V-Sperm *Gold*

USER GUIDE

Version 3.66
WHO 6th

Catalog # V-ML-01972-00

March 2024

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SECTION 1: Overview

Features and Benefits

- Import patient and control data from the SQA-V in a large archive.
- Import test results on-line.
- Attach a sperm image to a consolidated semen analysis report.
- View semen samples in "real time" on a PC screen.
- Attach video clips of semen samples to patient's records.
- Edit patient files and track changes with built-in traceability feature.
- Save, view and graph PATIENT and CONTROL test results.
- Set-up SQA-V system defaults.
- Customize reports by language, test range, test descriptions.
- Access V-Sperm via person/password security.

V-Sperm *Gold* package includes the following:

- User Guide
- Installation USB Drive
- V-Sperm Security device
- RCA video cable

System Requirements

- SQA-V with communication cable and power cable

PC / Hardware Requirements

Minimum requirements for V-Sperm software

- **PC:** Intel Core 15 M520 2.4GHz or equivalent
- **RAM:** 4GB
- **Video card:** 3D to support high resolutions 16:10 – 1440X900
- **Video color**: At least 16 bit (65,535)
-
- **300GB free hard disk space** for image capturing (approx. 3000 clips)
- **Monitor Screen:** Color, Wide screen – should support resolution 16:10 or 16:9 (1440X900)
- **Operating system compatibility:** Windows XP, 7, 8.1, 10 and 11; Excel/Word (required for V-Sperm GOLD)
- **Communication Ports:** Two FREE native RS232 USB; two USB ports
- **EXCEL and WORD required for export function and printing test reports**

SECTION 2: Log-on

After successfully installing V-Sperm, an icon will appear on the desktop of the computer. To start the program:

- Double click the **V-SPERM** icon

Enter the system from the log-on screen by typing in:

- **User Name: administrator**
- **Password: fertility**
- Click **OK**

NOTE: Each V-Sperm user can be set-up with a unique user name and password - please see the Set-up section of this User Guide.

SECTION 3: Navigating through V-Sperm

- Nine navigation buttons reside in the left margin of the V-Sperm screen. To navigate through the system, click on one of the buttons.

- When a navigation button is selected, sub-menu buttons appear across the top of the screen making it easy to access the features of the program.

- A variety of icons guide the user through V-Sperm features and options. Directional indicator buttons allow the user to easily move back to the previous menu.

NOTE: Before using V-Sperm, the system defaults must be set-up. See the Set-up section of this guide for instructions on how to do this.

SECTION 4: Patient Data

Patient Data

NOTE: Records must be imported from the SQA-V in order to locate them in V-Sperm.

Patient List

PATIENT DATA > PATIENT LIST

To select a record, click this icon.

Locating, Selecting and Authorizing Records

Click the **Patient Data** button and three options will appear: **Patient List, Search by Patient** and **Authorization List**.

Patient List – a complete list of all the patient records in the database.

Patient List

- Click on the **COLUMN TITLES** to sort the records by Patient ID, Name, Test date, etc.

- Select a record by clicking on the **ARROW** pointing to the record.

PATIENT DATA > PATIENT LIST > then select a patient record to view the:

PATIENT DATA SCREEN

Click this icon to run a graph of the selected test results.

- The **Patient Data Screen** will now appear and display all of the test records for the selected patient.

- The title bar above each test displays the sample number and icons indicating various attachments to the file such as pictures and videos.

- A graph icon is display to the right of the list of test parameters.

A number of functions can be performed from this screen:

Enter Patient Name:

- From the **Patient Data Screen**, click on the field for First Name, Last Name and type-in the information.

- Click: **Apply** to save.

Attach Video/Picture to a Test Record

- Insert a slide or testing capillary into the visualization system of the SQA-V.

- From the patient data screen, select the record (there could be multiple records for the same patient) by clicking the record **TITLE** bar to mark the test column.

- Click the **PREVIEW VIDEO** button to view the live specimen.

- Click **CAPTURE PICTURE** to attach a still image to the patient record.

- Click **CAPTURE VIDEO** to attach a live video to the patient record.

- A timer will indicate the recording time.

- Click the **STOP CAPTURING** button to stop the process.

- A message will indicate Video Saved.

- Click OK to end.

Graph Semen Parameters:

- Graphs can be run if a patient has more than one semen analysis record on file.

- From the **Patient Data Screen**, click the graph icon to the left of the semen analysis parameter. A graph will display the test results history for the selected parameter.

This icon indicates that the record has a video clip attached.

This icon indicates that the record has a picture attached.

Click this icon to run a graph of the selected test results.

Patient Data Screen

Attach Video/Picture

Semen Parameter Graph

PATIENT DATA > PATIENT LIST > then select a patient record to view the:

PATIENT DATA SCREEN in order to:

ENTER DATA, RUN A TEST REPORT, VIEW/ATTACH IMAGES or **AUTHORIZE** test results.

Enter Data: Patient Data>Patient List>Enter Data

Select a test record before clicking the enter data button. Please note that there can be more than one test per patient in the data base.

- Click the **Enter Data** button to input manual test results and add comments to the semen analysis record.

- Type-in the desired information – only editable fields will allow entries.

- All manual entries are tracked via a traceability function.

- Click the **Traceability** button at the bottom of this screen to run a **Traceability Report.**

Enter Manual Test Results

Traceability Report

Arrows indicate test results are out of range.

Click this icon to export the test report.

!

When test results are expressed as < or > a value (low quality specimens only) this icon indicates that test results possibly fall above or below the reference range (Example: Motility < 70% when the reference is set to Motility <50%)

Test Report Patient Data>Patient List>Test Report

The test report contains test results imported from the SQA-V AND manual data that is entered by the user.

Click the **Test Report** button to view and print the two-page semen analysis report (from the patient data screen).

- To move between pages, use the page bar at the bottom of the screen.

- Click the printer icon to print a report.

- Use the **ZOOM** to minimize/maximize the view of the report.

- Click the **X** in the upper right hand corner of the screen to exit the report.

- A yellow arrow will be displayed if the test results are out of range.

- Click the **FILE EXPORT** icon to export the report to a .doc file. Enter the path and file name; then click **SAVE**.

Click this icon to attach a picture to a report

This icon indicates a video clip is attached to a record.

This icon indicates a picture is attached to a record.

NOTE: If there are no saved images in a patient's file, the table will not appear.

NOTE: Click the image to maximize it.

NOTE: Click the image to **GRID** and **FREEZE** the image for easier cell counting.

PATIENT DATA > SEARCH BY PATIENT

NOTE: To insert the patient's name, locate the record by patient ID and enter the patient's name in the screen provided.

PATIENT DATA > AUTHORIZE TEST RESULTS

NOTE: Only the user with "Authorization Signature" rights can view the list.

Click the column with this icon to select tests to authorize.

Icon indicating the test is authorized

View/Attach Images: Patient Data> Patient List>View/Attach Images

- To view an image: From the **Patient Data Screen** select a test record with a video/camera icon displayed in the title bar.
- Click the **View/Attach Images** button.
- An **Image Browser** will display all the images attached to the selected patient's record.
- Select an image and it will be displayed in the **preview pane**.
- Click on the image to enlarge it.
- Click the **SAVE AS** button to save the picture to an external file on your PC.
- To attach an image (not video) to a semen analysis report, click on the report icon column in the row of the picture to be attached.
- A report icon will now appear in the column indicating that the picture is attached to the semen analysis report.
- To delete an image from the report, click on it and the report icon will disappear from the corresponding row.

Authorize: See "Authorizing Test Results" for single tests below.

Search by Patient – use this option to locate records by patient name or ID number.

- Enter the first or last name or ID number of the patient and click **SELECT**.
- The PATIENT DATA SCREEN will appear.

Authorizing Test Results:

- Click on the REPORT icon to view a record before authorizing it.
- **Single Tests**: Click on the √ column to the left of the record to be authorized.
- Click the **Authorize** button.
- The record will be deleted from the authorization list.
- **Group Authorization**: Refer to the section: Patient Data: Locating, Selecting and Authorizing Records.

Image Browser

Search by Patient

Authorization List

Delete Records

To delete Patient Records, Test Records or images in V-Sperm: Highlight the patient record, test record, or image and use the delete key on the PC keyboard.

SECTION 5: Controls

SQA-V Control Archive:

Control test results should be imported from the SQA-V online (See Import Test section).

Running a Control Test Report:

- Click the **CONTROLS** navigation button.

- From the Controls screen select:

  - **Control Media** – Latex Beads or Stabilized Sperm CAP or MES

  - **Control Level** – Level 1, 2 or Negative Control

  - **Date Range**

- Click the **RUN REPORT** button to display a list of Control Test Results based on the selected parameters.

- Click on the columns to sort data.

- Tests that are out of range will be noted.

- Select a corrective action for tests out of range by clicking on the appropriate "cell" in the "Corrective Action" column.

- A menu of corrective actions will be displayed. Select the appropriate corrective action.

- Click the **TEST REPORT** button to view the report.

Control Test Report

- Use the **PAGE BAR** to move between pages (if necessary).

- Use the **ZOOM** function to maximize/minimize the report.

This icon indicates that a test has been selected to include in the Control Test Report.

Control Set-up

Control Test Results Table

Menu of Corrective Actions

Click this icon to print a copy of the report.

Video

Control Test Report

SECTION 6: Video

Click on the **VIDEO** navigation button to view semen samples "live" from the SQA-V visualization system and to determine the video settings.

- **Real Time Video** – activates the video so samples can be viewed. Double click the mouse to maximize the image to full screen. Double click the mouse to return to normal size.
- **Video Settings** – select grid line width and color, video device, etc. (Note: video size is locked).

NOTE:
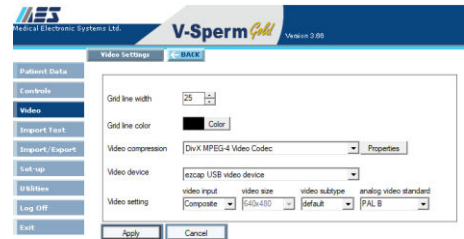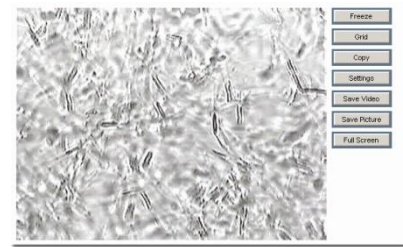
The optimal video device settings are described in the video device installation procedure supplied with the video device hardware.

Click **REAL TIME VIDEO** and six options are available:

- **Freeze** – Use this option to make cell counting easier.
- **Grid** – Use this option to display or remove the grid. The displayed grid is exactly the SAME as the SQA-V grid. 20 squares are displayed for ease of counting. If the ZOOM on the SQA-V is set to X300 each sperm cell visualized in the entire screen = 1M/ml.
- **Copy** – Copy a picture and paste it to another application (such as Word).
- **Settings** – Displays the video capture device settings.
- **Save Video** – Captures and saves a video clip to an external file.
- **Save Picture** – Captures and saves a picture to an external file.

SECTION 7: Import Test; Import/Export from the SQA-V

Importing SQA-V test results to V-Sperm

Import Test

Import/Export

Patient test results and Control test results can be imported individually from the SQA-V to V-Sperm by clicking the **Import Test** button directly after running the test. Patient test results can also be imported in batches (Import/Export) from the SQA-V to V-Sperm when the SQA-V and V-Sperm software are running:

Import a single test:

- After running a patient test a message will be displayed on the SQA-V a screen instructing the user: **TO TRANSFER TEST RESULTS TO V-SPERM: PRESSS IMPORT TEST BUTTON IN V-SPERM.**
- After running a Control test the following message will appear on the SQA-V instructing the user: **ATTENTION! TO AVOID LOSS OF DATA TRANSFER CONTROL RESULTS TO V-SPERM. PRESS: "IMPORT TEST" BUTTON IN V-SPERM.**

Patient Data

Controls

Video

Import Test

Import/Export

Set-up

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Log Off

Exit

NOTE: If a message has been displayed on the SQA-V stating that the archive is almost full, import the archive to V-Sperm and then select YES to delete the SQA-V archive.

Import the SQA-V archive (batches) of tests:

- The **SERVICE DATA** screen of the **SQA-V** must be displayed. To screen go to: **MAIN MENU>SERVICE>SERVICE DATA.**

- From the **V-Sperm** main screen select: **IMPORT/EXPORT>IMPORT DATA.**
- Click **CONTINUE** on the opened V-Sperm Import SQA-V Archive screen.
- Select **YES** or **NO** to delete the SQA-V archive once the tests have been imported to V-Sperm.

Exporting the SQA-V data:

The Export data option allows the user to Export the Patient data archive and the Controls archive to an external file (Excel format) on the PC:

- Click the **IMPORT/EXPORT** navigation button of the V-Sperm.
- Select **EXPORT DATA.**
- Select **EXPORT ARCHIVE** (Patient Data) or **EXPORT CONTROLS.**
- Enter the path and file name; then click **SAVE**.

SECTION 8: Set-Up

Set-Up

Click the **Set-up** button to select the system defaults for the:

- V-Sperm:
  - Authorized Users
  - Report (Test Parameters, Normal Ranges, Testing Facility and Language)
  - Ports
  - Auto Export
- SQA-V: **SQA-V Defaults**

V-Sperm

V-Sperm Set-Up

Authorized Users

Set-up: Authorized Users

Select **SET UP > V-SPERM > AUTHORIZED USERS** and the screens below will be displayed. Assign rights, passwords and enter information in the sections provided to add users. Only the administrator has the authorization to set-up passwords and new users.

NOTE: Click an open cell under the "Title" column to add a new user. A drop-down menu will appear. Select the type of user based on their rights to the system. Enter the required information and click Apply.

Title	First Name	Last Name	User Name	Password
Administrator	Administrator	Administrator	Administrator	*****
Ordering Physician				

Apply   Cancel

There are four types of users. Each type is permitted different "rights" to the system:

- **Administrator**: Has all rights, can authorize reports, set-up passwords and add new users.
- **Authorizing Signature**: Has all rights except for setting-up users/passwords.
- **Test Performed By**: Has all rights except for authorizing reports and setting-up users/passwords.
- **Ordering Physician**: Has no rights and can only view information.

- Changes can be made to Authorized User's passwords at any time by entering a new one over the old one and clicking apply.

- Changes cannot be made to an authorized user's "title" if a test report in the database contains their name/title.

- An authorized user cannot be deleted if a test report in the database contains their name/title.

Report

Set-up: Report

To set-up the test report, click **SET-UP** > **V-SPERM** > **REPORT**.

| Test Parameters | Normal Ranges | Testing Facility | Language | ← BACK |

Four option tabs will be displayed. Click one of the option tabs:

- **TEST PARAMETERS**

- **NORMAL RANGES**

- **TESTING FACILITY**

- **LANGUAGE**

Test Parameters

NOTE: **All** test parameters are **listed** on the patient's semen analysis report.

If a test parameter is not checked, results of that test will not be reported on the patient's semen analysis report.

Test Parameters: Set-up>V-Sperm>Report>Test Parameters

- Select the information to be viewed on the V-Sperm screens and reported on the test report.

- Click the √ column to select the test report parameters.

- Check / Uncheck "Show morphology recommendation note"

- Click **Apply** to enter.

Normal Ranges

NOTE: Some test ranges have been set by the manufacturer as a factory default based on WHO or MES guidelines (see SQA-V User Guide).

The user can input values based on internal lab protocols.

The test report will indicate if a test result is out of the range established by the user.

Normal Ranges: Set-up>V-Sperm>Report>Normal Ranges

- To set the normal range for a test result, click the **ARROW** pointing to the parameter to be set.

- The **Normal Range Settings** screen will appear.

- Enter the desired symbol (≥, <, =, etc.).

- Enter the desired value.

- Click **Apply** to enter.

Testing Facility

Testing Facility: Set-up>V-Sperm>Report>Testing Facility

- Enter the details of the testing facility that is to be displayed on the semen analysis report.

- Check the **Show in Report** box.

- Click **Apply** to save the changes.

Language

Language: Set-up>V-Sperm>Report>Language

- The system default is English.

- Select "Other 1" or "Other 2" from the Language drop-down menu to enter text in another language.

- Click **Apply** to save the changes.

Set-up: Ports

- Select **Set-up>V-Sperm>Ports** to view Communication Port options.

- Select the correct port for the PC and press **Apply**.

Set-up: Auto Export

- Select **Set-up>V-Sperm>Auto Export** to view the setting options.

- Check (√) **Automated Data Save**, define the **Tests File Path** and **Controls File Path** and click **Apply**.

- Each patient test and control result will be saved online automatically to the corresponding text file.

- Two separate files for patient tests and controls will be created.

- Only the last results will be presented.

- This feature can be used to send data to another online source.

SQA-V

SQA-V Set-up (SQA-V version 2.66):

- In order to set-up SQA-V (patient testing and controls) defaults both the SQA-V and V-Sperm must be connected and activated:

- Activate the **SERVICE DATA** screen of the **SQA-V** by going to: **MAIN MENU > SERVICE > SERVICE DATA.**

SQA-V Defaults

- Click: **SET-UP** > **SQA-V > CONTINUE** and the screen below will be displayed. Data must be entered in all fields of the table below or the SQA-V will not accept the default settings.

SQA-V set-up screen from   V-Sperm

CONTROL set-up screen from   V-Sperm

NOTE: All Set-up fields must have data in order to transfer information to the SQA-V. If CONTROL settings are not known, enter "0" LOT #/ Target Value/+/- Range. Enter current date for the date field.

NOTE: The **Set-up** data transfer may take several minutes! Please wait…..

- **SQA-V System Default settings;**
  - Date Format (DD/MM/YY) or (MM/DD/YY)
  - Local date setting
  - Conc./Chamber Standard 1 or 2 (See appendix section for more information)
  - LES: Check with your distributor for any changes
  - Printing options: automatically print test results/self test reports
  - Printer type: enter thermal or ink depending on the **printer on the SQAV**

- **Control Set-up (from the manufacturer's labeling):**
  - Select type of control: Latex beads or Stabilized Sperm.
  - Enter Lot Number for each control level (enter "0" if not known).
  - Enter +/- Range for each control level (enter "0" if not known).
  - Enter EXPIRATION date (use current date if EXP date is not known).

- Press the **Report** button to print the selected default settings.

- Press **Apply** to accept the default settings and transfer settings to the SQA-V.

Utilities

Self-Test Data

SECTION 9: Utilities

To view and print the SQA-V SELF TEST DATA for technical support purposes:

- Click on the **UTILITIES** navigation button
- Select: **SELF TEST DATA**
- Select: **PRINT or SAVE**

SECTION 10: Log-Off

Log Off

LOG-OFF V-Sperm by clicking the navigation button and confirming with a click.

- A new user can immediately log-on from the screen. The V-Sperm program does not need to be shut-down when a user logs-off.
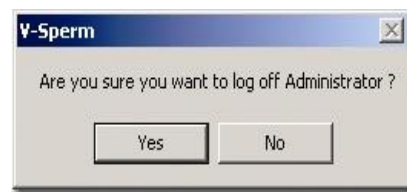
SECTION 11: Exit

Exit

To Exit – Click on the OK button.

SECTION 12: Installation of V-Sperm Software and Hardware

Overview: **The Video Capture Device should be installed prior to using V-Sperm!**

Step 1: Video Capture Device Installation

V-Sperm requires that the user install the video capture device provided by the manufacturer. For video capture device installation instructions, please refer to the package insert in the V-Sperm package.

Step 2: USB to RS232 driver installation

An RS232 link is required between the V-Sperm and the SQA-V. If the V-Sperm computer does not have an RS232 port an external USB to RS232 cable must be installed. For Windows 7, the drivers are installed automatically when the cable is plugged into the computer. For Windows XP, the drivers must be installed. Installation instructions are provided in the Section 14 of this guide for XP operating systems.

Step 3: V-Sperm Software Installation (Refer to User Guide for PC specifications)

Step 1: Insert the **V-Sperm** USB Drive and double click on "Setup.exe".

Step 2: The screen will display: **Initializing Wise Installation Wizard.**

Step 3: Close any programs that are open or running.

Step 4: Run the installation program and click **YES** when finished.

Step 4: MDAC Installation

(This step is required only if the MDAC component was not already installed in the computer)

Step 1: A message will appear if MDAC (2.6 or above) is not installed on the PC.

Step 2: Click **OK** to install.

Step 3: Once installed, restart the computer by clicking **OK** when prompted.

Step 4: After re-start, click **YES** to proceed.

Step 5: Collecting Information

Step 1: Click **NEXT** when the Welcome screen is displayed.

Step 2: Click **NEXT** when the default directory for V-Sperm is displayed.

Step 3: Click **NEXT** when the default name for V-Sperm is displayed.

Step 4: Click **NEXT** to begin copying files.
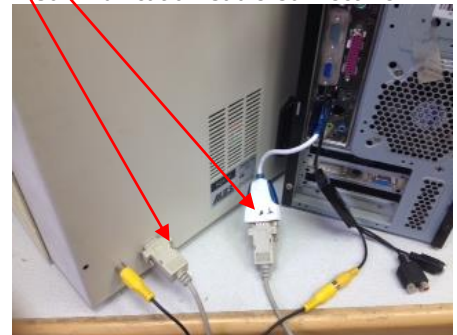
Step 6: Installation Completion

Step 1: When all files have been copied the message: **Updating System Configuration, please wait...** will be displayed.

Step 2: The security device driver will be installed and the screen will indicate that this operation is in process.

Step 3: When a screen is displayed to ask if you want to restart the PC to complete the software installation, Click **OK.**

SQA-V Communications Cable

Step 1:   Connect one end of the RS232 communication cable to the PC (Refer to picture: Communication Cable Connect Ver. 1 image) or to the USB to RS232 convertor (Refer to picture: Communication Cable Connect Ver. 2).

Step 2:   Connect the other end of the RS232 communications cable to the SQA-V as shown in the same Ver. 2 picture.
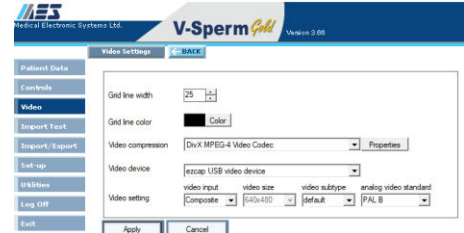
Video Capture Device Settings

Step 1:   Log into V-Sperm

- User Name - administrator
- Password - fertility

Step 2:   Go to: Video > Video Settings and this screen will appear

Step 3:   Select these settings:

- Video compression: DivX MPEG-4 Video Codec
- Video device – WDM
- Video input – Composite
- Video size and subtype – 640 x 480
- Analog Video – PAL B

Step 4:   Press: Apply, to save the changes.

Step 5:   Place a slide/sample in the SQA-V and select the VIDEO function in V-Sperm to test if the device is functioning properly.

Step 6:   Adjust the Video Settings to the optimal values

- From the V-Sperm GOLD main navigation screen select **Video > Real Time Video > Settings, and go to the "Video Proc Amp" tab.**

- The optimal settings are:
  - Brightness: 50
  - Contrast: 60
  - Saturation: 0

- **Please note:** The values of the "Brightness" and "Contrast" parameters can be slightly adjusted by the user is order to fit the preferences of every individual.

V-Sperm Settings Configuration

Step 1:   From the SQA-V **MAIN MENU** select: **SERVICE** and press **ENTER**.

Step 2:   From the V-Sperm GOLD main navigation screen select **SET-UP > SQA-V > SQA-V Defaults.**

Communication Cable Connect Ver. 1

Communications Cable Connect Ver. 2

V-Sperm Video Settings Screen

Step 3: Press: **CONTINUE** to view the screen below:

- Select the SQA-V Default settings by clicking on the desired preferences:
  - Date Format: Europe (DD/MM/YY) or USA (MM/DD/YY)
  - Local date setting
  - Conc./Chamber Standard 1 or 2 (See the Appendix of the SQA-V User Guide for detailed information)
  - Printing options: automatically print test results/self test report on start-up.
- Control Set-up (from the manufacturer's labeling):
  - Select type of control: Latex beads or Stabilized Sperm CAP or MES depending on what controls will be run routinely (for proficiency testing, other options can be selected just to run those samples).
  - Enter Lot Number for each control level (enter "0" if not known).
  - Enter EXPIRATION date (use current date if EXP date is not know).
  - Enter +/- Range for each control level (enter "0" if not known).
  - Press: **APPLY** to transfer the settings to the SQA-V (may take 2 minutes).

SECTION 13: V-Sperm Uninstall

STEP 1: From the desktop of the PC select: **START > PROGRAMS > V-SPERM > UNINSTALL.**

Step 2: A message will be displayed: **Initializing Wise Uninstall Wizard...**

Step 3: Select **AUTOMATIC** when the screen asks for an uninstall method.

Step 4: Click **NEXT** to continue.

Step 5: Click **FINISH** when the next screen notes the uninstall has been completed.

Step 6: Select **YES TO ALL** if a message asks to remove shared components.

Step 7: Uninstall will remove files and close automatically when finished.

## SECTION 14: Installation Instructions: USB to RS232 Converter

General Description

The USB to RS232 device provides the connection between the SQA-V and V-Sperm required to import test results which then can be viewed and analyzed from the V-Sperm PC. In order to properly install the USB to RS232 device, please follow the instructions below.

PLEASE NOTE: These instructions are for Windows XP users only. In Windows 7-10 the appropriate driver is automatically installed.

## USB to RS232 Device Driver Installation

1. Close all open programs.

2. Insert the **USB flash drive** into the PC.

3. From the PC click: **START > RUN** and type in: **X:\Win200-XP-Vista\CDM 2.04.06.exe**
   (X = letter of PC drive)

4. Wait a few seconds until the installation process is completed (the DOS window displayed below will disappear)
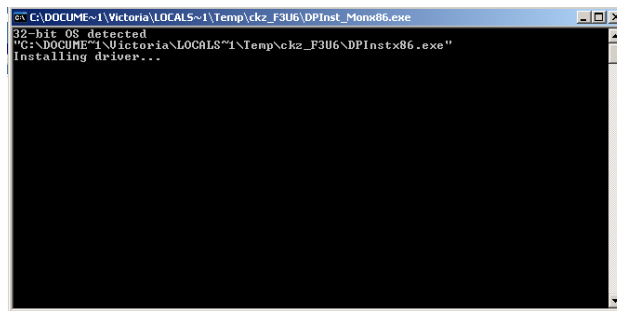
5. Plug-in the USB cable of the **USB to RS232 device** into a **USB port** on the PC.

Verifying Proper Installation

1. Click on **START > RUN**

2. Type: **devmgmt.msc** and click **ENTER** in order to open the Device Manager.
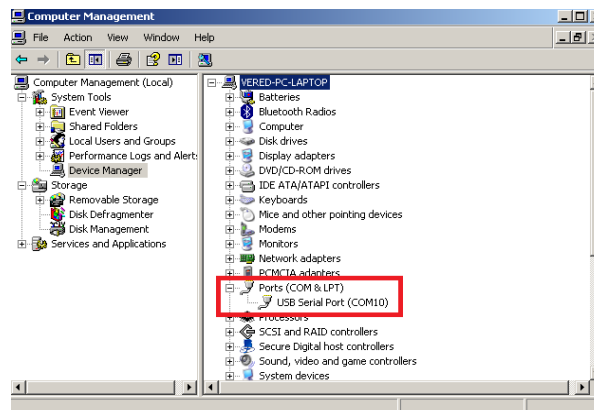
3. Verify that the driver is installed (check to see the driver in the red boxed area displayed above).

European Authorized Representative:
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Manufacturer:
Medical Electronic Systems, Ltd. 20 Alon Hatavor St., Zone 6, P.O.
Box 3017, Caesarea Ind. Park 3088900, Israel

Catalog # V-ML-01972-00