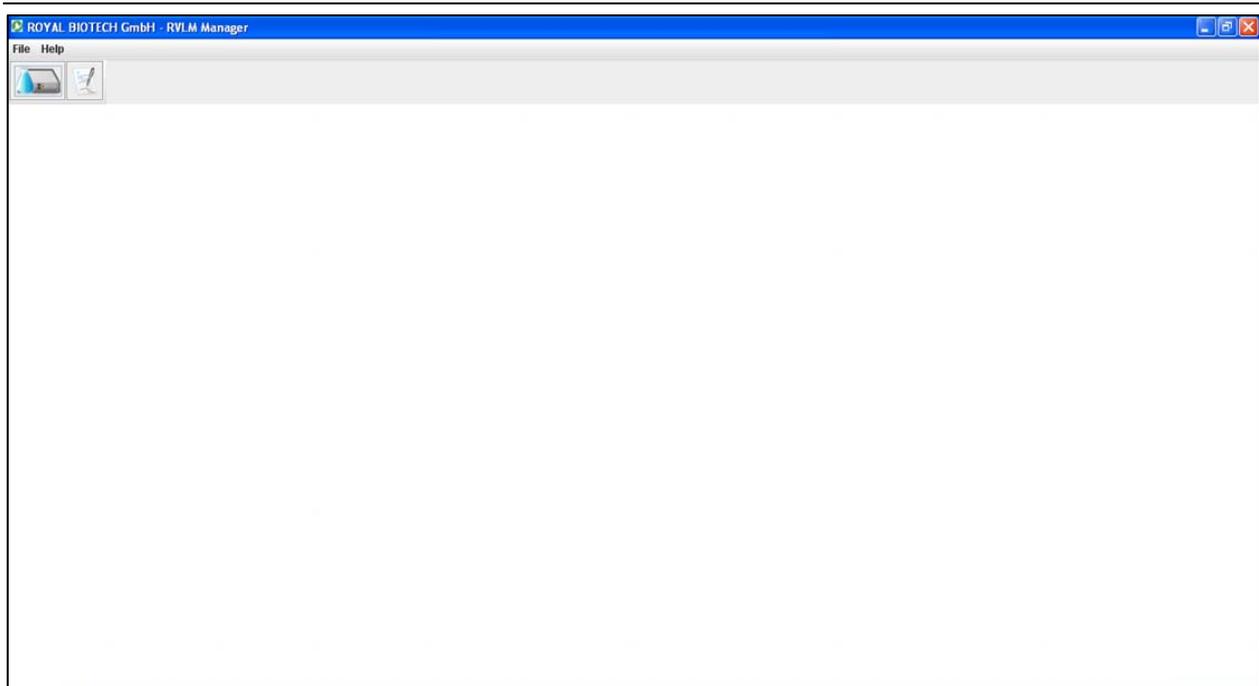


Fig. 2. RVLM – Startup screen

- Click on “File” and then on “Devices”. The user interface is now ready to use (fig.3). **Note:** the user interface can be also opened by clicking on the “Layout devices” button (see red arrow in fig.2).
- Click on “File” and then “Add devices” to connect other devices (fig.3). **Note:** another device can be connected also by clicking on “+ Add devices” button (see red arrow in fig.3).

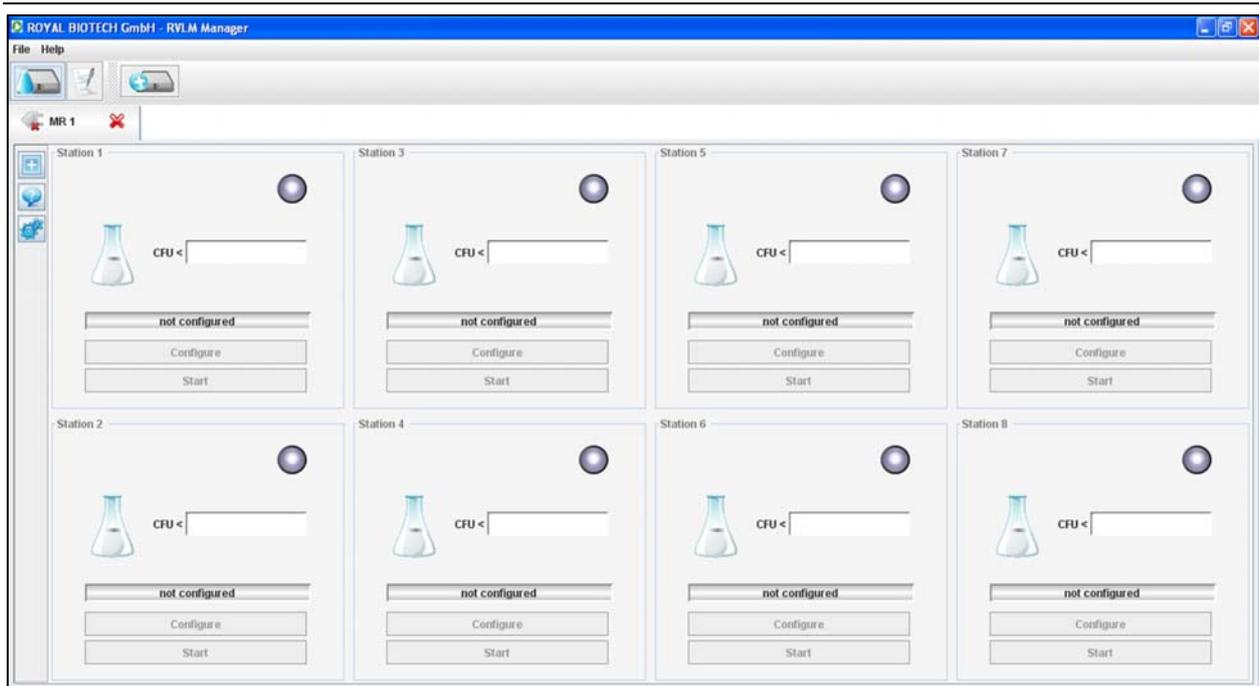


Fig. 3. RVLM – User interface

- Click on “Connect” USB. The configuration box will appear; from the wipe menu select the communication port that controls the RVLM (fig.4). Choose from the list of available COM and click “Connect”.

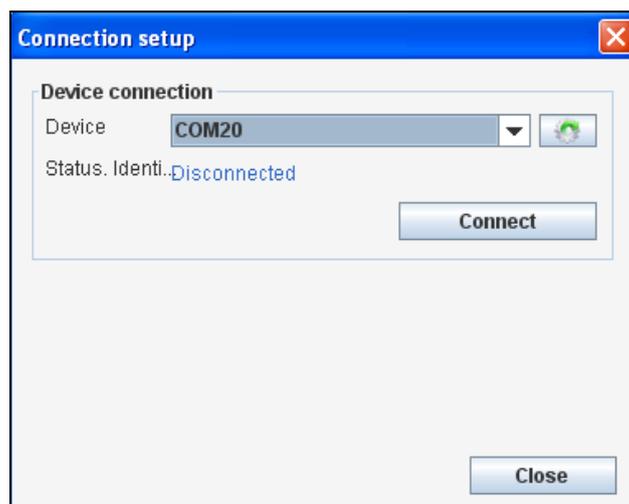


Fig. 4. RVLM – Connection to communication port

- If the communication port chosen is correct, the message “Connected to port COM...” will appear on the Connection setup panel.
- Rename the device in the field “Device alias”, click on “Apply” and then click on “Close” (fig.5). **Note:** when you connect the same device to the same pc, the RVLM software will recognize the alias device; it is important to give different alias to devices when you are connecting more devices at the same time.

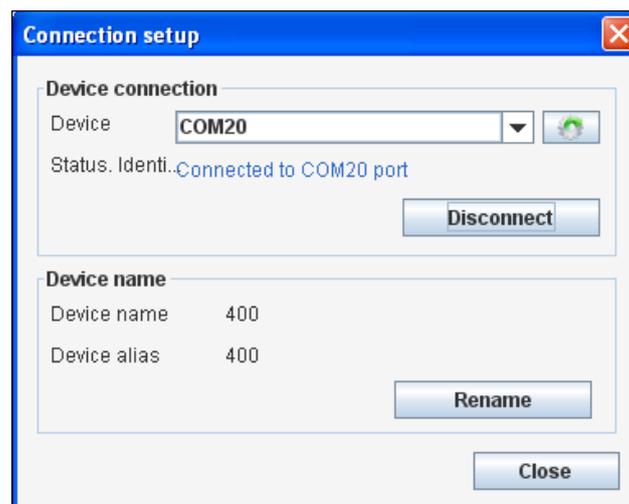


Fig. 5. RVLM– Device name

- Before the analysis is started all the RVLM station lights shown on the user interface are green (fig.6), thus indicating that it is possible to set the parameters of analysis through the configuration of the single stations. **Note:** if you want to enlarge the user interface, you can click on “-“ in the data log (see red arrow in fig.6).

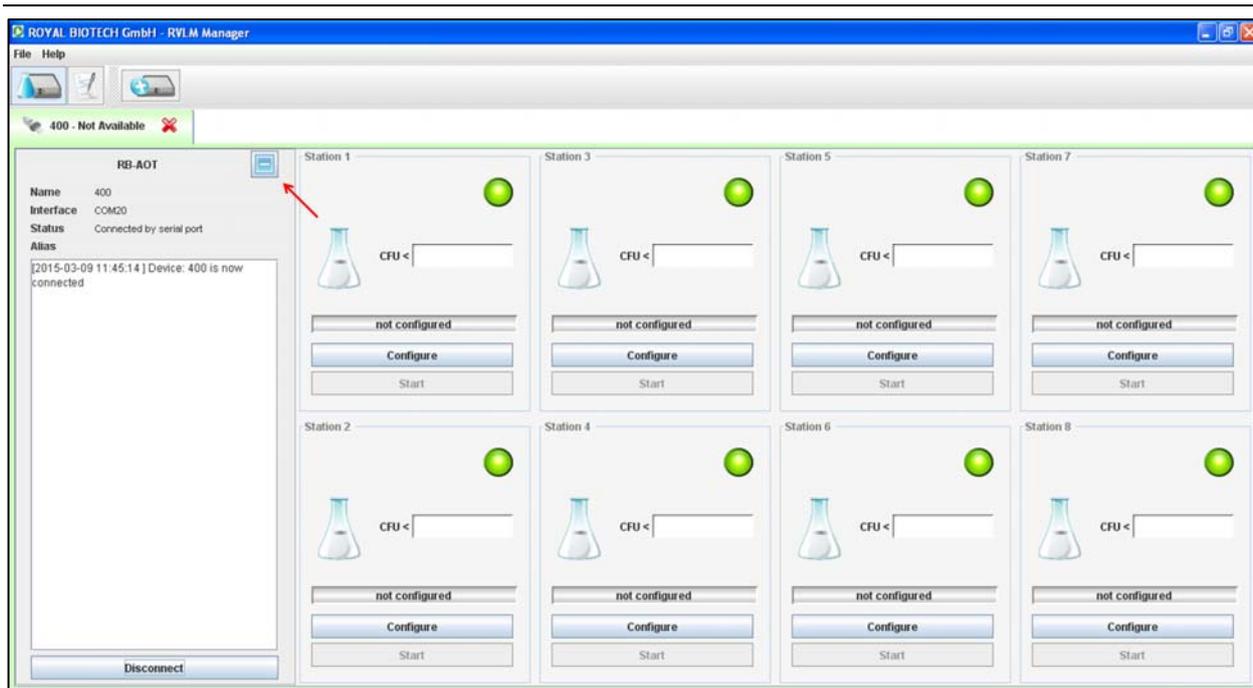


Fig. 6. RVLM – User interface, software ready

- The RVLM should not be disconnected from the computer while the tests are running, nor the computer can be shut down or the session closed. Any of these operations will immediately stop the test causing loss of acquired data and set up specifications.

4 ANALYSIS PROCEDURE

4.1 Setting the analysis station

- Click on the “Configure” button of one of the RVLM available stations (green light). The dialog box "User Configuration Panel" on the station will appear (fig.7);



Fig. 7. “User configuration panel”

- Fill in the editable fields:
 - Select the **Operator**: click on the “+” button to open the panel and insert the operator information (fig.8/1); click on “Insert” and fill in the fields then press “Add” (fig.8/2). Select the operator and click on “Accept” (fig.8/3); a “green light”

will appear on the panel. **Note:** If the operator has been previously registered, select it from the list and click “Accept”.

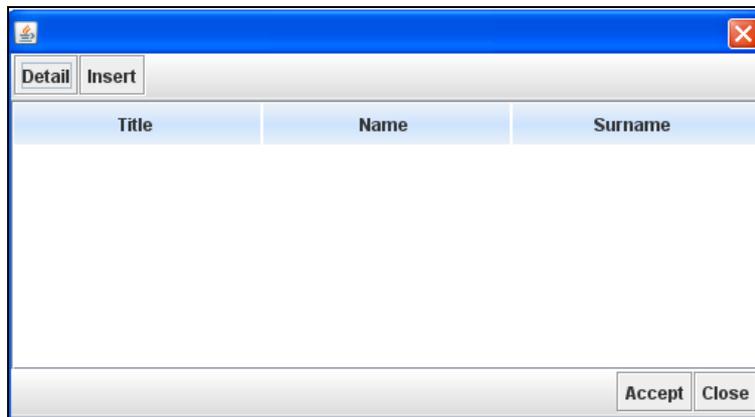


Fig. 8. “Operator” configuration panel (1)

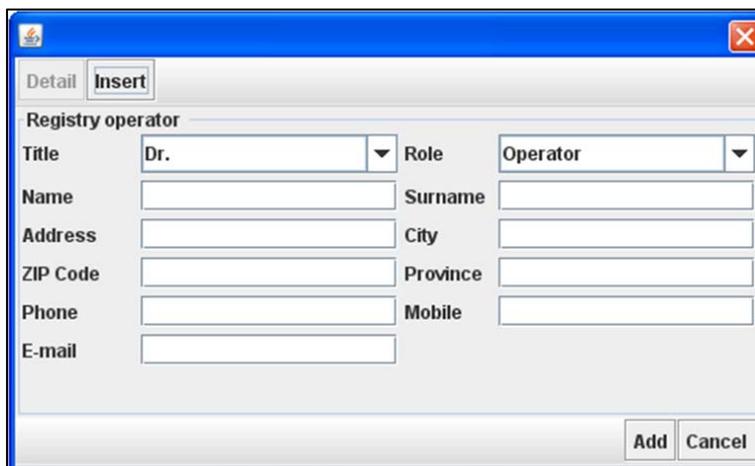


Fig. 8. “Operator” configuration panel (2)

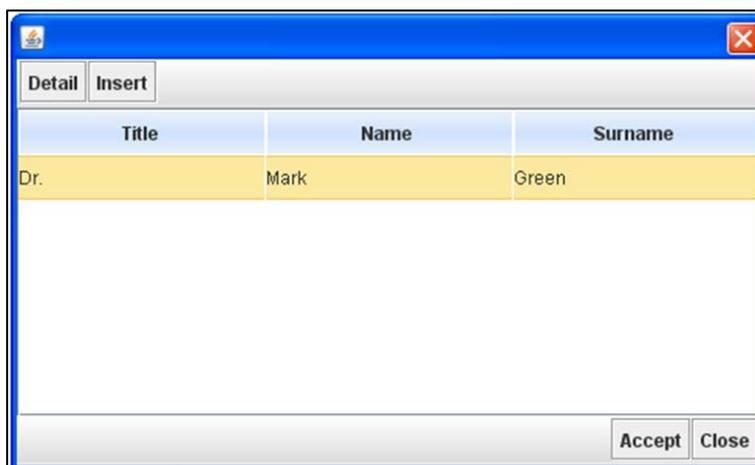


Fig. 8. “Operator” configuration panel (3)

- select **Customer**: click on the “+” button to open the panel and insert the customer information (fig.9/1); click on “Insert”, select the type of customer (company or private) and fill in the fields, then press “Add” (fig.9/2 or 9/3). Select the customer and click on “Accept” (fig.9/4); a “green light” will appear on the panel. **Note:** *If the customer has been previously registered, select it from the list and click “Accept”.*

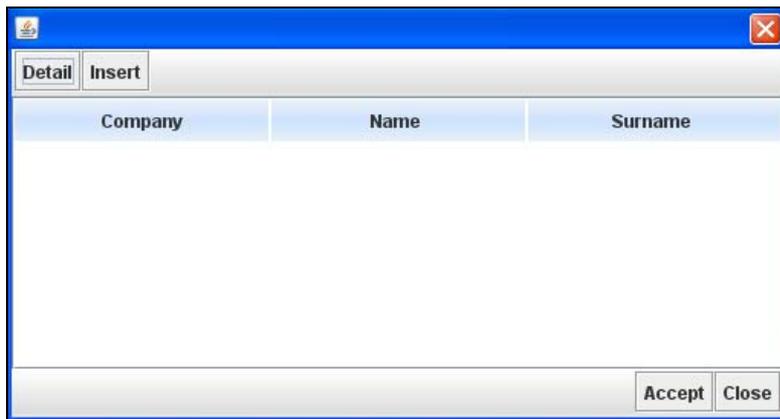


Fig. 9. “Customer” configuration panel (1)

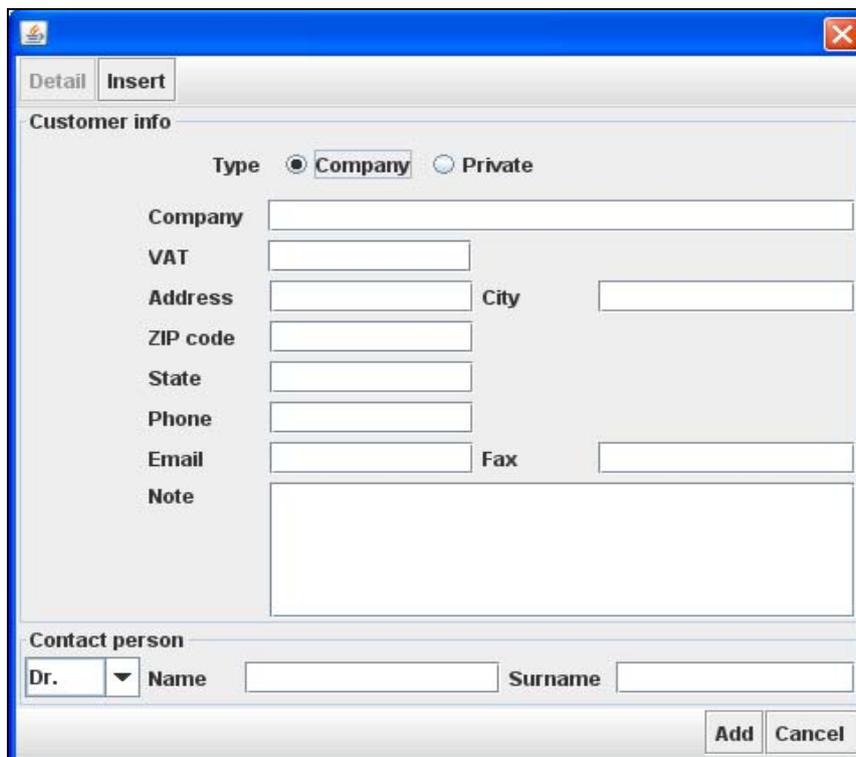


Fig. 9. “Customer” configuration panel - company (2)

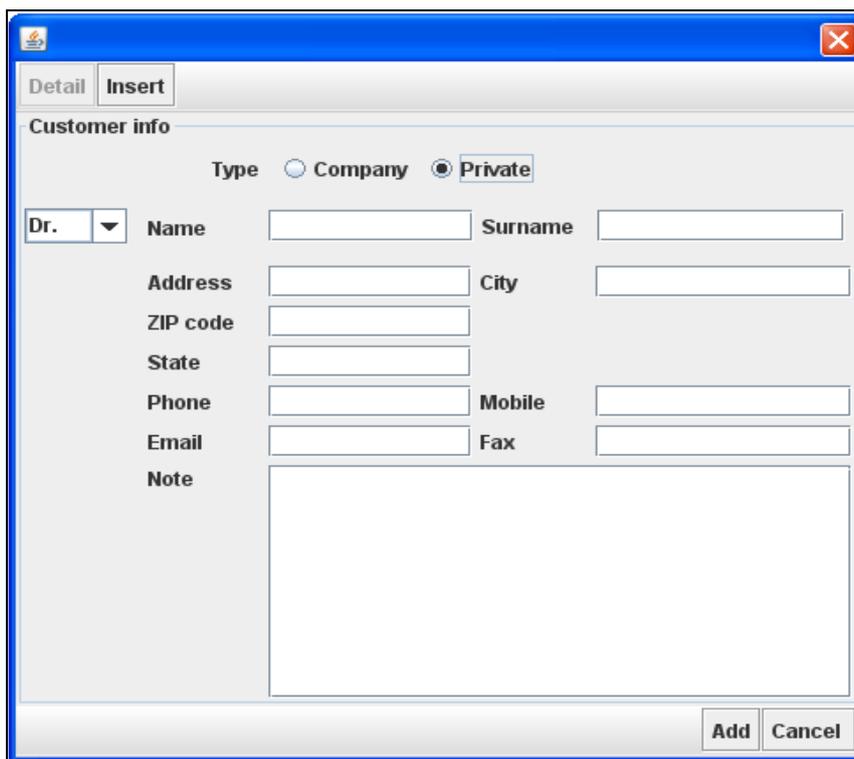


Fig. 9. "Customer" configuration panel - private (3)



Company	Name	Surname
HCQ Laboratories	Steve	Brown

Fig. 9. "Customer" configuration panel (4)

- select **Sample**: click on the "+" button to open the panel and insert the sample data (fig.10/1); click on "Insert" and fill in the fields, then press "Add" (fig.10/2). Select the sample and click on "Accept" (fig.10/3); a "green light" will appear on the panel. **Note**: *If the sample has been previously registered, select it from the list and click "Accept".*

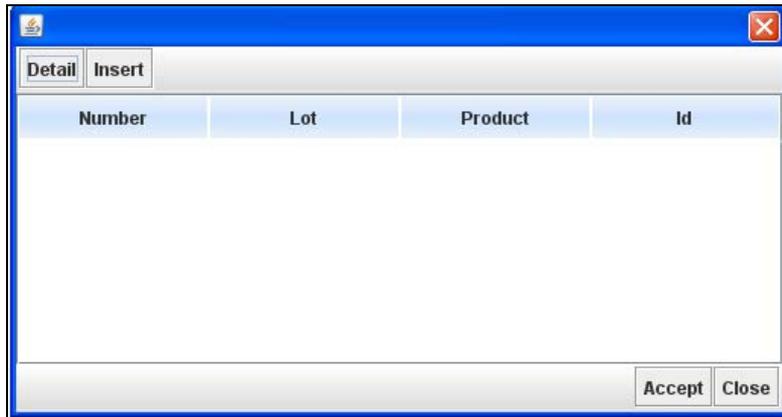


Fig. 10. "Sample" configuration panel (1)

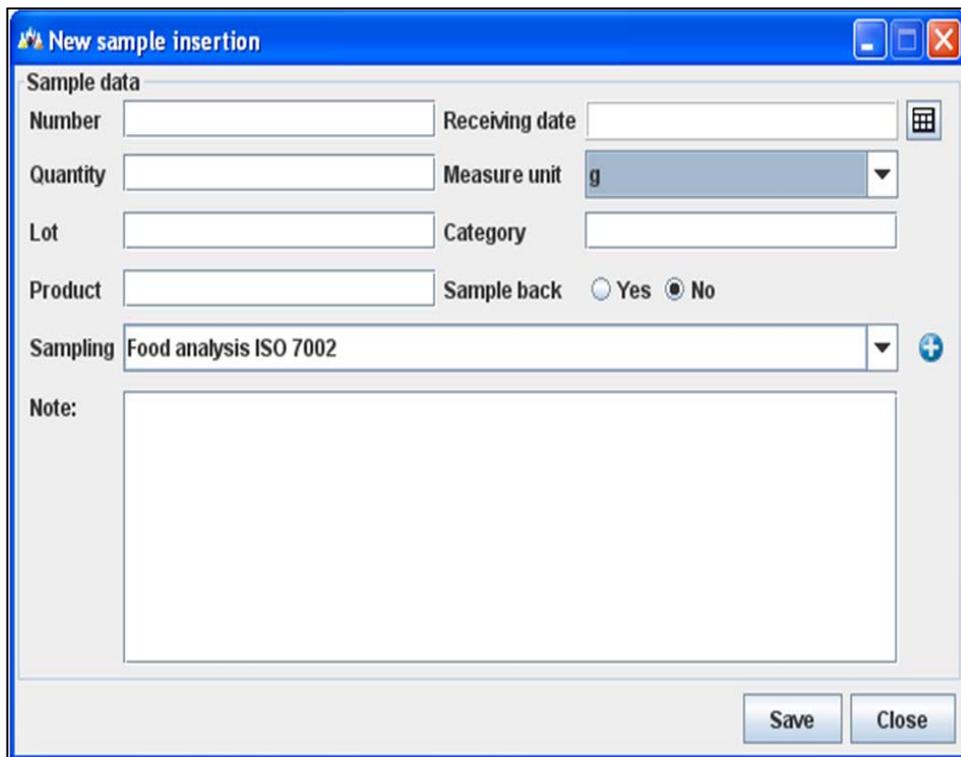


Fig. 10. "Sample" configuration panel (2)

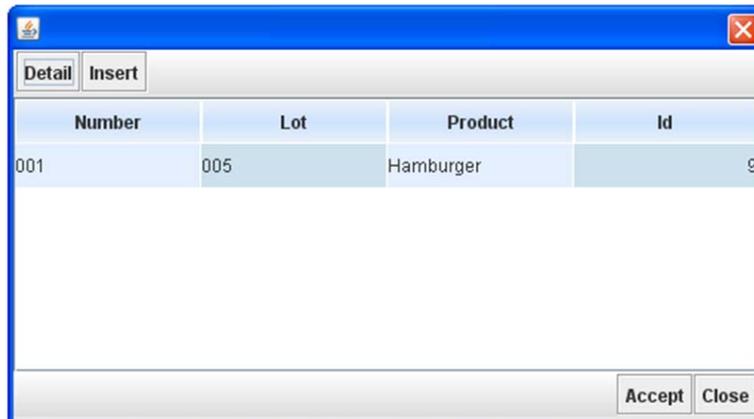


Fig. 10. "Sample" configuration panel (3)

- select **Analysis**: click on the "+" button to open the panel and select the type of analysis; it possible to choose between quantitative and qualitative analysis (fig.11/1 and 11/2). Once chosen the type of analysis to perform click on "Accept"; a "green light" will appear on the panel. **Note**: if you flag the message "Stop on lid open", the analysis will be stopped whenever the stations lid is open.

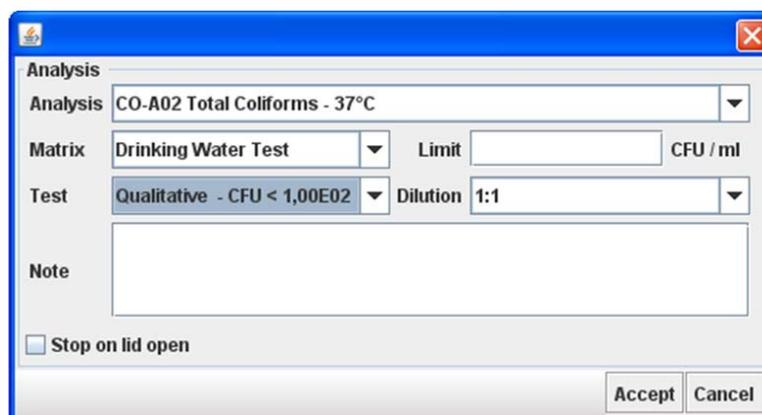
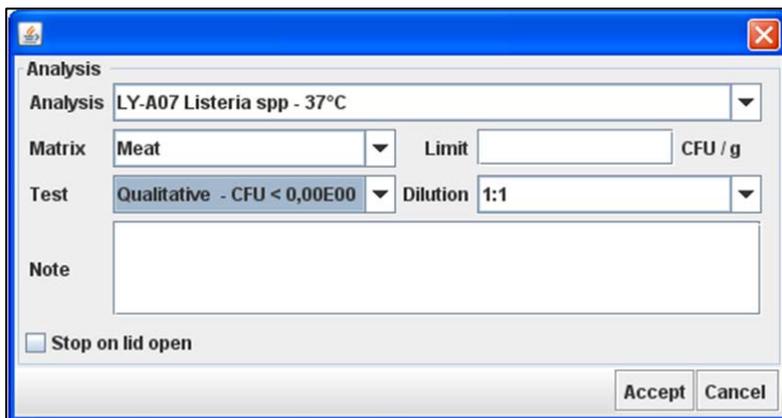


Fig. 11. "Analysis" configuration panel – quantitative analysis (1)



The screenshot shows a software window titled "Analysis" with a blue header and a close button. The main area contains several fields: "Analysis" is a dropdown menu with "LY-A07 Listeria spp - 37°C" selected; "Matrix" is a dropdown menu with "Meat" selected; "Limit" is a text input field with "CFU / g" to its right; "Test" is a dropdown menu with "Qualitative - CFU < 0,00E00" selected; "Dilution" is a dropdown menu with "1:1" selected; and "Note" is a large empty text area. At the bottom left, there is a checkbox labeled "Stop on lid open" which is currently unchecked. At the bottom right, there are "Accept" and "Cancel" buttons.

Fig. 11. "Analysis" configuration panel – qualitative analysis (2)

- When all fields are filled, click on "Accept" (fig.12).



The screenshot shows a software window titled "Station: 7 - Device: 400 As null" with a blue header and a close button. The window is divided into several sections: "Operator..." with "Dr. Steve Brown as Operator"; "Customer..." with "HCQ Laboratories" and address "55 Boldsover Street London"; "Sample..." with fields for "Number" (001), "Receiving date" (2015-03-09), "Quantity" (100.0), "Measure unit" (g), "Lot", "Category" (Frozen), "Product" (Hamburger), "Sample back" (No), and "Sampling" (Food analysis - ISO 7002); and "Analysis..." with "Analysis" (Total Coliforms - 37°C), "Matrix" (Meat), "Limit" (-), "Criteria" (Quantitative), and "Dilution" (1:1). A "Note" field is also present. At the bottom right, there are "Accept" and "Cancel" buttons.

Fig. 12. Configuration panel filled fields

- The station is now configured and the message "Configured" will appear on a green box (fig.13).

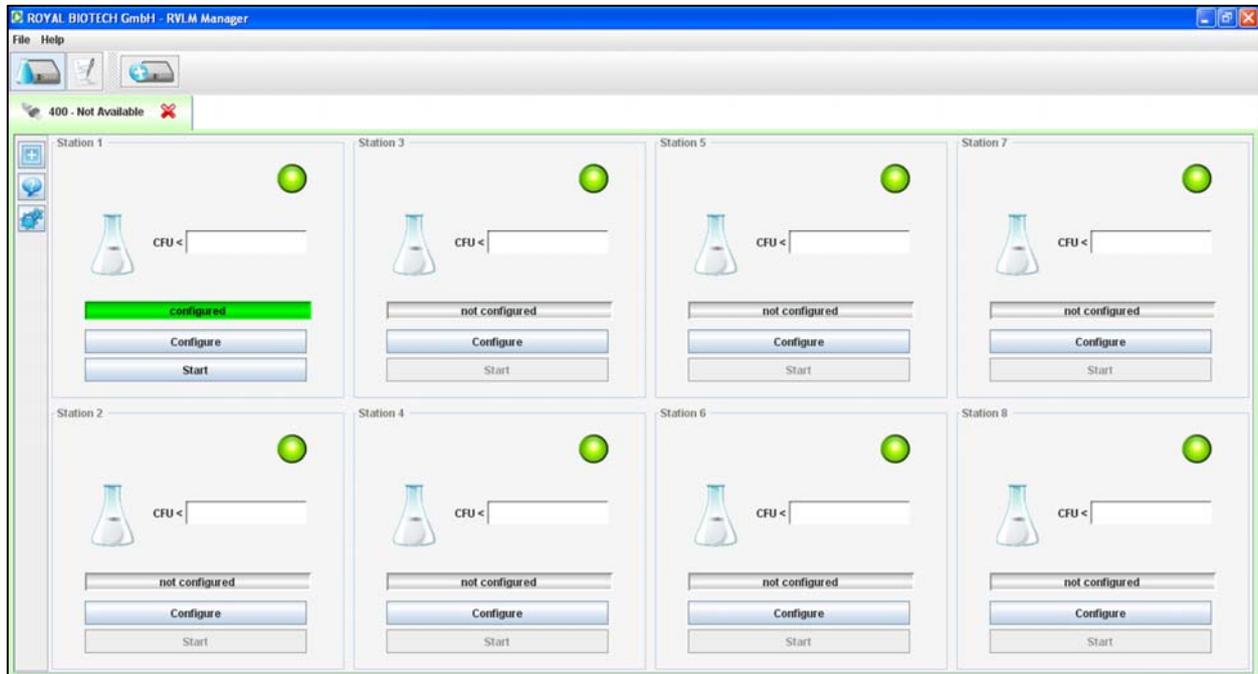


Fig. 13. R – User interface, configured station

4.2 Starting the test

- Prepare the analysis vial as described in the "Royal Biotech GmbH - VIAL LAB – Basic System" (par.1.2). Place the vial in the configured station of the RVLM and close the lid. **Note:** you should not mark or label the vial of analysis, but if unavoidable, vials must be marked with a symbol/label **only on the vial cap.**
- You can now begin the test by clicking once on the "Start" button of the configured station. The light will turn red and the message "Running" will appear on a red box (fig.14);

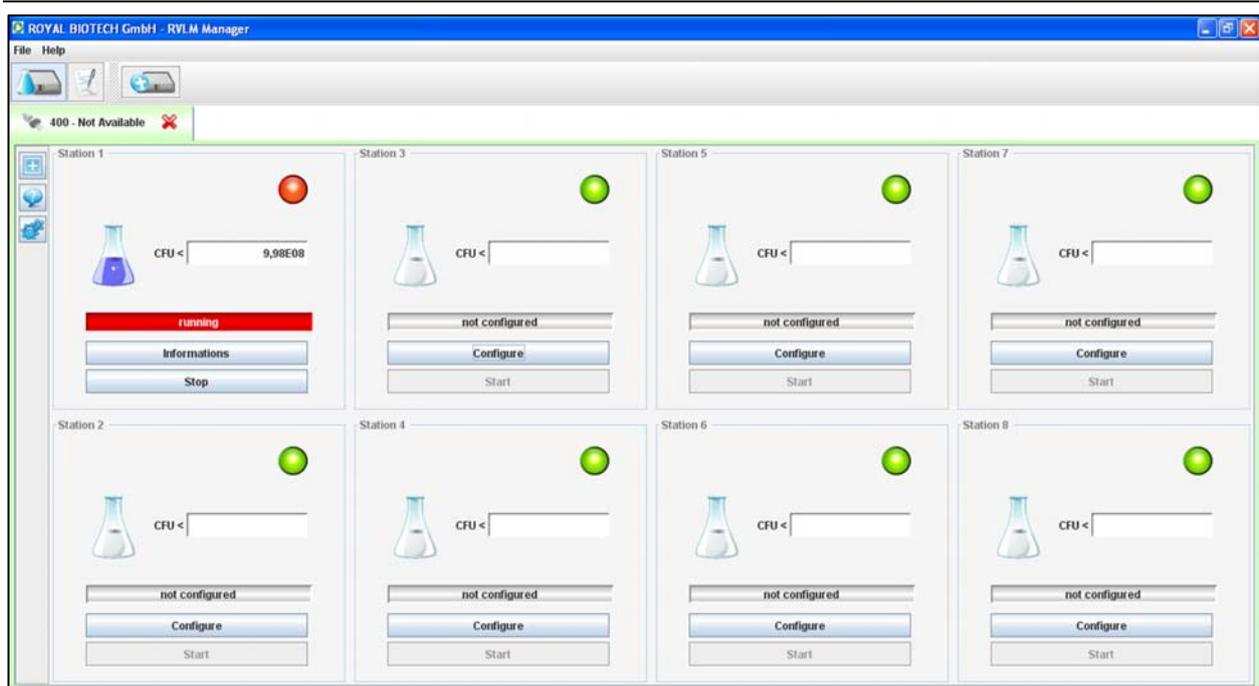


Fig. 14. RVLM – User interface, test start

- To perform simultaneously several tests repeat the configuration of the desired stations as described above. There is no order or priority between the different stations of the device (fig.15);

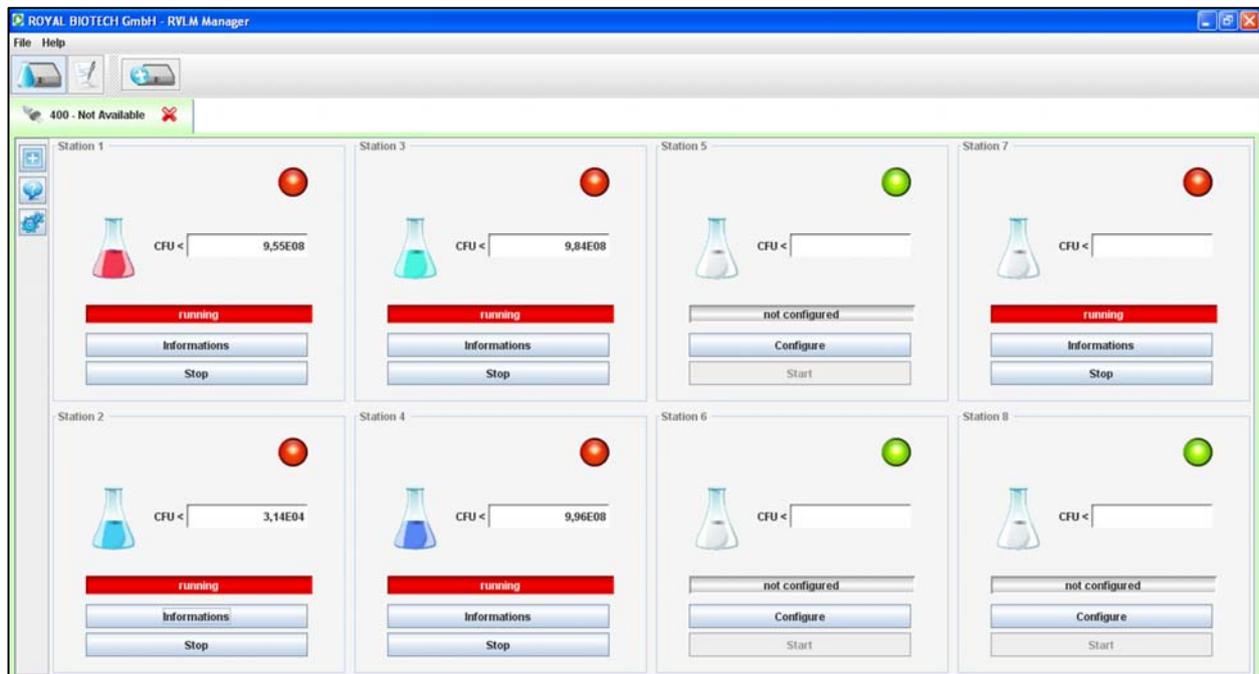


Fig. 15. RVLM – User interface, test start

-
- Once the analysis is running there are two buttons for each station:
 - “Informations”: by clicking once on the button of the selected station a not editable window containing the data inserted in the configuration will appear.
 - “Stop”: by clicking once on the button of the selected station it is possible to stop the test confirming “Yes” when asked. In this case the analysis is stopped and the station is reset and available for further analysis.
 - For each station the user Interface shows the field “CFU <”: the value indicates an “on time” result that would be the one obtained if the analysis was stopped at that time. This value cannot, in any case, be considered the final result of the test. **Note:** *The value format of the “CFU <” is a scientific format (2,75E07 is equal to 2,75 x 10⁷ CFU.*
 - Click on “File” and then “Lock application” to block the user interface by entering a password; you can easily unlock the interface reinserting the same password.
 - Click on “File” and then “Exit” to close the interface but not the software, that will continue to work; with a double click on the RVLM icon in the System Tray, you can open again the interface.

4.3 End of the test

- The results obtained using the RVLM can be (fig.16):
 - **positive** (indicating the presence of microorganisms and thus the value of the contamination);
 - **negative** (indicating the absence of microorganisms and thus the value zero). In this case the contamination value is fixed and equal to “0.00E00”;
- In both cases the stations lights turn yellow and the message “Running ...” changes to “Completed analysis”;
- Click on “Reset” to clean the configuration panel and press “Yes” to confirm the operation. In this way it will be possible to start a new analysis in that station.

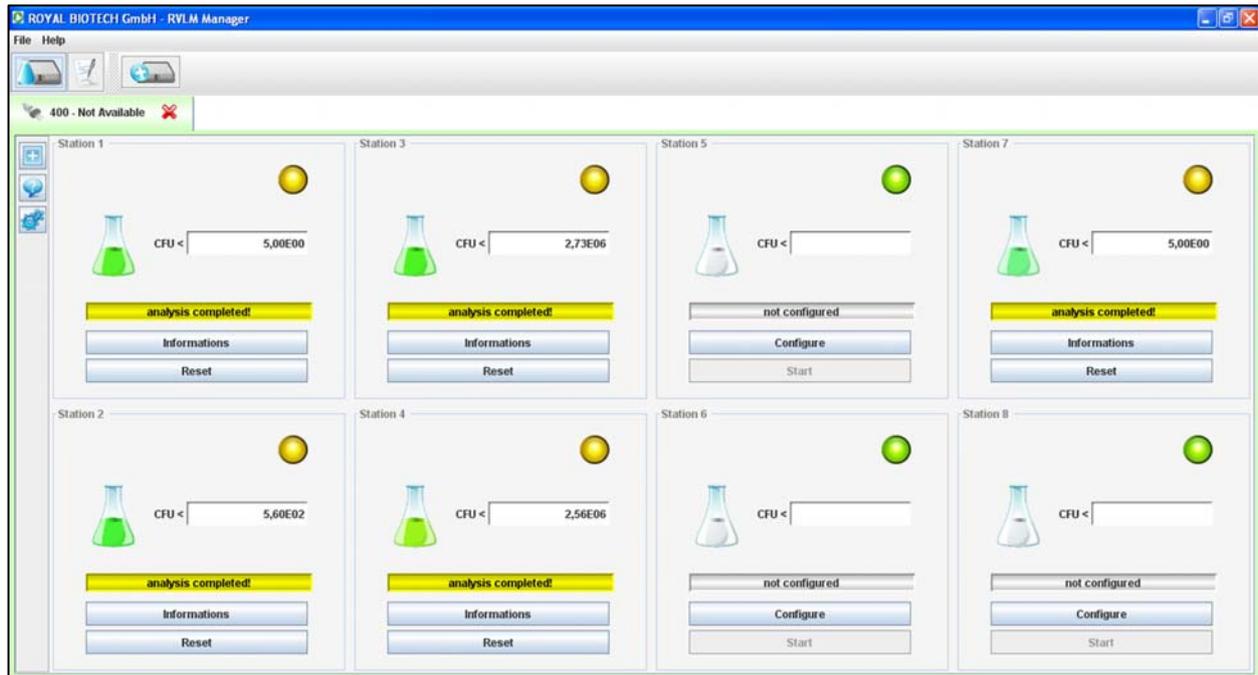


Fig. 16. RVLM – End of analysis

- When analyses are ended, click on “Close” and press “Yes” to close the software.
- Turn off the RVLM device using the power switch (Fig.1).

5 DATABASE

This section contains all information regarding the performed analyses and allows the storage of all entered data. It is possible to access to this section also when the device is not connected.

- Click on “File” and then on “Database”, you can see and modify the information that you entered in the configuration phase (fig.17). **Note:** *you can also click on the “Layout data” button (red arrow) to open the Database.*

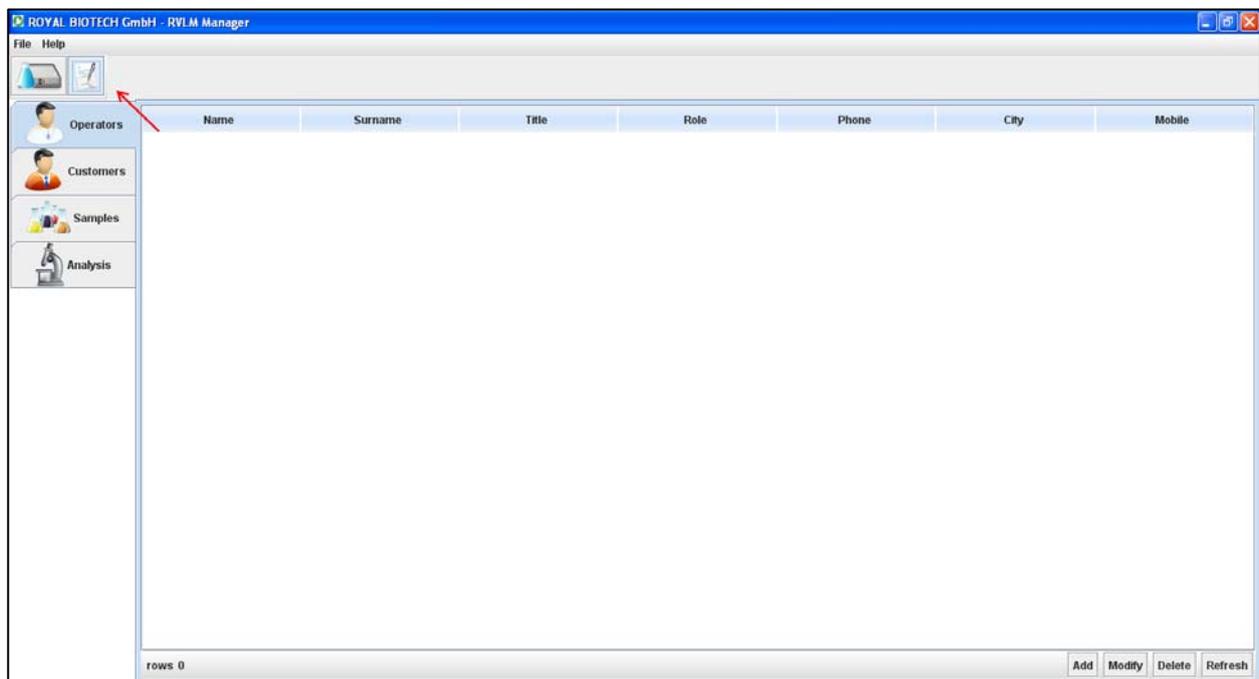


Fig. 17. RVL Manager – Database

- Click on “File” and then on “Devices” to return to the User interface (fig.3). **Note:** *you can also click on “Layout devices” button.*

5.1 Operators

- Click on “Operators” to see the list of all operators, with a double click on a row of

interest you can see all data referred to a specific operator;

- Click on “Add” to insert a new operator; fill in the panel then click on “Save“ and close the panel;
- Click on “Modify” to modify data referring to a selected operator; change the details of interest then click on “Save“ and close the panel;
- Click on “Delete” to remove an operator from the list; click on “Yes” to confirm the operation;
- Click on “Refresh” to update the list.

5.2 Customers

- Click on “Customers” to see the list of all customers, with a double click on a row of interest you can see all data referred to a specific customer;
- Click on “Add” to insert a new customer; fill in the panel then click on “Save“ and close the panel;
- Click on “Modify” to modify data referring to a selected customer; change the details of interest then click on “Save“ and close the panel;
- Click on “Delete” to remove a customer from the list; click on “Yes” to confirm the operation;
- Click on “Refresh” to update the list;
- To filter a given customer insert in the “Search” fields the specific data (eg: Vat no., Surname,...) and then click on “Enable”. To go back to the complete list, click on “Disable”.

5.3 Samples

- Click on “Samples” to see the list of all samples, with a double click on a row of interest you can see the data referred to the specific sample and build the Analysis Report (see par.5.5);
- Click on “Add” to insert a new sample; fill in the panel then click on “Save“ and close the panel;

-
- Click on “Modify” to modify data referring to a selected sample; change the details of interest then click on “Save“ and close the panel;
 - Click on “Delete” to remove a sample from the list and click on “Yes” to confirm the operation;
 - Click on “Refresh” to update the list;
 - To filter a given sample insert in the “Search” fields the specific data (eg: Product, Lot,...) and then click on “Enable”. To go back to the complete list, click on “Disable”.

5.4 Analysis

- Click on “Analysis” to see the list of all analyses;
- Click on “Open” to see the specific data; press “Close” to close the window;
- Click on “Delete” to remove an analysis and click on “Yes” to confirm the operation;
- Click on “Refresh” to update the list;
- To filter a given analysis insert in the “Search” fields the specific data (eg: Product, Analysis,...) and then click on “Enable”. To go back to the complete list, click on “Disable”.

5.5 Building the Analysis Report

- To build the Analysis Report, click on “Samples” and double click on the sample of interest;
- Click on “Build Report”, select an operator and one or more analysis to insert in the Analysis Report, then press “Accept” (fig.18). A PDF file will be generated with the possibility to save it on your pc. **Note:** *the name of the analysis is made from: analysis id – RVLM station @ date of test start – analysed matrix – type of analysis performed.*

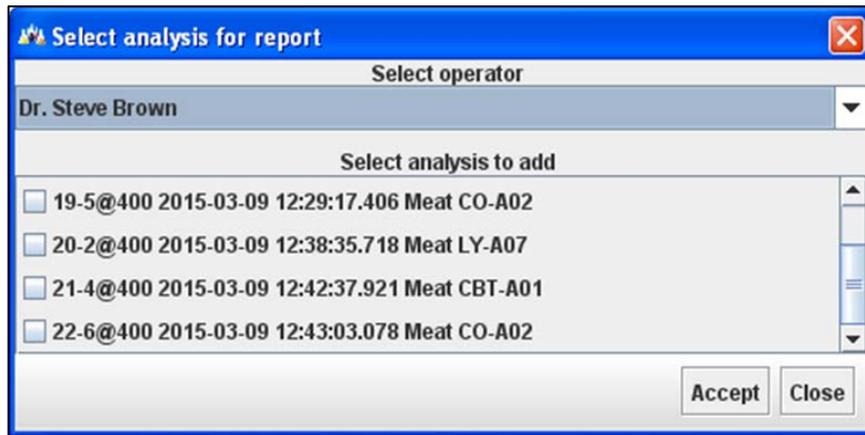


Fig. 18. RVLM – Building Report

- The Analysis Report (fig.19) contains, in addition to the tests results, all the information entered in the set-up phase. **Note:** *When one or more fields are not compiled in the configuration panel the Analysis Report will lack those specific information.*
- The microbial concentration found in the analysed sample is expressed as CFU (Colony Forming Units):
 - for the analysis of solid or liquid samples, the value of CFU refers respectively to 1g or 1ml of sample (eg: 5,10E03 CFU/g or 5,10E03 CFU/ml);
 - for the analysis of surfaces, however, the result calculated by RVLM refers to the CFU present in cm² (eg: 5,10E03 CFU/cm²);



Analysis Report

2015-03-09 12:46:15 CET

Company: HCQ Laboratories 55 Boldsover Street - London

Contact Person: Dr.

Receiving date: 2015-03-09

Sample Number: 001

Quantity: 100.0 g

Product: Hamburger

Category: Frozen

Sampling: Food analysis - ISO 7002

Sample back: No

Sample notes:

This report refers only to the given sample

Start Date End Date	ID Analysis Analytical Method Matrix Criteria	Dilution	Results	Unit	Note
09-03-2015 12:42:37 09-03-2015 12:46:03	CBT-A01 - Total Viable Count - 30°C Micro Biological Survey® Meat Quantitative	1:1	5,60E02 CFU/ml	-	
09-03-2015 12:43:03 09-03-2015 12:46:00	CO-A02 - Total Coliforms - 37°C Micro Biological Survey® Meat Quantitative	1:1	2,56E06 CFU/ml	-	

Operator

Dr. Steve Brown

Fig. 19. RVLM – Analysis Report



6 WARRANTY CONDITIONS

Royal Biotech GmbH warrants this device to be in compliance with its specifications under normal use and service, and to be free from material defects in materials and workmanship for a warranty period of twelve (12) months from the date of purchase. Royal Biotech GmbH is not responsible for accidental damage due to physical shock, exposure to corrosive agents or to a use not in accordance with the instructions described in this manual.

For more details on this warranty, please contact Royal Biotech GmbH.

7 CONFORMITY DECLARATION

Royal Biotech GmbH declares, under own responsibility, that the product RVLM is made in accord to:

- EN 61010-1 (2001);
- EN 61326-1 (2006);
- 2002/95/CE (RoHS);
- 2002/96/CE (RAEE/WEEE).

RVLM device also meets the essential requirements of the directives:

- 2006/42/CE (EC) Machine;
- 2006/95/CE (EC) Low voltage;
- 2004/108/CE (EC) Electromagnetic compatibility;