H 009334 02.06

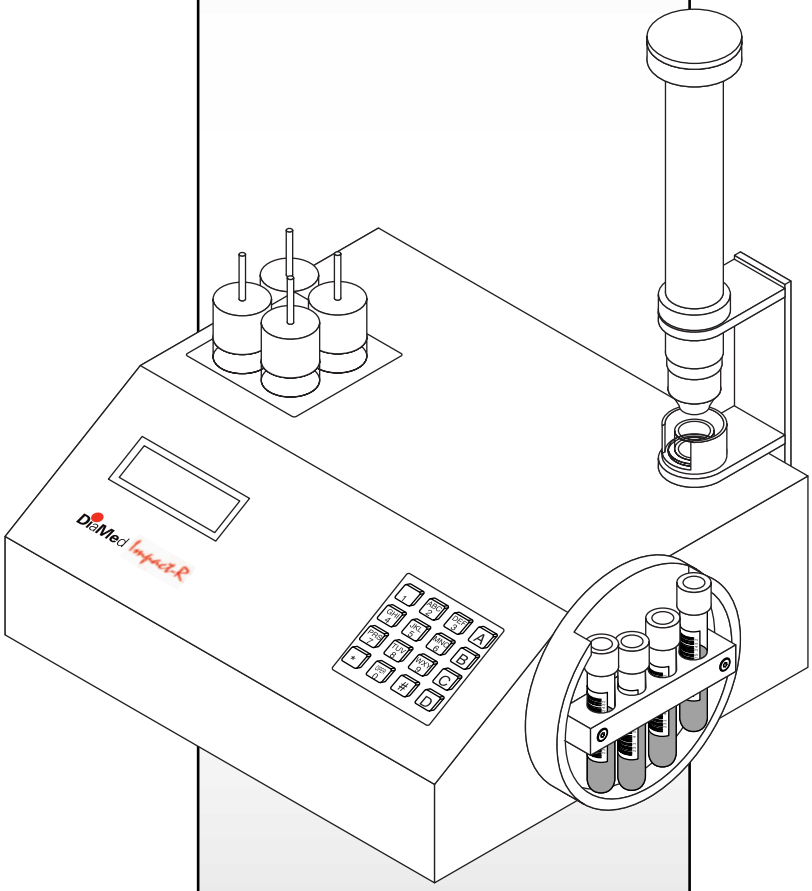
DiaMed
Haemostasis

Service Manual

Impact-R

Cone and plate(let) (CPA) technology

A test device for platelet function analysis



Caution

Before performing any service activities on the Impact-R, read this manual and take special note of all safety instructions.
This manual is designed to be used in synchronization with, and to add to the information written in the "User Manual"

Document

Impact-R Service Manual

Version : 1.2

Nb. : H 009334

Version	Date	Comment
1.0	17.03.05	First issue. This manual corresponds to the following versions: - Impact-R device hardware version 1.07 (version 0); - Impact-R device hardware version 1.12 (version 1); - *Image Analysis* software version 1.21
1.1	20.05.05	Minor editorial changes
1.2	24.02.06	Adaptation to software version 1.28

Printed in Switzerland

Table of Contents

Chapter overview

This chapter contains basic information on the structure of the document, its specifications and on the documentation.

1.1 Appropriate use

The DiaMed AG's Impact-R is a novel test device for testing platelet function under close to physiological conditions

The DiaMed AG's Impact-R may only be used by trained and authorized personnel in a medical laboratory. It may not be used in the patient's direct environment.

Using the DiaMed AG's Impact-R is only permited in conjunction with the corresponding software or in a configuration which is authorized by DiaMed AG.

The use of any material other than the one specified in the Service Manual (e.g. non-authorized substances) is forbidden.

The instructions contained in the present Service Manual must be adherred to in order to avoid possible operational conflicts and / or personal danger.

1.2 Warranty limitations

Although the software has been tested, it is highly recommended to perform a backup of the computer before any installation and use of the software.

DiaMed AG denies any responsibility in case of:

- wrong use of the software;
- unauthorized modification (willingly or unwillingly);
- damages linked with the use of the software, in particular any data loss or any financial loss, which could possibly be attached to the use of the software.

When the device is connected to a host, the user takes the entire responsibility for an errorless transmission of the results (hardware, software, firmware, etc...) to this system.

In case of doubt, the English version of the present document is binding.

1.3 Conformity to directive and standards

The present product has been conceived in order to fully comply with the safety at work and function requirements. It is in conformance with the following European Union directives :

- 89/336/EEC (electromagnetic compatibility) and amended by the directives 92/31/EEC and 93/68/EEC;
- 73/23/EEC (low voltage equipment) amended by the directive 93/68/EEC;
- EC61326-1 Class B;
- CRF 47 FCC Class B;
- Europe Directive Safety EN 61010-1.

1.4 Glossary

The following terms, among others, are used in the present Service Manual.

1.4.1 Persons

Manufacturer

The manufacturer of the Impact-R is :

DiaMed SA, CH-1785 Cressier sur Morat.

Operator

The operator is the owner of a DiaMed AG's Impact-R both when using it as its owner and when transferring it to a third-party.

Personnel

The personnel gathers persons who have any kind of activity with the DiaMed AG's Impact-R and who are qualified in accordance with the manufacturer's requirements and who are consequently authorized.

Technical personnel

This terme designates the duly trained persons, who are allowed to perform specific tasks on the DiaMed AG's Impact-R.

For instance, an electrician is designated as technical personnel for the activities linked to wiring the DiaMed AG's Impact-R to the electrical network.

Personnel qualifications

Several kinds of personnel qualifications are required in order to perfom the activites related to the DiaMed AG's Impact-R. These qualifications are described in the corresponding sections of the present Service Manual.

The personnel qualifications define the minimum requirements, which must be met by the authorized personnel.

Serious injury

A serious injury is an injury (ICAO definition) which is sustained by a person in an accident and which :

- requires hospitalization for more than 48 hours, commencing within seven days from the date the injury was received;
- results in a fracture of any bone (except simple fractures of fingers, toes, or nose);
- involves lacerations which cause severe hemorrhage, nerve, muscle or tendon damage;
- involves injury to any internal organ;
- involves second or third degree burns, or any burns affecting more than 5 per cent of the body surface;
- involves verified exposure to infectious substances or injurious radiation.

Light injury

Any injury not corresponding to the definition of a serious injury is considered as a light injury.

1.4.2 Product

This is the DiaMed AG's Impact-R distributed by the manufacturer.

1.5 Typographical conventions

The following styles are used in this manual.

1.5.1 Description

This style, use in conjunction with illustration numbers, is preceded with the corresponding numbers:

Example:

(1) First element

(2) Second element

(3) Etc...

1.5.2 Command

Any software command, button, function key, window, icon, option, tab, checkbox, selection box, article, menu, tool bar, field and section used in this document is represented by a bold italic font.

Example:

The ***Exit*** command allows to quit the software.

1.5.3 Procedure

Each procedure step to be carried out step-by-step by the user is preceded by a letter.

Example:

A. Open the drawer.

B. Put the microplate into position as shown.

C. Close the drawer.

1.5.4 Procedure result

A procedure result is shown by the following symbol ↳.

Example:

A. Click on the ***Parameters*** button.

↳ The parameter window is displayed.

1.5.5 Cross reference

This style is used to help the user find complementary information linked to the current subject.

Example:

See section “4.2.4 Sensor Board Positioning” on page 4-7.

1.5.6 List of items

This style is used in order to display a list of elements.

Example:

- item 1;
- item 2;
- item 3.

1.5.7 Troubleshooting

The complete description along with the error message, the explanation and the remedy appears as follows :

Problem

- **Explanation, possible cause**

  ✔ Remedy

Warnings

In relation to the importance of the warning and its related risks, three warning styles are defined.

The safety aspects are used in accordance with the requirements contained in the following norms :

- ANSI Z535.4;
- ISO 3864 and ISO 3864-1:2002.

1.5.7.1 Danger

Used to designate an imminent and dangerous situation which, if not avoided, may lead to death or serious injury.

The primary risk is given in capital letter below the ⚠ DANGER symbol. However, mentioning a specific risk does not exclude the presence of subsidiary risks.

Example

⚠ DANGER

ELECTROCUTION

Never touch an exposed electrical wire. A contact with an electrical wire may cause an electrocution.

1.5.7.2 Warning

Used to designate a potentially dangerous situation which, if not avoided, may lead to death or serious injury.

Example

⚠ WARNING

Always disconnect the electrical cord before opening the device. A contact with an exposed electrical wire may cause an electrocution.

1.5.7.3 Caution

Used to designate a potentially dangerous situation which, if not avoided, may lead to light injury or cause equipment damage.

Example

⚠ CAUTION

Do not manipulate a broken mirror with bare hands as this operation may result in cuts.

The use of the CAUTION sign without the warning triangle means that the only risk consists in equipment damage.

Example

CAUTION

The use of other cleaning agents or hard objects may damage the device. Do not use other cleaning agents or products without obtaining first the authorisation of the manufacturer.

1.5.8 Recommendation and Note

When complementary information is required and if their non-compliance only leads to minor inconveniences, recommendations and notes are given.

1.5.8.1 Recommendation

Used to designate a prefered procedure or a recommended practice. DiaMed AG denies any responsibility in case of non-compliance with the recommendations.

Example

☞ ***Recommendation:*** *Check that the device is closed before switching it on.*

1.5.8.2 Note

Used to accompany a general remark or an purely informative comment.

Example

Note: *The reassembly of the device is performed in the opposite order of its disassembling.*

Chapter Overview

This chapter defines the safety instructions which guarantee a safe and troublefree operation of the DiaMed AG's Impact-R.

2.1 Introduction

2.1.1 Principle

The user must have read and understood this chapter before any intervention on the DiaMed AG's Impact-R device.

In case of unclear information, please contact the manufacturer or your local DiaMed dealer.

2.1.2 Importance of the safety instructions

Every safety and protection instruction which can be found in this manual must be adhered to in order to avoid personnel injury, property damage or environmental pollution.

In a similar manner, the legal bylaws, the measures in prevention of accidents and for the protection of the environment, as well as the recognized technical rules aiming at appropriate and safe working conditions which as applied in the country and at the place of use of the DiaMed AG's Impact-R device must be adherred to.

2.1.3 Disregarding the safety rules

Disregarding the safety rules, as well as existing legal and technical regulations, may lead to accidents, property damages or to environmental pollution.

2.2 Environmental conditions

⚠ WARNING

The DiaMed AG's Impact-R must not be located near a water tap or any other source of water.

This system may only be used in closed rooms and never in the immediate environment of patients.

The electrical safety of the DiaMed AG's Impact-R device is only guaranteed if the electrical installation is conform to the reglementation related to medical use buildings and laboratories and if this installation works properly.

The DiaMed AG's Impact-R device may not be used in buildings prone to explosion hazard.

CAUTION

The DiaMed AG's Impact-R must be kept away from any interference source.

The DiaMed AG's Impact-R device may not be stored under exposure to a direct sunlight, heat, dust or an excessive humidity (only use the device in a clean laboratory environment).

2.3 General safety instructions

⚠ DANGER

ELECTROCUTION

During maintenance operations, when the DiaMed AG's Impact-R is powered and its cover is removed, the device must not be left without proper watch.

⚠ WARNING

Maintenance and repairs may only be performed in conformance with the instructions and by the technical personnel authorized by the manufacturer.

The sole possession of the Service Manual does not allow the personnel to perform any kind of repair on the DiaMed AG's Impact-R.

Take into account all the warnings and follow all the instructions displayed on the DiaMed AG's Impact-R screen and which are printed in the documentation.

The DiaMed AG's Impact-R device may only be connected to an electrical power source given under «Operating Conditions», on page 6 of the Service Manual.

It is mandatory to use the products specified in the present Service Manual to clean the DiaMed AG's Impact-R device. If you plan to use another product, only do so after obtaining the authorization from the manufacturer.

Using materials other than those defined in the Service Manual (unauthorized dangerous goods for instance) is forbidden. Breaching this rule will be considered by the manufacturer as guilty negligence.

Never try to use replacement pieces other than those authorized by the manufacturer of the DiaMed AG's Impact-R device.

CAUTION

The DiaMed AG's Impact-R device must be used on an appropriate table.

Ensure that the ventilation around the DiaMed AG's Impact-R device is sufficient to avoid any excessive heating. A space of 100 mm behind the Impact-R device must be left clear of any obstacle.

The DiaMed AG's Impact-R device must only be used with software and with accessories supplied by the manufacturer.

The manufacturer's agreement must be obtained before using the DiaMed AG's Impact-R device in conjunction with other equipment.

Never let any liquid enter the device. In case of liquid spill inside the device, act immediately as follows:

A. Switch off the device using the main switch

B. Unplug the power cord

C. Dry up the device.

D. Clean and decontaminate the device.

E. Check electrical functions.

☞ ***Recommendation:*** *For further information, please contact your local DiaMed dealer or the manufacturer.*

2.3.1 Observations and informations

In case of defective operation or any other technical incident for which no remedy is described in this manual, please contact immediately the manufacturer or your local dealer.

3.1 General Overview

☞ ***Recommendation:*** *Please refer to the instruction manual.*

Note: *Valid Software interface version for both builds is 1.28.*

3.1.1 General view

(1) LCD screen
(2) Well pad (motor 1)
(3) Microscope unit
(4) USB camera module
(5) Keypad
(6) Tube stir (motor 2)
(7) CMM sample tray

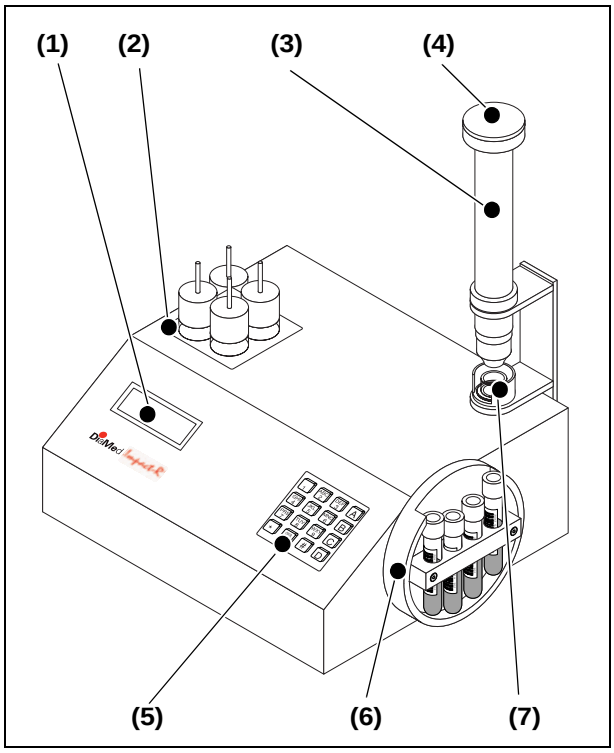


Fig. 3-1: General view

3.1.2 Internal view

Note: *The following figure is for your information only.*

(1) Input + 5 VDC
(2) Main board
(3) Input + 24 VDC
(4) Keypad
(5) Motor 2 (tube stir)
(6) Motor 1 (well pad)
(7) Inlet 220 VAC
(8) Power supply PS_1
(9) Power supply PS_2

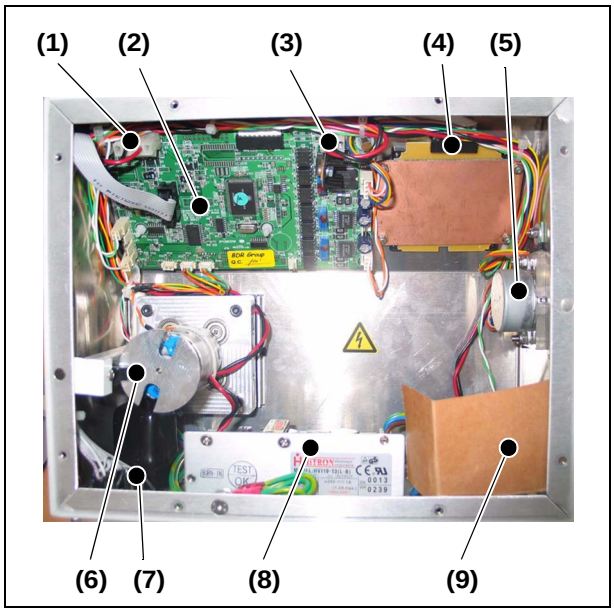


Fig. 3-2: Internal view

3.1.3 Rear view

Note: *In batches 2 and 3, a small hole above the 220 VAC inlet indicates the buzzer position.*

(1) Backlight LED
(2) Inlet 220 VAC
(3) Screw of PS_1
(4) COM port
(5) COM cover

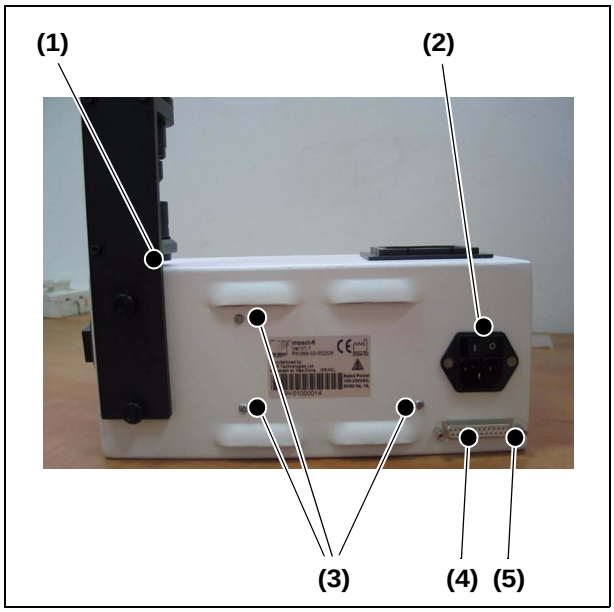


Fig. 3-3: Rear view

3.2 Main external differences between batches

The Impact-R" device was produced in the following three batches:

- **Batch 1** – Also referred to as "Impact-R Research"
  Carry the serial numbers 01000001 to 01000025.
  Internal software version is 1.07.
  The batch is non-IVD and used for research purposes only.
- **Batch 2** – "Impact-R Diagnostics"
  Carry the serial numbers 00000001 to 00000055.
  Internal software version is 1.12.
  This batch is IVD compliant.
- **Batch 3** – "Impact-R Diagnostics"
  Carry the serial numbers 00000056 and following.
  Internal software version is 1.12
  This batch is IVD compliant.

3.2.1 Well pad

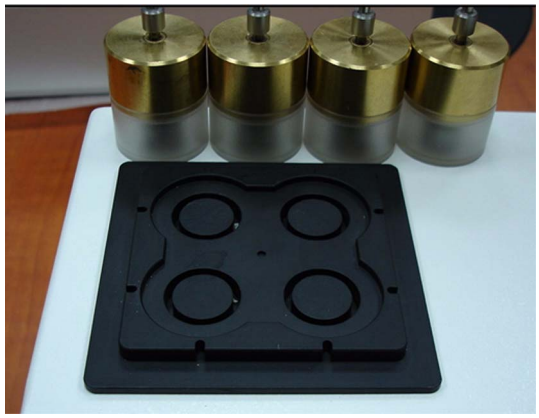


Fig. 3-4: Batch 1 Well pad (Motor 1)

Note: *As of January 2006, batch 2 well pads are upgraded to conform to batch 3 design.*

Fig. 3-5: Batch 2 Well pad (Motor 1)

Fig. 3-6: Batch 3 Well pad (Motor 1)

3.2.2 Rotator

Fig. 3-7: Batch 3 (and upgraded batch 2) Rotator (Motor 2)

3.2.3 CMM sample tray

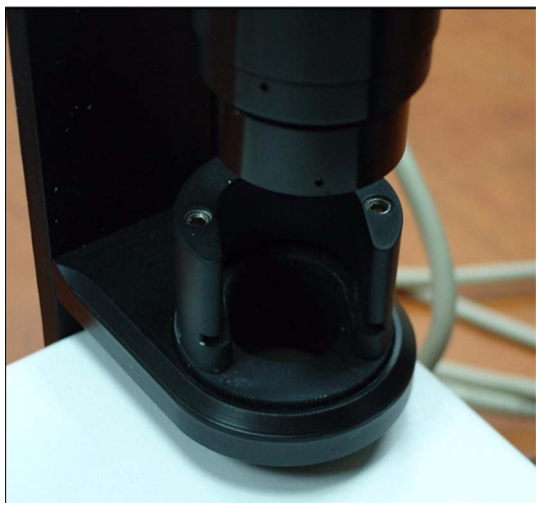


Fig. 3-8: Batch 1 (I-R Research) CMM tray

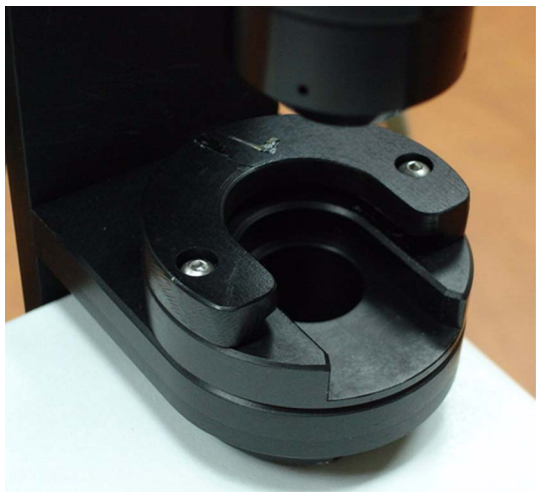


Fig. 3-9: Batches 2 & 3 (I-R Diagnositc) CMM tray

3.3 List of Possible Replacement Parts for field level repair

CAUTION

For replacing failed parts use ONLY replacements that were supplied by the manufacturer.

- power cord;
- microscope assembly;
- microscope holder;
- rotor housing (bell).

3.4 System requirements

3.4.1 Minimum PC requirements

Please refer to the instruction manual.

3.5 Operating conditions

3.5.1 Environmental

Please refer to the instruction manual.

3.5.2 Power

Please refer to the instruction manual.

3.5.3 Maintenance

⚠ WARNING

By an authorized technician only.

3.5.4 Rated motor speeds

Please refer to the instruction manual.

3.6 Functional description

The Impact-R has three functional units :

- the well pad, on the top, where the blood processing takes place, also referred to as "Motor 1";
- the tubes rotator where tubes can be rotated under controlled time and duration in order to mix the blood before use, also referred to as "Motor 2";
- the CMM (Camera/Microscope module), where processed-wells may be analyzed.

All three units are independent of each other and may be used simultaneously.

3.6.1 Well pad

The well pad has four magnets, situated under the four well locations. The magnets are rotating in the specified speed for the specified duration. The Bell housings have a magnet built into the collet (the part that catches the plastic rotor) and the magnetic attraction makes the collet spin in synchronization with the lower magnet, thereby turning the rotor inside the well. Since the collet is vertically free in the housing, the rotor touches the well at the apex as it turns.

3.6.2 Tubes mixer

The tubes mixer turns in the specified speed for the specified duration in order to homogenize the blood against the tendency of the red cells to sink. As the rotation time ends, the holder will continue to move until the tubes become vertical. The detection of the vertical position is by means of a magnet behind the rotating holder.

Note: *Both modules speed and time limitations are specified in the User Manual.*

3.6.3 CMM

The CMM has two functions: there is the microscope itself, with an attached CCD camera, that sends the image (digitally) to the PC; and there is the microscope holder that holds both the microscope and the stage. The stage holds the well and enables the user to rotate the well while keeping it in focus and also keeping the inspection area within the specified radius relative to the center of the well.

4.1 Device / Camera Installation

A. Connect the Camera / Microscope module (CMM) to the "Impact-R" device back panel by using the supplied screws (see Figure 3-1).

CAUTION
Do not use the CMM to carry the device.

B. Install the "Image Analysis" setup program.

Recommendation: *Make sure your computer supports USB 2.0 standard.*

See chapter "4.2 Image Analysis Software" on page 4-23

C. Connect the CMM module USB cord to an available USB-2 port on your computer.

Note: *On several occasions, a screen prompting you to install a new camera driver will be displayed (see caution on driver installation on page 24).*

D. Connect the supplied power cord to the "Impact-R" and to the power outlet.

E. Switch the "Impact-R" on using the "On/Off" switch located on the back panel.

4.2 Image Analysis Software

To Install the Image Analysis Software for the "Impact-R", use the following procedure :

A. Place the installation disk in your CD-ROM drive.

The auto-installer will open the setup box.

Note: *If no screen appears, you may need to start the installation manually. In this case press START> RUN > BROWSE (your CD-ROM drive) > "BIP.exe" > OK.*

B. Press the ***Next*** Button and follow the on screen instructions. If you need to change the destination drive/folder, press ***Browse*** to allocate the program in the desired place. Press ***Next*** when finished.

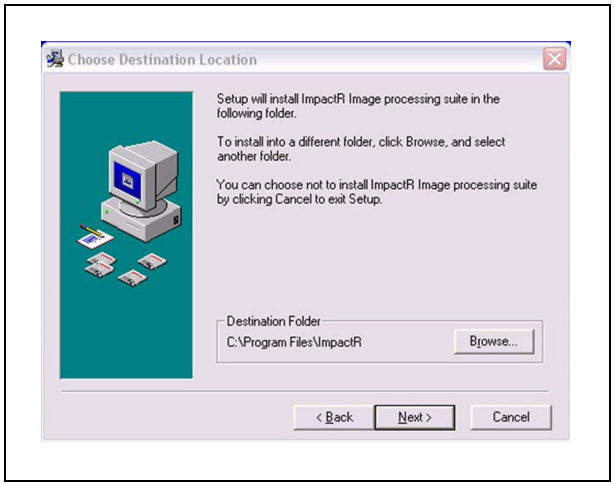


Fig. 4-1: Location screen

C. Define in what group name you wish to give this program. If there are no preferences press ***Next***.

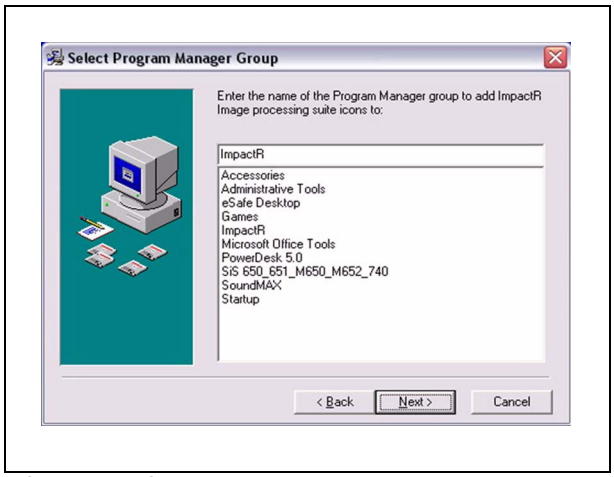


Fig. 4-2: Select Manager screen

Install screens :

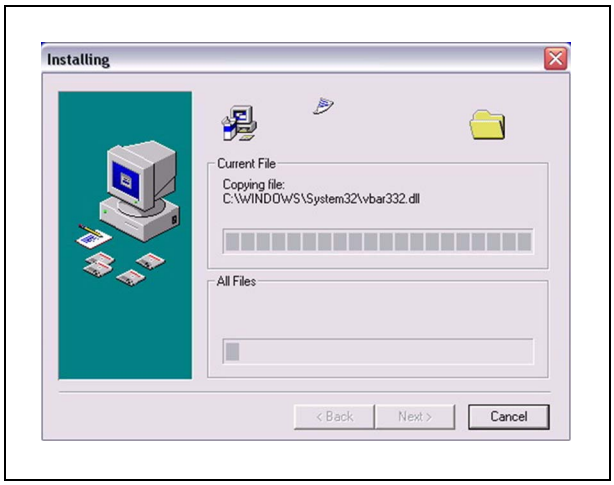


Fig. 4-3: Installation

D. Press the ***Finish*** button after setup complete.

⇨ The program will create a desktop icon "Diamed ImpactR Image Processing".

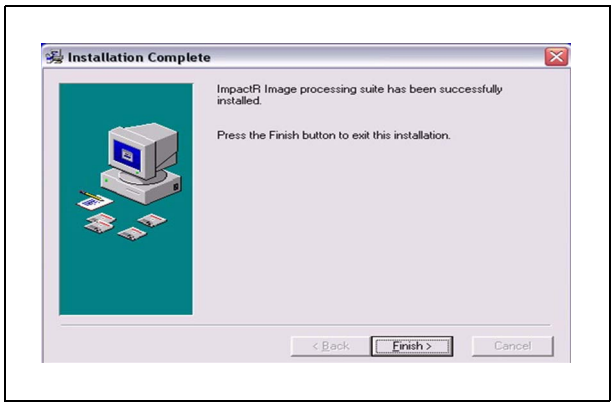


Fig. 4-4: Install Complete

CAUTION

DRIVER INSTALLATION

On several occasions connecting the CMM USB cord to the computer will result in an error message (Usually on Microsoft© Windows© XP based systems) prompting the Technician / Installer to guide the program to the correct drivers.

To correct this, when prompted, guide the driver installer to a specific folder in the "Impact-R" main folder, which is called "Drivers" (e.g. YourDisk:/program files/ ImpactR/Drivers).

The driver installer will locate ad install the correct drivers automatically.

4.3 Initial Activation

After the installation process is complete, the user will be required to accomplish a simple sequence to define and calibrate system parameters.

To activate the program double click on the program icon :

A. At the "User identification" screen (Figure 4-5), enter your user name and password.

Note: *Initial administrator logon is :*

User : administrator
Password : impactr

☞ ***Recommendation:*** *After logging in the user may change his/her password via the "Users" screen found under the file menu.*

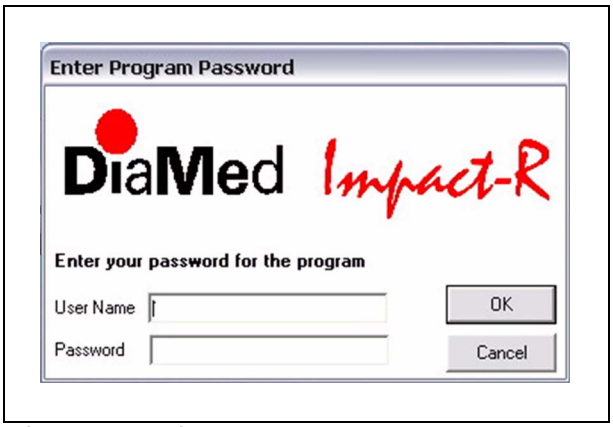


Fig. 4-5: User logon screen

CAUTION

A word about "Users":

In order to better identify system users and to manage the ability to manipulate a test, the system access was divided between an "Administrator" which is the regulating authority of the software, and to regular users that are limited to routine procedures such as test analysis and archive usage. It is highly recommended to maintain this separation to avoid mishandling of tests.

The user will be required to enter his login and password information every time the system starts.

The user will now be prompted to enter the laboratory code (Figure 4-6).

Note: *This code is unique to a specific computer on which the system is installed. This code can be found on the back side of the CD cover.*

Recommendation: *If re-installment is required due to malfunction, please consult your local dealer before proceeding.*

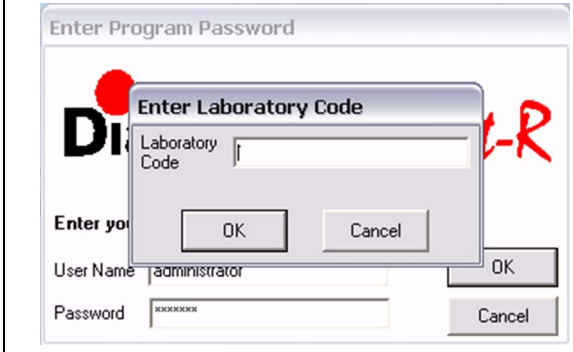


Fig. 4-6: Laboratory Code

CAUTION

Failure to comply with the requirement above may create rejected analysis and false analysis identification.

Note: *After authentication of the laboratory code the user is now required to accomplish an "Auto-calibration".*

To learn more about "Auto-calibration" turn to section “4.5 Light Calibration” on page 28.

Recommendation: *Follow the on-screen instructions to complete the procedure.*

Note: *Calibration time is normally between 3-30 seconds depend on the user's computer.*

Note: *Failure to complete the Auto-Calibration as requested will lock the program for further analysis.*

4.4 Microscope Focus and Validation Well

Note: *Each device is delivered with a Validation Well designed to allow the user to periodically (Every 3 months) test the microscope focus and the analyzer performance.*

Note: *For validation purposes use the regular "Platelet function" test. The test type entitled "Validation" is used in conjunction with artificial validation well only.*

A. Insert the Validation Well into the well slot (1) in the Microscope, switch the "Impact-R" on using the "On/Off" switch located on the back panel, analyze the well and repeat the analysis three times.

B. Then calculate the mean SC and AS of the three tests.

Note: *If the mean SC and AS are in the range indicated on the Validation Well no further adjustment is needed.*

Recommendation: *If the results are out of the range (in particular the AS) you have to check and correct the lens focus.*

C. Select the "Live Video" option as described in the User manual.

D. Rotate the well in the slot "clockwise" and if the picture is not in focus slightly release the locking ring on the microscope, turn the lower part of the lens until you get a sharp and in-focus picture. Hold the lens in place and tight the locking ring.

E. Analyze the Validation Well again.

Recommendation: *If the results are not in the specified range ask for technical service.*

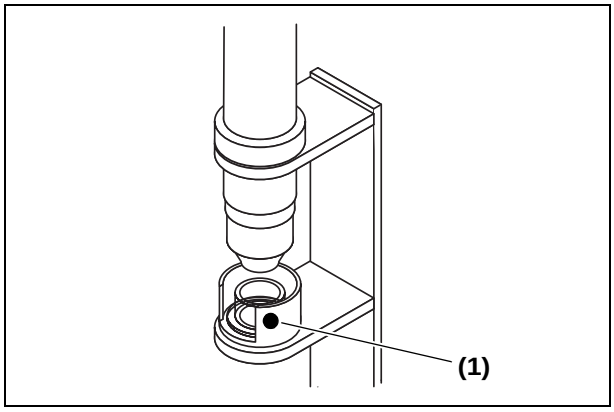


Fig. 4-7: CMM (Version 0) with well

4.5 Light Calibration

In order to avoid changes in results due to variations in LED illumination, ambient light and different parameters associated with camera operation an "Auto-Calibration" was introduced.

Once the installation is complete and every 24 hours (based upon the system clock), or after disconnection of the CMM USB cord from the computer, the user will be requested to perform light calibration to assure that his/her device correspond to these parameters.

Failure to complete the Auto-Calibration as required will lock the program for new analysis, however the user will still have access to the program archive and will be able to edit previous results.

The user is highly encouraged to repeat the calibration every time the device surroundings are changed (e.g. changing device site) or when unreliable readings associated with illumination take place.

CAUTION

Make sure that during the Auto-Calibration procedure there will be no well in the tray and no direct light source will pointed at the device.

Changing the device parameters will alter sample reading. Abnormal and unreliable readings are expected if the calibration parameter is changed.

Changing the device parameters will render your Validation Well useless.

☞ ***Recommendation:*** *As a routine maintenance procedure, the user is also encouraged to check the Microscope reading every period which is recommended not to exceed 3 month.*

Note: *By placing and reading an empty well and receiving a result not more then SC of 0.3, the user can ensure that the Microscope is working properly.*

Any other result will require the CMM unit to be replaced by an authorized technician.

5.1 Image Analysis Settings

5.1.1 User Settings

The described user buttons are available for a quick start :

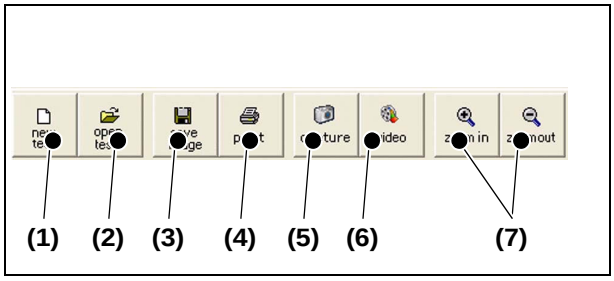


Fig. 5-1: Button Layout

(1) Open new Patient file

(2) Open Archive / Saved files

(3) Save Image
To save a single captured image outside the regular full test mode.

(4) Print file / Images / Analysis

(5) Capture button - Capture image from CMM

(6) Start live video mode

(7) Image zoom in / out

***Note:** Only **.bmp** images can be used to receive image analysis results.*

5.1.2 Advanced Settings

5.1.2.1 File menu

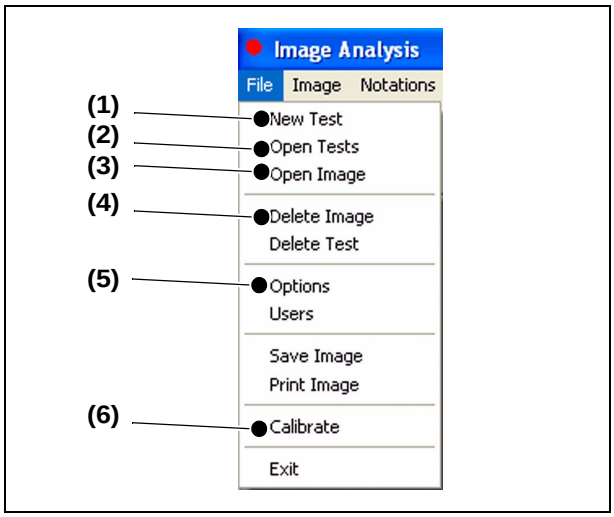


Fig. 5-2: File menu

(1) ***New*** - Open new file

(2) ***Open tests*** - Open previously saved tests

(3) ***Open Image*** - Open saved images

(4) ***Delete Image*** - Delete saved image

(5) ***Options*** - See Options window in user Manual

(6) ***Calibrate*** - Start Auto-Calibration

5.1.2.2 Options window

- change settings for a specific test according to required parameters;
- enter technician name for patient screen;
- change settings for max captured Images.

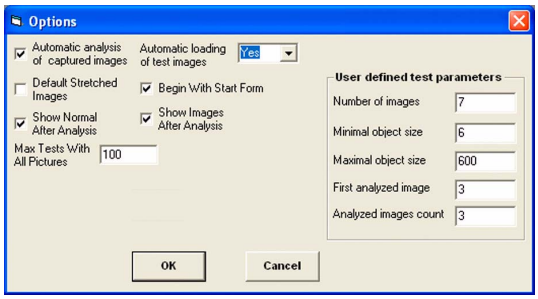


Fig. 5-3: Options window

5.2 Speed measurement

The speed of rotation of the bell housings can be measured with a stroboscope (LUTRON DT2249 or similar). Attach some adhesive tape on the top of the shaft of the bell housing, to form a little "flag". Point the flashes at this flag while the rotor in rotating, starting with a flashing frequency like the rotational speed that is indicated on the display of the Impact-R. If the rotational speed equals to the flashing frequency then the flag will seem to be standing still, if there in some difference then the flag will seem to be moving (slowly) either clockwise or counterclockwise. When the flag will seem to stand still then the frequency indicated on the stroboscope is the actual rotational speed of the rotor.

Note: *The rated motor speeds approved for use are :*

- *400 - 1800 RPM for motor 1*
- *4 - 10 RPM for motor 2*

Approved speed tolerance for measurements in this range is ±2.5% from the rated speed.

Note: *Intense fluorescent light (room lighting) can interfere with this measurement.*

5.3 Known software conflicts

The following software conflicts were noticed during field trials :

- using DiaMed "Maestro" master control program on the same computer with the "Impact-R" will cause considerable system slowdown or even system crash;
- using the program with a Picport PCI card installed will cause system crash.

6.1 Camera Microscope Module

The CMM is an autonomous unit; it needs to be connected to a good USB-2 port in the computer and to have the software installed and running. In order to be useful it needs to be focused on a target (well) and to have illumination from beneath the well.

PC not communicating with the Camera (Camera pop-up screen error) or PC screen does not have picture/video

- **Computer not compatible**
  - ✔ Verify that the computer complies with the requirements (instructions manual).
- **Computer USB-2 fault**
  - ✔ Verify that the USB port is operational and that it is type USB-2 (not USB-1.1).
- **Camera fault**
  - ✔ Replace the CMM.

Black screen, while attempting to analyze a sample

- **Microscope illumination is off**
  - ✔ If the Backlight (Green) LED does not light, make sure the Impact-R power switch is "on".
  - ✔ If the Impact-R power switch is "ON", turn it off, and turn it on again.
  - ✔ If the LED still does not light, and the "Impact-R" seems to be working (display is working), then the Impact-R should be sent to the repair facility.
  - ✔ If the "Impact-R" is not working, check it according to section “6.2 Main "Impact-R" unit” on page 6-33.

"White" screen, while attempting to analyze a sample

- **CMM error**
  or
- **Out-of-calibration light exposure**
  - ✔ Disconnect and reconnect the CMM to the computer.
  - ✔ Remove any source of direct light illuminating.
    The machine (e.g. desktop fluorescent light located above the device).
  - ✔ Make sure there are no software error messages on the screen.
  - ✔ Try to reinstall software / Drivers.
  - ✔ Run "Auto-Calibration".

Image is not sharp (always)

- **Focus not adjusted**

  ✔ Adjust the focus by the objective of the microscope, according to the instructions manual, using the "live video" mode. Note that tightening the objective nut may alter the focus.

Image changes from sharp to blurry as the well turns around

- **Well rotating stage is faulty**

  ✔ Replace the microscope holder.

6.2 Main "Impact-R" unit

The Impact-R performs power on tests upon power on. It checks the electronics, then the cone-rotating assembly, then the tubes mixer assembly. If all is good then the operational text shows on the LCD screen, else an error message appears.

Display does not show any text and Backlight (Green) LED does not emit green light

- **Power cable disconnected / Power feed interruption**
  or
- **Internal fault**

✔ Verify that the power cable is firmly connection to a good power outlet and to the Impact-R power inlet.

✔ Verify that the mains outlet is functional.
If all seems OK then the Impact-R should be sent to the repair facility.

Display does not show any text, Backlight LED works (or vice versa)

- **Internal fault**

✔ The Impact-R should be sent to the repair facility.

No response or unexpected response to keyboard

- **Internal fault**

✔ The Impact-R should be sent to the repair facility.

Motor error (Displaying "ERR" on the screen)

- **Internal fault**

✔ The Impact-R should be sent to the repair facility.

Tube falls out from holder

- **Loose Metal spring**

✔ Correct the spring (by bending) or replace, if needed.

Tube Holder does not rotate

✔ Try to rotate the plate manually. If it rotates freely but will not turn by the motor, or if it will not move at all, The Impact-R should be sent to the repair facility.

Rotor speed seems wrong

- **Impact-R unit**
  or
- **Bell housing**

✔ Measure speed of rotation on all four positions with one bell housing. If incorrect try with another bell housing. If still wrong on one or all positions then the Impact-R should be sent to the repair facility. If one bell housing malfunctions it should be replaced.

6.3 Bell housing

The bell housing is a cylindrical block, with bearings, that holds a collet, that can "catch" a plastic rotor.

The collet has a conical outline that fits to the internal contour of the rotor. In order to engage the rotor onto the collet, the user puts the housing on the rotor-and-well couple in a concentrical manner, and pushes downwards lightly on the shaft. As the proces has ended and the rotor needs removal, the user will lift the housing in one hand, place in abobe a disposal bin and pull (with the other hand) the shaft upwards. The rotor will dissengage and drop down.

The bell housing would be damaged only if it will fall down or it got contaminated.

Visible damage

- **Accident**

✔ Replace.

Collet contaminated

- **Routine use**

✔ Clean with a damp cloth.

Not rotating

- **Stuck bearing (?)**

✔ Replace.

7.1 Feedback

Note: *Your feedback is welcomed !*

In the process of developing new technologies there is always room for improvements.

If you note any omisions or unsatisfying information or you just have a suggestion for upgrading this system, please let us know.

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Headquarters

Attn : Productmanagement IH/Coag.

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Or email us at haemostasis@diamed.ch