

Micro-Cube User Manual





MicroVet Diagnostics 2300 W. Sahara Ave Suite 650 Las Vegas, NV 89102, USA

Tel: 800.640.7780 Fax: 846.382.3131

www.microvetdiagnostics.com

SYMBOLS & ABBREVIATIONS

The following symbols and abbreviations are used in the product labeling and instructions for the MVD Micro-Cube laboratory photometer.

Symbol / Abbreviation

Explanation

C€	Conformity marking according to the directive 2014/30/EU of the European Parliament and of the European Council				
REF	Catalogue number / Order number				
LOT	Lot number				
SN	Serial number				
*	Bluetooth				
Ð	Connection				
*	Power Supply / Device Readiness				
	Use by				
	Temperature limitations				
<u></u>	Relative humidity limitations				
	Manufacturer				
	Production date				
STERILE	Sterile				
\triangle	Warnings and precautions, see accompanying documents				
$\sqrt{2}$	Operator's action				
<u>i</u>	Refer to the user's manual and follow the instructions				
X	Do not dispose with household waste				
LED	Light Emitting Diode				

PC	Personal Computer	
ID	Identification	
HIS / LIS	Hospital Information System / Laboratory Information System	
AC	Alternating Current	
DC	Direct Current	
RFID	Radio Frequency Identification	

Table 1: Product Labelling and User Manual Symbols

TABLE OF CONTENTS

SYMBOLS & ABBREVIATIONS	2
TABLE OF CONTENTS	4
INTRODUCTION	7
Intended use of the MVD Micro-Cube Laboratory Photometer	7
About this user manual	7
Inspecting the package contents	7
MVD Micro-Cube packaging	8
SYSTEM DESCRIPTION	9
Description of the MVD Micro-Cube Analyser	9
MVD Micro-Cube Instrument Interfaces	9
MVD Micro-Cube Indicator lights	10
How to handle the MVD Micro-Cube Laboratory Photometer	10
How the MVD Micro-Cube Laboratory Photometer works	11
Manufacturer calibration	11
PICTOGRAMMS / BUTTON SYMBOLS	12
Tablet PC symbols and their functions	12
GETTING STARTED	13
The proper placement of the MVD Micro-Cube Laboratory Photometer	13
Transport lock	13
Connecting the power supply	13
Proper Grounding	14
The Tablet PC	15
Starting & Operating the Tablet PC	15
The MVD Micro-Cube Launcher	15
Changing the language of the MVD Micro-Cube application	16
How to switch the MVD Micro-Cube Laboratory Photometer ON	16
The automatic start-up and warm-up processes	16
CONFIGURING THE MVD MICRO-CUBE	17
Setting normal values and limits	17
Setting units	18
Configuring inputs (Species, Sampletype, Operator)	18

Configuring interfaces	19
Host configuration	21
OPTIONAL EQUIPMENT	24
Printer, barcode scanner or PC	24
Using a barcode scanner to scan patient ID and/or operator information	25
How to wake the MVD Micro-Cube Analyser up or switch it OFF	
TEST PROCEDURES	26
Overview of the testing and measuring procedures	26
Operating safety precautions	
Analysing a patient sample	
Viewing and processing test results	
Transmitting results to host	
-	
Analysing a patient sample that was requested by the host over ASTM	31
MicroVet Online Services (MVOS)	33
MVOS Synchronization	34
Synchronizing all test results	34
MicroVet Online Services Registration	35
MicroVet Online Service Login	36
Synchronizing a single result	36
Synchronizing a filtered result list	37
MVOS Web Access	38
Recommended web-browsers	38
Login Mask	38
Measurement Result List	39
Export of Measurement Result List	40
Printing of Measurement Result list	
Header UI Elements	41
QUALITY CONTROL	42
Choosing quality control (QC) materials	42
Handling the QC control materials	42
Frequency of QC testing	43
CORRELATION	44
Performing a parameter correlation adjustment	
CLEANING INSTRUCTIONS	
Cleaning the touch display of the Tablet PC	
Cleaning the Door & Cartridge Area	
Cleaning the Exterior	45

EXTERNAL INTERFACE DESCRIPTION	46
Serial Interface	46
USB Interface	
ERROR INFORMATION AND TROUBLESHOOTING	47
Error messages and possible causes	47
Service information	48
TECHNICAL SPECIFICATIONS	49
MVD Micro-Cube Instrument	49
Power supply	49
Options	49
DECLARATION OF CONFORMITY	50
SHUT DOWN AND WASTE MANAGEMENT	51
MANUFACTURER INFORMATION	52

INTRODUCTION

Intended use of the MVD Micro-Cube Laboratory Photometer

The MVD Micro-Cube Analyser consisting of the Micro-Cube Instrument laboratory photometer and the Micro-Cube Tablet PC is for veterinary in vitro diagnostic (clinical chemistry) use only.

The Micro-Cube Instrument is highly compact and is designed as a veterinary point-of-care measuring Instrument for the dedicated RS (Reagent System). It is easy to use and provides quick, reliable and accurate results.

About this user manual

This user manual will guide you through the installation, operation and maintenance of your MVD Micro-Cube Instrument. The user manual also explains how the photometer works, describes the quality assurance system and assists you in troubleshooting any errors or problems. When not used according to the user manual the Micro-Cube Instrument may be influenced or damaged.

We recommend that you familiarize yourself with these instructions before operating the MVD Micro-Cube Instrument. Some of the information in this user manual is marked with following symbols:



Operator's action



Warnings and precautions; see accompanying documents



Refer to the user manual or test kit package insert and follow the given instructions

Inspecting the package contents

When unpacking the Micro-Cube Analyser, check the contents against the list below and examine the components for signs of shipping damage (see illustration on the following page).

The MVD Micro-Cube package contains:

- the MVD Micro-Cube Instrument
- a main adapter
- a power cable
- this User Manual (on a CD)
- the Quick Reference
- a Test-Kit Rack
- a Tablet Stand

If any part of the package is missing or damaged, please report this to your supplier immediately. It is recommended to keep the original packaging, in case the Instrument ever needs to be transported.

MVD Micro-Cube packaging

In case of returning the Micro-Cube Instrument to the manufacturer and/or before transporting the Instrument, please repack the Micro-Cube Instrument contents in the original packaging according to the following illustration:



- 1. Tablet Stand
- 2. Test-Kit Rack
- 3. Power Cable
- 4. Main Adapter
- **5.** Micro-Cube Instrument

Note: In case of a necessary return of the Instrument to the manufacturer or before transport please repack the Micro-Cube Instrument contents in the original packaging according to the illustration above! Moreover, please remember to reinsert the red transport lock into the Micro-Cube Instrument door before repacking (see Transport lock on page 13)!

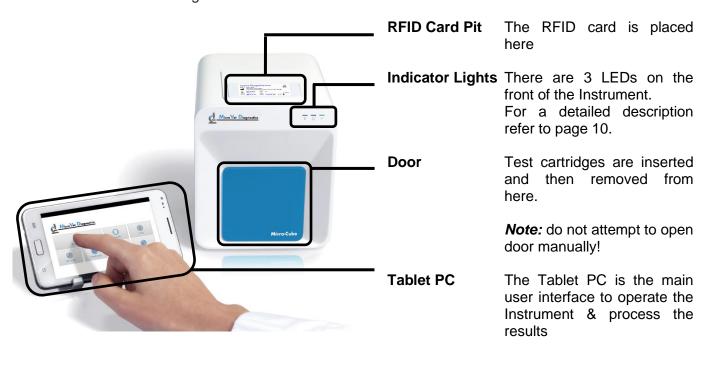
Note: The Micro-Cube Tablet PC is delivered in a separate package and must be returned in this if necessary.

WARNING: Wrong packing and/or the use of inappropriate packaging can cause severe damage to the Instrument!

SYSTEM DESCRIPTION

Description of the MVD Micro-Cube Analyser

This section introduces the general characteristics of the MVD Micro-Cube Instrument and Tablet PC.



MVD Micro-Cube Instrument Interfaces

MVD Micro-Cube Instrument Interfaces



Power supply

USB Socket for connecting a PC (for data transfer)

Tablet PC-Lock eyelet Bluetooth on/off switch (left: Bluetooth OFF)

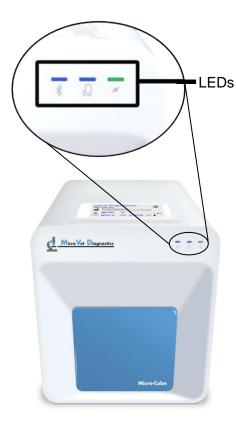
USB Port for connecting a Tablet PC

RS 232 socket for connecting a printer, a barcode reader or a PC (for data transfer)



- Do not use liquid cleaners on the Instrument or Tablet PC! Use a lint-free, slightly damp cloth only!
- Do not attempt to open the door manually

MVD Micro-Cube front



LEDs on the MVD Micro-Cube Instrument

- This green LED indicates the readiness of the photometer Flashing: the Instrument is warming up and testing cannot be started yet (*Note*: this takes approximately 10 min.) Constantly lit: the Instrument is warmed up and ready for use Off: the Instrument is not plugged in
- This blue LED indicates a connection to a Tablet PC

 Constantly lit: a connection with a Tablet PC is established

 Off: the Tablet PC is not connected
- This blue LED indicates a Bluetooth connection to Tablet PC
 Constantly lit: a connection with a Tablet PC is established
 Flashing: Bluetooth is activated on the photometer but no
 Tablet PC is connected via Bluetooth
 Off: Bluetooth is switched off

How to handle the MVD Micro-Cube Laboratory Photometer

The Micro-Cube Instrument is operated solely by means of the Tablet PC. All the basic operating steps are displayed as symbols. An overview of these symbols can be found in Table 1 (p. 3) and Table 2 (p. 12). To activate a symbol tap it with a finger.

In order to perform a test, the RFID card enclosed in the test kit must first be placed on the Instrument. This card contains all the data needed to perform the tests. No analysis can be started without the RFID test card!

The door opens automatically once a test is initiated by pressing the button. After entering all the requested data on the Tablet PC and inserting the test cartridge into the slot, close the door and the testing procedure begins automatically. After the analysis is completed, the door opens automatically and the test cartridge has to be removed.

The door prevents ambient light, dust, dirt and humidity from entering the instrument during the testing process and when the Instrument is not in use.

Please make sure the door is closed whenever the instrument is not in use.

How the MVD Micro-Cube Laboratory Photometer works

The MVD Micro-Cube Instrument is an open measuring system. This means that it is able to use various reagents from multiple manufacturers. To perform a test the Micro-Cube Instrument is loaded with a cartridge filled with reagents from the respective reagent manufacturers. The Instrument can process endpoint tests, kinetic tests and coagulation tests. Due to the latest LED technology used it is maintenance-free.

The instrument is equipped with an RFID card-reader module. RFID cards are necessary for performing any testing procedures. They are included in the test kits from the respective test manufacturers and contain all the specific steps for the various tests, the lot data, as well as the calibration data. The instrument performs the tests automatically according to that data. Numerous types of tests can be selected and performed automatically.

The sample and the reagent are automatically mixed within the instrument. The photometer unit performs the analysis with a light diode. The absorption of light rays is measured during this process and the measured value is then converted into the test result using mathematical methods. The result is displayed on the Tablet PC. Optionally, results can be exported to an external computer or an HIS/LIS and can also be printed out using an external printer.

After the test process the door opens automatically and the cartridge can be removed and discarded. After confirming the result on the Tablet PC and closing the door on the instrument the system is ready to perform the next analysis.

Manufacturer calibration

The MVD Micro-Cube Instrument is manufactured according to the highest quality standards in order to yield safe and accurate testing results. Every instrument is inspected and calibrated during the manufacturing process, using the EU-stipulated reference methods.

PICTOGRAMMS / BUTTON SYMBOLS

Tablet PC symbols and their functions

Tapping one of these symbols on the Tablet PC activates the described function.

Symbol	Name	Function
	MVD Micro-Cube	Starts the MVD Micro-Cube app
MVD Micro-Cube	App Icon	
Browser	Browser	Opens the Web Browser on the Tablet PC
Settings (C)	Android Settings	Opens the Android settings menu
⊅	Return arrow	Cancels an input OR return to the previous screen or menu
<	Return to main menu	Returns directly to the main menu
Measurement	Measurement	Opens the menu for test data entries
Print	Results	Opens the result list screen
Settings	Micro-Cube Settings	Opens the Configuration menu
	Edit	Opens an entry or value so it can be edited
✓	Confirm	Confirms the input
×	Abort to main menu	Cancels an action and returns to the main menu
	Start analysis	Starts the test process
	Transmit	Opens the export dialogie
	Print	Opens the print dialogue
•	Filter	Opens the Filter Options
	Transmit	Opens the Export dialogue
	Chart	Displays the photometric data curve of a test result
>>	Page forward	Displays the next page
«	Page backward	Displays the previous page
	Recycle bin	Opens the delete dialogue
	Synchronize	Synchronises result(s) and Instrument status with the MVD servers

Table 2: Micro-Cube Tablet PC symbols

GETTING STARTED

The proper placement of the MVD Micro-Cube Laboratory Photometer



Place the Instrument on a dry, clean, stable and level surface. Make sure the Instrument has at least 4" of table surface and clearance on each side and that the Instrument can be easily disconnected from the power source. Allow the Instrument to acclimate to the ambient room temperature before operating it.

The Instrument can be damaged and its results possibly adulterated by:



- Condensing humidity and water
- Heat and large temperature fluctuations
- Direct sunlight
- Vibrations (e.g. from centrifuges or dishwashers)
- Electromagnetic radiation
- Electrostatic discharge

Transport lock



Upon first use the red transport lock is to be removed from the door of the instrument.

Note: keep both the transport lock and the original packaging. In case of a defect the Instrument is to be returned in the original packaging with the transport lock installed to prevent any damage during transportation!

Connecting the power supply

MVD Micro-Cube Instrument Interfaces



Power supply

USB Socket for connecting a PC (for data transfer)
Tablet PC-Lock evelet

Bluetooth on/off switch (left: Bluetooth OFF)

USB Port for connecting a Tablet PC

RS 232 socket for connecting a printer, a barcode reader or a PC (for data transfer)



- Connect the power cable to the power supply unit.
- Insert the plug from the power supply unit into the power socket on the back of the Instrument
- Plug the power cable into the wall socket.



Always connect to the proper supply voltage. The power supply voltage must comply with the regulations cited in the technical specifications on page 49. Ensure a properly installed electrical grounding. The Instrument is to be operated only using the power supply unit provided.

Proper Grounding

To ensure that the instrument is properly grounded, it is necessary to use a 3-pole power outlet, as they not only feature two slots (one neutral slot and one hot slot) for the power connection but also a ground connection socket. The MVD Micro-Cube has to be connected to such a power outlet with the included 3-pole plug.

Illustration of different power outlets with grounding

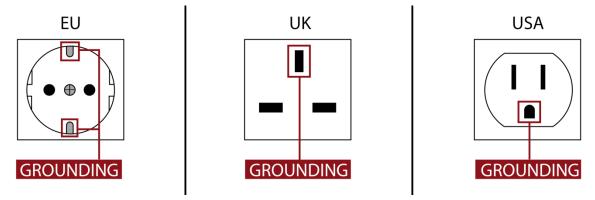


Figure 1

To make sure that proper grounding exists it would be best to let it be checked by a certified electrician.

EMC Related Caution:

This equipment and/or system complies with the International Standard EN61326-1 for electromagnetic compatibility for electrical equipment and/or system for measurement, control and laboratory use. However, an electromagnetic environment that exceeds the limits or levels stipulated in the EN61326-1, can cause harmful interference to the equipment and/or system or cause the equipment and/or system to fail to perform its intended function or degrade its intended performance. Therefore, during the operation of the equipment and/or system, if there is any undesired deviation from its intended operational performance, you must avoid, identify and resolve the adverse electromagnetic effect before continuing to use the equipment and/or system.

The following describes some common interference sources and remedial actions:

- Strong electromagnetic interference from a nearby emitter source such as an authorised radio station or cellular devices:
 Install the equipment and/or system at another location if it is interfered with by an emitter source such as an authorised radio station. Keep the emitter source such as cellular devices away from
- 2. Radio-frequency interference from other equipment through the AC power supply of the equipment and/or system:

 Identify the cause of this interference and if possible remove this interference source.
- 3. Effect of direct or indirect electrostatic discharge:

 Make sure all users and patients in contact with the equipment and/or system are free from direct or indirect electrostatic energy before using it. A humid room can help lessen this problem.

the equipment and/or system.

4. Electromagnetic interference with any radio wave receiver such as radio or television: If the equipment and/or system interferes with any radio wave receiver, locate the equipment and/or system as far as possible from the radio wave receiver.

If the above suggested remedial actions do not solve the problem, consult your dealer for additional suggestions.

The Tablet PC

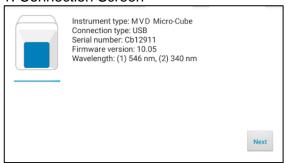
The MVD Micro-Cube Instrument is operated with a Tablet PC.

Connect the Tablet PC to the USB port of the plugged-in Instrument and then turn on the Tablet PC.

An independent Tablet PC manual is delivered with the Tablet PC. It describes in detail the operating of the Tablet PC, how to manage settings and the establishing of a Bluetooth or USB connection between the Micro-Cube and the Tablet PC.

Starting & Operating the Tablet PC

1. Connection Screen



The connection screen appears upon connecting the Tablet PC with the Micro-Cube Instrument.

Tap *Next* to continue.

2. Main Menu

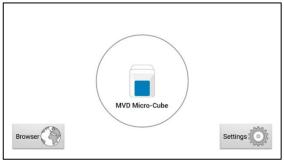


The Micro-Cube app starts and the main menu appears.

Note: while the MVD Micro-Cube Instrument is warming up (indicated by the flashing green LED on the front) the "Measurement" Button is grey and inactive.

The MVD Micro-Cube Launcher

MVD Micro-Cube Launcher



When the Tablet PC is not connected to the Instrument or by pressing the Home Button the MVD Micro-Cube Launcher appears:

Tapping *Browser* opens the Android web browser

Tapping MVD Micro-Cube starts the Micro-Cube app

Tapping Settings opens the Android settings menu

Note: If the standard Android Desktop appears instead, switch the Tablet PC off, back on, select "MVD Micro-Cube Launcher" and confirm by tapping "Always".

Changing the language of the MVD Micro-Cube application

The language of the application is automatically set according to the language of the operating system of the Tablet. It can be changed by pressing the home button on the Tablet PC (the launcher appears), then pressing to open the settings. Swipe down and select *Language and input* in the category "Personal". Tap *Language* and choose a language. Press the home button to return to the launcher.

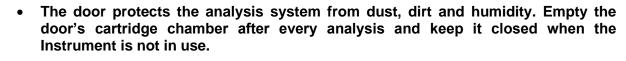
Note: the MVD Micro-Cube application supports several languages. If you choose a language in the system settings that is not supported by the Micro-Cube app English will be used.

How to switch the MVD Micro-Cube Laboratory Photometer ON



The Instrument is switched on by plugging the power cable into the socket. This launches the Instrument's automatic start-up and warm-up processes. Please wait for these to be completed (approximately 10 minutes).

When operating the Instrument:





- The door opens automatically. Do not attempt to open the door manually!
- If an error message appears during an analysis, please consult the "Error information and troubleshooting" section on page 47.

The automatic start-up and warm-up processes

1. Warm-up menu



2. Main Menu



The automatic start-up procedure (indicated by the flashing green LED) starts as soon as the Instrument is connected to the power supply. The Instrument is warmed up to its proper working temperature in approximately 10 - 15 minutes.

As soon as the initialization of the optical unit is completed, the button turns from black and white to color and reacts to tapping. The Instrument is now operational.

CONFIGURING THE MVD MICRO-CUBE

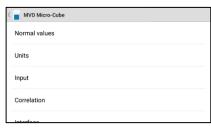
You can configure your MVD Micro-Cube laboratory photometer according to your needs before using it. To access the configuration menu follow these steps:

1. Start-up menu



Tap to open the Settings menu.

2. Settings menu



Tap the setting you want to configure. Swipe down to view all available options.

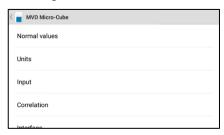
 \bigwedge

All following descriptions are examples. The configuration of the MVD Micro-Cube Instrument models may vary depending on the tests used.

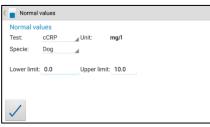
Note: The normal values, units and sample types for a test can only be displayed if the respective test RFID card has been placed on the Instrument and read.

Setting normal values and limits

1. Settings menu



2. Normal values/limits menu, e.g. cCRP



Tap *Normal Values* to open the Normal Values / Limits menu.

To change a limit tap the value and change it using the appearing Tablet PC keyboard.

To change the test for which the normal values are displayed tap and select a test in the appearing drop down menu.

Setting units

1. Configuration menu



Tap *Units* to open the Unit selection menu.

2. Unit selection menu



Tap ____ and select a unit in the appearing drop-down menu. Confirm the change(s) with ___.

Configuring inputs (Species, Sampletype, Operator)

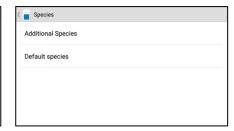
1. Configuration menu



2. Input menu



3.1 Species menu



Tap *Input* to open the input menu.

Tap a parameter and the respective menu will open. The following descriptions are provided in the order of the parameters in the Input menu. Tap either on *Additional Species* or *Default Species* to open the respective menus.

3.1a Additional Species menu



To enter an additional type of species, type the species' name in the box and then tap

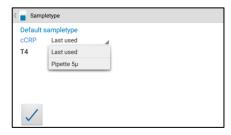
To delete a species, tap and select a species in the drop down menu, then tap

3.1b Default Species menu



First, select a test to define which species will be selected as the test's default species in the input menu. Then tap ______ to select the default species.

3.2 Sampletype menu



Tap and a drop down menu opens, select which type of sample should be selected by default. Last used means the sample type last used will be selected. Confirm with Press to cancel.

3.3 Operator menu



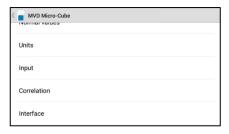
Enable the operator mode by tapping the button. To create a new operator, type the name in the box and then tap

To delete an operator, tap

and select a name in the drop down menu, then tap

Configuring printer

1. Configuration menu



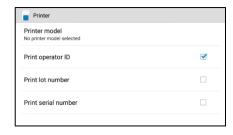
Tap *Interface* in the Configuration menu. The Interface menu appears.

2. Interface menu



Tap on Printer.

3. Printer configuration menu



Tap on *Printer model* to select the standard printer model (see 3.1)

Print operator ID, lot number and serial number are additional information that can be added to the printout. Tap a checkbox next to an option to select or de-select it.

Note: the screenshot above is for demonstration purposes only. By default all boxes are unchecked.

3.1 Standard printer model selection



Tap on the corresponding printer model to select your default printer. If *No printer model selected* is chosen you will be prompted to choose the desired printer model directly before the first printout.

Host configuration

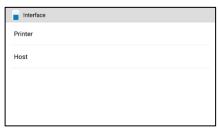
1. Configuration menu



Tap *Interface* in the Configuration menu. The

Interface menu appears.

2. Interface menu



Tap on *Host.* The service password is required to change interface host options. Tapping on the input field opens the Tablet PC keyboard and the password can be typed. After pressing OK on the password screen, the host configuration menu opens.

If you do not know the Service Password please contact your dealer.

3. Host configuration menu



Tap on WiFi Network information to see the network data of your Tablet PC.

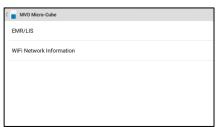
3.1. Wifi Network Information



The IP Address and Port number of your Tablet PC are shown.

Tap on to go back to the previous menu.

4. Host configuration menu



In the previous menu tap on *EMR/LIS*.

5. EMR/LIS protocol menu



By default the EMR protocol is disabled. Tap on _____ to show the different protocols and choose the desired one

5.1. ASTM TCP/IP protocol



There are several options to consider for the *ASTM TCP/IP* protocol:

If Automatic transmission is set to <u>Yes</u>, test results will automatically be transferred to the host immediately after measurement.

Enter the *IP* and *Port* number of your desired host below.

Setting Send ordered only to <u>Yes</u> (only available if Automatic transmission is set to <u>Yes</u> as well) will enable the function that only results requested by the host will be transmitted.

Under *Receiving Facility* the name of the LIS/HIS can be entered.

Tap on to confirm your settings.

5.2. HL7 TCP/IP protocol



The options for the *HL7 TCP/IP* protocol are as follows:

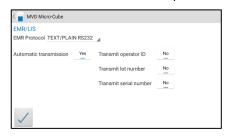
If Automatic transmission is set to <u>Yes</u>, test results will automatically be transferred to the host immediately after measurement.

Enter the *IP* and *Port* number of your desired host below.

*Please see the HL7 user manual for details on the options to the right.

Tap on to confirm your settings.

5.3. TEXT/PLAIN RS232/USB protocol



The two options, *TEXT/PLAIN* RS232 or *USB* act the same way, except for the type of cable they are transferred over.

If Automatic transmission is set to <u>Yes</u>, test results will automatically be transferred to the host immediately after measurement.

The options to the right define which type of data will be transmitted. They can be toggled *On/Off*, depending on your demands.

Tap on to confirm your settings.

5.4. E-Mail protocol

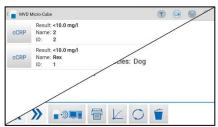


The last option, E-Mail, lets you enter and safe a specific E-Mail address to send the results to.

<u>Note:</u> If the E-Mail section is left blank you will be prompted to enter an address everytime you want to transfer a result

Tap on to confirm your settings.

5.4.1. E-Mail transfer



After hitting one of the transfer buttons (on a single result or in the result list), you will be prompted to set up your Email account, from which the results will be sent.

This is different according to the provider (Microsoft, Gmail, GMX, ...) you are using.

OPTIONAL EQUIPMENT

Printer, barcode scanner or PC

The following optional devices (not included in the standard delivery package) can be connected to the Instrument:

- An external printer for optional test result printouts
- An external barcode scanner
- A PC for the transfer of test data into a HIS or laboratory software



Connect optional equipment only when the Instrument is switched off. Please note that attaching optional equipment (e.g. a printer) can increase the amount of leakage current. All optional equipment must be connected before such leakage current can be measured.



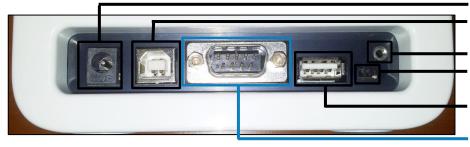
If the Instrument is not used according to the instruction manual the provided levels of safety will be lowered.

To install a printer or barcode reader (see "Technical specifications" section on page 49) please connect the RS232 cable to the RS232 socket at the Instrument (see illustration below).

If a printer and barcode reader should be installed simultaneously an adapter has to be interconnected (e.g. barcode-printer-interface-cable, order number: *SZ0405*).

For selection of a default printer model please refer to section 3 of Configuring interfaces on page 19.

MVD Micro-Cube Instrument Interfaces



Power supply
USB Socket for connecting a
PC (for data transfer)
Tablet PC-Lock eyelet
Bluetooth on/off switch
(left: Bluetooth OFF)
USB Port for connecting a
Tablet PC
RS 232 socket for connecting a
printer, a barcode reader or a

PC (for data transfer)

Using a barcode scanner to scan patient ID and/or operator information

1. Main menu



Start a test by tapping

Make sure that a RFID card is placed on the Micro-Cube Instrument.

2.Test screen



The MVD Micro-Cube displays the type of test and number of tests remaining on the RFID card.

Tap to proceed to the input menu or to exit to the main menu.

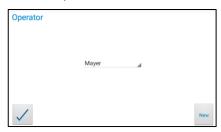
3.Input menu



Scan patient information with the barcode scanner. It will automatically be set as "ID" value.

Tap \checkmark to confirm the input or × to exit to the main menu.

4. Select operator screen*1



On this screen an operator can now be selected by scanning the operator barcode and tapping to continue.

If <u>new</u> information is scanned (i.e. the operator has not been created in the operator menu yet) a new operator will be created automatically.

5. Insert cartridge and close door



The door opens automatically. Insert the cartridge and close the door. The test procedure starts automatically.

How to wake the MVD Micro-Cube Analyser up or switch it OFF



When the Tablet PC displays the main menu, the "power safe" function dims the screen. Pressing the Lock Switch will re-illuminate the display to its customary level of brightness. It is not necessary to switch the Instrument off every day. Switching the Instrument off completely can only be done by disconnecting it from the power supply.

^{*1} This screen only appears if the operator input has been enabled (see 3.4 on page 18)!

TEST PROCEDURES

Overview of the testing and measuring procedures

Allow the test cartridge to reach room temperature before use. If the Micro-Cube Instrument has been disconnected from the power supply, plug it in soon enough for it to be at the proper operating temperature when it is needed.

To analyse a patient sample:

- Place the provided RFID card from the test kit on the Instrument.
- Prepare a test cartridge and a patient sample according to the instructions on the test kit insert
- Enter the required patient data.
- Insert the test cartridge into the Instrument and start the analysis.
- The result will be displayed on the Tablet PC.
- The result will be saved in the Tablet PC's memory.
- If desired, export the result to an (optional) external computer, print the result with an (optional) external printer or send it via email (see p. 30)

How to run a control test:

- Place the provided RFID card from the test kit on the Instrument.
- Prepare the control serum according to the instructions on the control package insert.
- Enter the lot number instead of the patient data.
- Prepare the test just like a patient sample and start the analysis.
- The result is displayed on the Tablet PC.
- Record the result according to your laboratory's quality guidelines.
- The result will be saved in the Instrument's memory just like a patient's results.
- If desired, export the result(s) to an (optional) external computer, print the result with an (optional) external printer or send it via email (see p. 30)
- Verify that the result lies within the mandatory limits for the control material (according to the control material's package insert).

Be sure to follow the detailed instructions for the analysis processes that are provided in the following sections and to comply with the information provided on the package insert enclosed with each testing kit.

When operating the Micro-Cube Analyser:

• Use only your fingertips to operate the Tablet PC! Do not use pens or any other objects that may scratch or damage the screen.





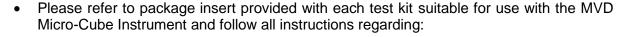


- If an error message appears on the screen, please consult the "Error information and troubleshooting" section on page 47.
- The door protects the analysis system from dust, dirt and humidity. Empty the
 door's cartridge chamber after every analysis and keep it closed when the
 Instrument is not in use.
- The door opens automatically. Do not attempt to open the door manually!

When handling a test cartridge:



- Do not use test cartridges after their expiration date, or when the test cartridges have not been stored in accordance with the regulations
- Do not use the test cartridge if the packaging is damaged or if fluids have leaked.
- The test cartridge must reach room temperature (20 28°C; 68 82.5 °F) before use
- Use gloves when handling and disposing the test cartridges, patient samples and sample collection equipment, because they may pose a potential biohazard





- o The proper temperature a cartridge must have before a test is performed
- o The exact amount of the sample volume
- The regulations for the proper storage of the test cartridges

Analysing a patient sample

1. RFID card placement



Take the provided RFID card out of the test kit package and place it on the RFID card pit on top of the Instrument.

4.Input menu

2. Main menu



Tap in the main menu to start a measurement.

The MVD Micro-Cube Instrument automatically reads the RFID card and the Test Menu appears.

5. Select operator screen*1



Tap the desired input field (e.g. "Name"), the Tablet PC keyboard appears. Enter the information and confirm with "Done".

Next, tap and select an entry from the drop down-menu.

All saved operators will be shown in the drop down list. Tap and select an operator or tap to create a new operator (see. 3.4 on p. 18 for details).

Tap to confirm the input.

Note: when testing for the first time, you will be prompted to create an operator.

Tap to open the operator menu (see 3.4 on p. 18 for details).

3.Test screen



The MVD Micro-Cube displays the type of test and number of tests remaining on the RFID card.

Tap to proceed.

Tap to return to the main menu.

6. Insert cartridge and close door

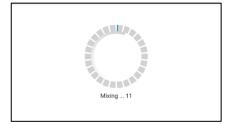


The door opens automatically. Insert the cartridge and close the door. The test procedure starts automatically.

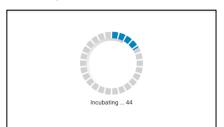
^{*1} This screen only appears if the operator input is enabled (see 3.4 on page 18)

The Instrument displays the following information during the testing process (varies by test type):

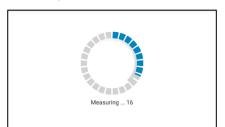
Mixing



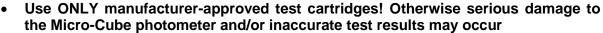
Incubating



Measuring



- Be sure to handle the test cartridge according to the instructions on the package insert
- Be sure the test cartridge is properly sealed before inserting it into the Instrument
- Be sure the test cartridge is fully inserted into the proper opening in the Instrument



Do not attempt to open the door manually!



Viewing and processing test results

After processing a test, the result screen appears on the Tablet PC:

1. Result Screen



The test result is displayed on the Tablet PC.

Use and to scroll back and forth within the results.

Tap to export to a HIS/LIS or PC or send as Email.

Tap to open the photometric data curve.

Tap to synchronize the result with MVOS.

Tap to delete the result.

Tap to exit to the main menu.

All test results are stored on the Tablet PC. They can be accessed as follows:

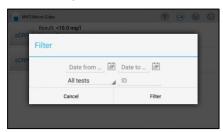
1. Main Menu







2.1 Filter Options



Tap in the main menu to open the Result List.

The stored results can be browsed by swiping up and down.

Tap a result to open the result screen (see above), to return to the result list from a result screen press the *Return Arrow*Tap to open the filter options

Tap to mail or export.

Tap 🗐 to print.

Results can be filtered by date, test type and Patient ID.

Tap to set the desired start date, bate to set the desired to set the desired end date. Tap to select a test type in the drop down menu (e.g. cCRP). Tap Patient ID... to filter by patient ID



 Whenever the transmission of the operator ID, lot number and serial number is activated in the appropriate settings menu (see p. 19) the according data will be transferred to the printer or host system automatically and will appear on the printouts and/or the computer or host system.

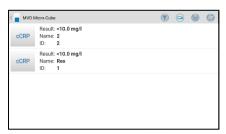
Transmitting results to host

1. Main Menu



Tap in the main menu to open the Result List.

2. Result List Screen



Tap to export results to host.

3. Result export



A dialogue will appear. Tap on *OK* to export all results.

By tapping on *Filter*, you have the opportunity to filter the to be exported results by date.

After export, an emb icon will appear next to the exported result.

Reset or change the filter by tapping on .

Analysing a patient sample that was requested by the host over ASTM

1. Main Menu



If the ASTM TCP/IP protocol is

activated and the host has sent requests for measurements, the text

X Pending Request(s) will flash in

the top left corner of the main menu.

Tap on the text itself or the

2. Pending Request list



Tapping on a request will open a dialogue window.

Tapping on the button in the top right corner will temporarily skip the pending requests and enable you to analyse a sample that was not requested.

3. Analysis request prompt



In the dialogue window, tap on Run Measurement to execute the requested analysis.

Tap on *Delete* to delete the request.

4a.Wrong RFID card on instrument



Please make sure that the correct RFID card is placed on the analyser.

If a wrong card is placed, the indication **Test does not match EMR Order** is displayed.

Tap on \times to go back to the main menu or place the correct RFID card on the instrument.

4b. Correct RFID card on instrument



If the requested order matches the RFID card the analysis can be processed.

Tap on the button to enter the test screen. Tap on to return to the main menu.

5. Test screen



Enter data and tap on \checkmark to start the analysis. Tap on × to return to the main menu.

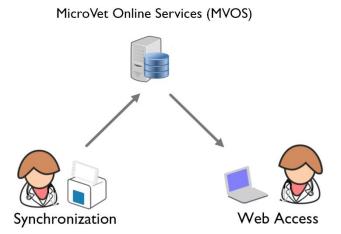
Process the test as usual.

Note: It is obligatory for the host to enter a patient ID in the request. Therefore it is greyed out and can not be changed by the operator.

The host may also enter a patient name. If he chooses to, it can not be changed either. If he does not, however, the operator can enter a patient name themselves.

MicroVet Online Services (MVOS)

The MVD Micro-Cube offers the possibilty to store test results on the encrypted MicroVet Online Services (MVOS) servers. Before test results can be synchronized a registration with the MVOS is needed.



The feature to synchronize data from the Micro-Cube app into the MVOS account can be used according to the steps described on page 34, MVOS Synchronization.

The synchronized data can be viewed by using a web-browser on e.g. a PC or tablet. A description of the possibilities of the MVOS Web Access and an explanation of the user interface can be found on page 38, MVOS Web Access.



- Sensitive data is encrypted by using industry standard cryptographic algorithms (following ENISA recommendations) directly on the instrument before transmitting data
- Data decryption is done on the web-browser. MicroVet Diagnostics has no access to personal passwords and cannot retrieve them in case of a loss.

MVOS Synchronization

Once registrated and logged in with an MVOS account the synchronization is enabled.

Generally there are three possibilities of synchronizing data:

- Synchronizing all currently stored measurement results at once
- Synchronizing a single measurement result
- Synchronizing a filtered measurement result list

Synchronizing all test results

1. Main Menu



Tap in the main menu to open the Result List.

2. Result List Screen



Tap in the upper right corner to synchronize all test results.

When not logged in with an MVOS account the registration or login mask will appear.

3. MVOS Registration & Login Mask



Use to register a new MVOS account or to log in with an already existing MVOS user (see MicroVet Online Services Registration on page 35 respectively

MicroVet Online Service Login on page 36). After a successful registration or login the results will be synchronized. The MVD Micro-Cube application asks the user to register or login to the MVOS once before synchronizing. The following steps describe the process of a registration.

1. MVOS Registration & Login Mask



In the registration and login mask press to open the registration screen.

2. Terms of Services



Before registering with the MVOS system the terms of services need to be read and accepted. Please read through the terms of services thoroughly. The terms of services are accepted by ticking the "Accept" checkbox and pressing.

3. Registration



Register with the MVOS system by providing an e-mail address and a strong and secret password. Accept the account information by pressing . The registration confirmation appears.

4. Registration Confirmation



Please double check the registration details and accept by pressing . After successfully registering with the MVOS system the login is done automatically at each synchronization request.



 Do not lose the password! MicroVet Diagnostics has no way to retrieve the password!

1. MVOS Registration & Login Mask

First Use Press register to create a new Online Service Account. Press login to connect with an existing Online Service Account. Register Login

Press to open the login mask.

2. Login Mask



Provide your MVOS account information and tap to log in.

Synchronizing a single result

1. Main Menu



Tap in the main menu to open the Result List.

2. Result List Screen



Tap a result to open the result detail screen.

3. Result Detail Screen



Tap or to synchronize the result currently viewed.

1. Main Menu



Tap in the main menu to open the Result List.

2. Result List



Tap to open the filter options.

3. Filter Options



Set a filter according to 2.1 Filter Options on page 30

4. Filtered Result List (e.g. CRP)



Tap in the upper right corner to synchronize the filtered test results.

MVOS Web Access

Once results have been synchronized into the users MVOS account they can be viewed independently with a web-browser using a personal computer, tablet or smartphone.

The web application can be accessed by navigating to the following URL:

http://mvd.analyserinfo.com



Recommended web-browsers

Web browsers that are recommended to use for accessing the MVOS Web Access are shown in the table below. It is not recommended to use a browser which is not listed.

Windows • Internet Explorer 10 or higher

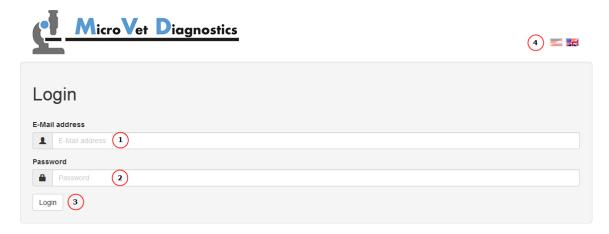
- Mozilla Firefox 24 or higher
- Google Chrome 33 or higher

Mozilla Firefox 24 or higher

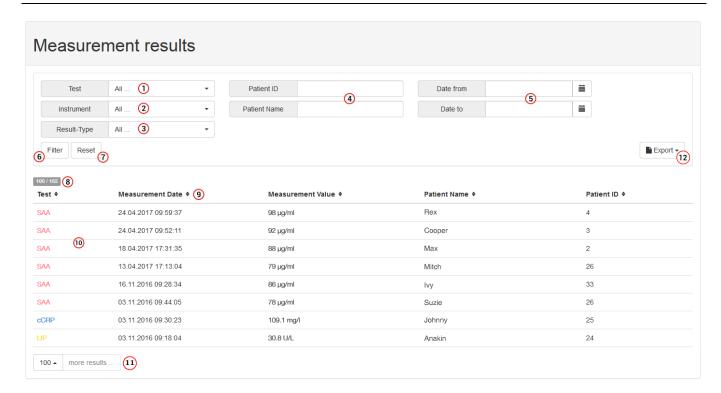
Mozilla Firefox 24 or higher

Always use the most recent version of a browser to make sure that the latest security updates are applied. Older browsers might not provide all functions and features correctly in the MVOS Web Access.

Login Mask

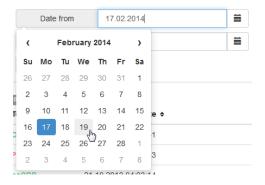


- (1) Email address which has been used for registration on the App
- (2) Password which has been used for registration on the App
- (3) Button to perform login after filling email address and password
- (4) Possible language switch



Filtering:

- (1) Test: Choose which test type should be filtered
- (2) Instrument: Choose an instrument that is connected to the MVOS account
- (3) Result-Type: Choose if sample or controls should be displayed
- (4) Patient ID/Patient Name: Choose which Patient IDs/Names should be displayed
- (5) Date pickers: A time frame for filtering can be chosen:



- (6) Button to apply the chosen filter criteria
- (7) Button to reset the filter

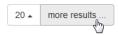
Result list:

- (8) Displays the amount of currently viewed results and the total number of results connected to the MVOS account
- (9) The currently viewed result list can be sorted by pressing the table headlines
- (10) Measurement result list (filtered). Click on the entries to toggle detail information

(11) Button to display 'x' more results up to the maximum of all stored results connected to the MVOS account:



Click the "more results" button to add the chosen amount of results to the view of the result list:



(12) Button to export currently shown results as Excel or CSV file. Choose the desired file format in the drop down menu:

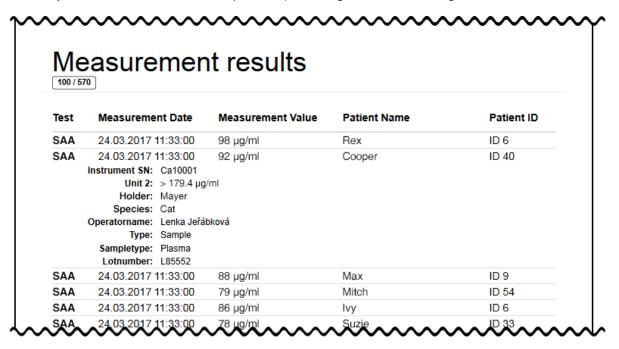


Export of Measurement Result List

Before being exported, the results can be filtered with the filter button in the measurement result list screen. Only the results currently shown on the screen are exported (the "more results" button may be pressed to display further results).

Printing of Measurement Result list

The measurement results can simply be printed out through the browser. Depending on the type of browser usually through the browser's menu, or by pushing CTRL+P simultaneously. Only the results currently shown on the screen are printed (including details for a single measurement, if shown).



Header UI Elements



This shows the currently logged in user as well as a language switch

QUALITY CONTROL

A quality control program should be performed on a regular basis to verify that the MVD Micro-Cube Instrument is working properly and providing reliable results. Data integrity can only be assured when controls and GCLP practices are used routinely. The frequency of performing QC differs from laboratory to laboratory; please comply with your national quality control regulations.

Choosing quality control (QC) materials

The authorized manufacturers of the Micro-Cube test cartridges also supply control materials. These control kits contain control materials, which allow you to assess the measuring accuracy of the Instrument.

Ensure the measuring methods are compatible with the MVD Micro-Cube Instrument before using QC kits from other suppliers.

The measuring methods are listed on the test cartridges' package insert.

Handling the QC control materials



Please refer to the package insert provided with each control kit for detailed instructions on storage and handling of control materials.

Follow the instructions in the "Analysing a patient sample" sections (starting on p. 28) on how to properly perform a control test. The measured values must be within the range of target values specified on the control vial label or in the control package insert. If the control results fall within the specified range, the testing of patient samples may begin.

If one or more controls tested are outside the specified control range:

- Verify that the control materials have been stored according to the directions and that the expiration date has not passed
- Verify that the handling and testing procedures were performed according to the directions on the package insert
- Repeat the control test, using a new control from the same lot

If one or more control results are still outside the specified range:

- Perform a test using a control from a new lot.



If all instructions have been followed but control results are still not within range please contact your local MicroVet Diagnostics supplier for assistance before proceeding on testing any patient samples.

Frequency of QC testing

Control testing is recommended when:

- a new shipment of test kits is about to be used.
- a new lot is about to be used.
- if it's possible that the test cartridges have not been properly stored.
- if an unexpected patient result is obtained.
- when new personnel is being trained to use the equipment .
- if local regulations require more frequent control testing than described above, then the number of control tests performed must comply with these regulations.

CORRELATION

Performing a parameter correlation adjustment

1. Start-up Menu



Tap Settings to open the settings menu.

2. Settings menu



Tap *Correlation* to open the correlation menu.

3.1 Password mask



Enter the password. The default setting is 3010.

4. Correlation menu



Tapping opens a drop down menu. Select which parameter is to be adjusted. Enter the factor and the offset accordingly and tap to accept the new correlation settings.

5. Test Screen



An active correlation adjustment is marked by Correlated as seen in the test screen when starting a measurement process.

CLEANING INSTRUCTIONS

Cleaning the touch display of the Tablet PC

Clean the touch display of the Tablet PC with a clean, lint-free cloth moistened with water.

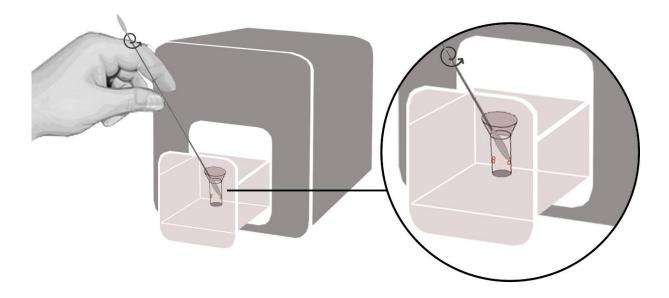


Do not use any other liquid except water when cleaning the Tablet PC!

To avoid damage do not spill too much water on the Tablet PC!

Cleaning the Door & Cartridge Area

Clean the door with a clean, lint-free cloth moistened with isopropyl alcohol. Wipe down the surface. The cartridge area may be cleaned with a cotton swab moistened with isopropyl alcohol.



Cleaning the Exterior



Do not clean the surface of the Tablet PC with isopropyl alcohol!

The surface of the MVD Micro-Cube Instrument should be cleaned with a clean, lint-free cloth only moistened with isopropyl alcohol. Wipe down the exposed surfaces.

EXTERNAL INTERFACE DESCRIPTION

Serial Interface

Interface signals

Pin	Signal	
1		
2	TxD	
3	RxD	
4		
5	GND	
6		
7		
8		
9		

Interface parameters

Parameter	Value
Baud rate	9600
Data bits	8
Parity	None
Stop bits	1

Data format

Data is transmitted in blocks of data sets.

One data set contains the data from one analysis.

Data sets consist of data fields.

A data field consists of an identifier (7 characters) and its respective value or text.

Data fields are concluded with one carriage return and line feed.

Data sets are concluded with three carriage returns and line feeds.

Data Fields

Identifier	Format	Example	Remarks
Name:	Text	Name: Rex	
ID:	Text	ID: 1234	
Specie:	Dog/Cat/Control/	Specie:Dog	
Sample:	Serum/Plasma	Sample:Serum	Optional
Holder:	Text	Holder:Mayer	
Testname:	Value and unit	cCRP: 2.48 mg/dl	
Calculatedname:	Value and unit	eAG: 100 mg/dl	Optional
Range:	Value - Value	Range: 0.00 - 1.00	Optional
Time:	hh:mm	Time: 14:44	
Date:	dd-mm-yyyy	Date: 08-02-2017	
Operat:	Text	Operat:Max Muster	Optional
Lot No:	Value	Lot No:4111	Optional
Ser No:	Value	Ser No:Ca00001	Optional

USB Interface

The USB interface emulates the serial interface.

ERROR INFORMATION AND TROUBLESHOOTING

Error messages and possible causes

Error message	Cause	Correction
Invalid card	A wrong, defective or expired RFID	Use a new test kit.
	card;	
	A defective RFID module;	Contact your dealer.
Tests expired	The test cartridge has passed its	Use a cartridge from a new test kit
	expiration date.	that has not expired.
Wrong date set	The date set on the Tablet-PC is	Change the date to "today" like
	wrong.	described in the Tablet-PC Starter
		Manual.
Door blocked		Reposition the test cartridge or
	door because the cartridge has not	tighten the cap on the cuvette.
	been inserted completely or the	
	cuvette has not been capped firmly	
Wrong cap Missing cap Missing	enough. The wrong cap is being used or the	Lies the correct cortridge and con
cartridge	cap is missing or the cartridge is	Ose the correct carthage and cap.
Carmage	missing or an already used cartridge	
	is inserted.	
Bolt blocked	The test cartridge blocks the bolt	Use the correct cartridge and cap
Don brooked	because the wrong cap is being	coo ine comeet carmage and cap.
	used.	
Measurement overflow	The photometric measurement value	Repeat the test using a new
	lies outside the measuring range	
	(e.g. a cold cartridge has been used).	-
Blank error	The photometric measurement value	Repeat the test after restarting the
	is outside the measuring range	Instrument.
	(without the cartridge).	
Temperature error	•	Repeat the test after restarting the
Maria a sa	range.	Instrument.
Wrong sampletype?	The wrong sample type has possibly been selected.	Select the correct sample type.
Linearity error		Repeat the test using a new sample
Linearity error	linear (e.g. if a cold cartridge has	
	been used, if wrong sampletype was	and a new cartinge.
	set, if wrong samplevolume was used	
	or if a cartridge with integrated	
	capillary was not used correctly).	
Mix error	Instrument fails to perform test due to	Please contact your local dealer.
	possible hardware error.	
Coagulation error	Coagulation can not be measured.	Repeat the test using a new
		cartridge.
Sample volume error	The provided sample volume is not	Repeat the test using a new cartridge
_	correct (e.g. pipetting error).	with correct sample volume.
Cartridge temperature error	The cartridge's temperature is too	Repeat the test and refer to the
	low for a proper test.	package inserts for proper cartridge
		use.
Measurement not assignable		Repeat the test using a new
	assigned	cartridge.

Service information

If the problem persists after the corrective actions are taken, contact your local Micro-Cube Instrument dealer for technical assistance.

Before asking for assistance, please have the following information ready:

- the serial number of your Micro-Cube Instrument
- the test type
- the test lot number
- the control lot number
- the control results obtained so far
- a description of the problem, including any of the Micro-Cube's error messages

TECHNICAL SPECIFICATIONS

MVD Micro-Cube Instrument

Photometer resolution 0.0001 ABS

Reproducibility <1.5% CV at 1 OD

Linearity 0.1000 - 3.0000 OD better than +/- 1.5% and +/- 0.01 OD

Temperature control Electrical temperature control of the photometer unit to 37 °C +/- 2 °C

98 °F +/- 2 °F

Fuse 2.5 A, self-healing

Dimensions 6.3" x 5.31" x 5.71" (H x W x D)

Weight 4.85 lbs (unpackaged)

Communications interface RS232, USB, Bluetooth

Tolerance conditions: Work space: $20 - 28 \,^{\circ}\text{C}$ (68 – 82 $^{\circ}\text{F}$); relative humidity: 10 - 85%

Transport/Storage: $0 - 50 \,^{\circ}\text{C}$ (32 - 122 °F); relative humidity: 5 - 85%

Work surface: A dry, clean, level surface. Avoid direct sunlight.

Power usage: 12V DC, 2A

Power supply

Manufacturer Globtek

Type GTM21097-5012

Mains adapter A separate AC to DC mains adapter with double insulation

Input 90 - 264V AC, 47 - 63 Hz

Output 12V DC, 4.17A Power usage Max. 30 VA

Options

Thermo printer Seiko Label Printer 650SE

Interface Serial

Mains adapter 100 - 240 VAC

Barcode reader (scanner) Datalogic Heron D130 Honeywell Voyager 1200g

 Reading area
 $0.79 \sim 10.63$ " (20 mils)
 $1.5 \sim 2.2$ " (5 mils)

 Max. resolution
 0.0039" (4 mils)
 0.0035" (3.5 mils)

 Mains adapter
 100 - 240 VAC 100 - 240 VAC

DECLARATION OF CONFORMITY

CE

The MVD Micro-Cube Analyser, consisting of the Micro-Cube Instrument and the Micro-Cube Tablet PC is in conformity with the directive **2014/30/EU** of the European Parliament and the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility.

To fulfil the requirements, of the mentioned directive, the product is in conformity with the following standards:

IEC 61010-1

EN 55011 Class B

EN 61000-4-2

EN 61000-4-3

EN 61000-4-4

EN 61000-4-5

EN 61000-4-6

EN 61000-4-11

EN 61326-1

SHUT DOWN AND WASTE MANAGEMENT

Before shutting down the Micro-Cube Instrument for the purpose of a repair or disposal it is necessary to ensure that there is no cartridge left within the Micro-Cube Instrument. For the purpose of delivering the Micro-Cube Instrument it is also required to protect the photometer with its original delivered packaging and packaging inserts.

For proper waste management according to the directive 2002/96/EG please contact your local dealer. Used cartridges need to be disposed with laboratory waste and according to the corresponding regulations.

MANUFACTURER INFORMATION



MicroVet Diagnostics

2300 W. Sahara Ave Suite 650

Las Vegas, NV 89102

USA

Tel: 800.640.7780

Fax: 864.382.3131

Email: Admin@VetDiagnosticSolutions.com

Web: www.microvetdiagnostics.com