



V-Sperm *Gold*

USER GUIDE

Version 3.48

WHO 3rd and 4th

Catalog # 5130

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SECTION 1: Overview

V-Sperm *Gold* 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 Disk-on-Key or link
- V-Sperm Security device
- RCA video cable

System Requirements

- SQA-V with communication cable and power cable
- PC
 - Hardware requirements
 - 1Ghz or higher CPU
 - 256 megabytes RAM
 - AGP Video Display Card with at least 16 megabytes of RAM memory
 - RS232 communications port (serial)
 - Two available USB ports
 - Software requirements
 - Compatible operating systems:
 - Windows XP (Graphics display MUST be set to "Windows Classic Style")
 - Win 8.1
 - Win 10
 - Win 11
 - DirectX 8.1
 - At least 40 Gbyte of free hard disk space (if not using a compression tool) or 400 MB if a video compression tool is used.
 - Video resolution $\geq 640 \times 480$
 - Video color quality ≥ 16 -bit

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.

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.

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



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**



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.



SECTION 4: Patient Data

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.

- 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.

V-Sperm Management System				
Medical Electronic Systems Ltd. V-Sperm ^{Gold} Version 3.48				
Patient List				
Patient Data	Patient ID	First Name	Last Name	Test Date
Controls	1284583885307425157	POSTVASECTOMY	Zachary	01/02/2008 14:30
Video	14725639635953652663	FRESH	Monroe	02/02/2008 12:36
Import Test	1503865955025986073	POSTVASECTOMY	Jefferson	01/02/2008 14:19
Import/Export	1502596863594123682	WASHED	McKinley	01/05/2008 15:13
Set-up	1502596863594123682	WASHED	McKinley	02/02/2008 13:28
Utilities	1596352963594123682	FRESH	Taft	02/02/2008 12:35
Log Off	1787118019524123856	POSTVASECTOMY	Jackson	05/02/2008 16:16
Exit	1787118019524123856	POSTVASECTOMY	Jackson	02/02/2008 12:42
	1787118019524123856	POSTVASECTOMY	Jackson	01/02/2008 13:59
	19455485768952030940	FRESH	Harrison	05/02/2008 13:51
	19455485768952030940	FRESH	Harrison	01/02/2008 15:56
	1802068686388650749	FRESH	Carter	06/02/2008 14:19
	32523635369532866395	WASHED	Filmore	02/02/2008 13:06
	32595638952145365256	WASHED	Bush	05/02/2008 16:09
	3352408655527809528	POSTVASECTOMY	Buchanan	06/02/2008 12:25
	3352408655527809528	POSTVASECTOMY	Buchanan	06/02/2008 12:13



this icon.

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.



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



This icon indicates that
the record has a
picture attached.

- 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.

Patient List

Patient Data

Patient ID: 8294768729376476276

First Name: Penny

Last Name: Core

Birth Date: 08/11/1959

Buttons: Enter Data, Test Report, View/Attach Images, Authorize, Apply, Cancel, Preview Video

Test Parameters	33047564373494763945	730495564764755594735
Date Test Performed	15/01/2003 20:56:00	15/01/2003 21:00:00
# Immobile Sperm (PV)	N.A.	N.A.
# Immobile Sperm/Vol MVol (PV)	N.A.	N.A.
# Mobile Sperm (PV)	N.A.	N.A.
# Mobile Sperm/Vol MVol (PV)	N.A.	N.A.
# Total Sperm (PV)	N.A.	N.A.
# Total Sperm/Vol MVol (PV)	N.A.	N.A.
% Normal Forms (%)	N.A.	N.A.
Abstinence (# of days)	2	2

Patient Data Screen

Patient Data

Patient ID: 12845639685397425157

First Name: POSTVASECTOMY

Last Name: Zachary

Birth Date: 7/12/1955

Buttons: Enter Data, Test Report, View/Attach Images, Authorize, Capture Picture, Capture Video, Close Video

Test Parameters	2/1/2006 2:30:00 PM
# Immobile Sperm (PV)	4
# Immobile Sperm/Vol MVol (PV)	0.1
# Mobile Sperm (PV)	4
# Mobile Sperm/Vol MVol (PV)	0.5
# Total Sperm (PV)	8
# Total Sperm/Vol MVol (PV)	0.6
% Normal Forms (%)	N.A.
Abstinence (# of days)	2

Attach Video/Picture



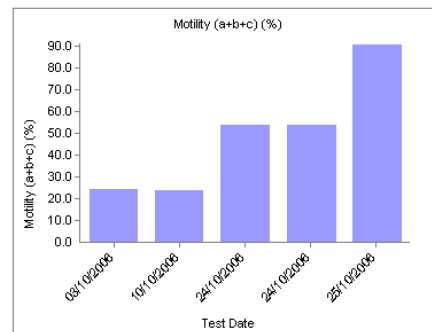


Click this icon to run a graph of the selected test results.

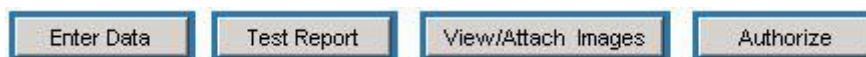
- A message will indicate Video Saved.
- Click OK to end.

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.



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**.

Test Data

Patient ID: 2838474839476839474
 First Name: Abnormal
 Last Name: Clinton
 Test Date: 1/14/03 10:54:00 AM
 Sample ID: 47847505748393948949

Biochemistry

a-glucosidase
 Fructose in Seminal Plasma
 Zinc

Other

Acrosome Reaction Assay
 Anti-Sperm Ab
 Immature Germ Cells
 Immunobead Test
 MAR (Mixed Antigen/antibody Reaction)
 Other

Morphology WHO/Kruger

Normal Forms: 25
 Abnormal Forms: 75
 Head Defects: 15
 Neck/Midpiece Defects
 Tail Defects
 Cytoplasmic Droplets

Comments

Traceability Apply Cancel

Enter Manual Test Results

Test Parameters	1/20/04	1/30/04
Updated Time	22:07	22:02
Editor	Martha Spanjer	Martha Spanjer
Test Performed by	Martha Spanjer	Martha Spanjer
Authorizing Signature	Martha Spanjer	Martha Spanjer
Ordering Physician	Martha Spanjer	Martha Spanjer
Acrosome Test (%)		
a-glucosidase		
Fructose (mmol/l)		
Zinc (mmol/l)		
Immature Cells (Mm)		
MAR (%)		
Normal Forms (%)		25
Head Defects (%)		15
Neck/Midpiece (%)		45
Tail Defects (%)		10
Cytoplasmic Droplets (%)		5
Vitality (%)		
vWBC (Manual)		
RBC (Mm)		
Anti-Sperm Ab (%)		
Other		
Abnormal Forms (%)		75

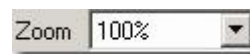
Traceability Report

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.



Test Report



Arrows indicate test results are out of range.



Click this icon to export the test report.

IVD

CE



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%)

View/Attach Images



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.

- 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**.

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.

Pages: 1

Date	Time	Image Type
10/03/2003	18:06:42	Picture
10/03/2003	18:05:05	Video



Save As

Date	Time	Image Type
1/1/2004	20:27:58	Picture
1/11/2004	13:18:51	Picture
1/11/2004	13:20:44	Video

Image Browser

Patient ID
29384748394765839474

First Name

Last Name

Select

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

Controls



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

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.

Search by Patient

✓	Patient ID	First Name	Last Name	Test Date	Sample ID
<input type="checkbox"/>	39480204372657480394	Victoria	Johnson	1/1/03 7:14:00 PM	3834847559590403489
<input type="checkbox"/>	48374950968487637848	Lora	Hoover	1/1/03 12:22:00 PM	28374745754949330942
<input type="checkbox"/>	58394857685949382738	Lili	Buchanan	1/1/03 12:29:00 PM	484839349596654034
<input type="checkbox"/>	59483746554839478756	Diana	Coolidge	1/1/03 11:02:00 AM	28384756859493304895
<input type="checkbox"/>	78373483726374859737	Katie	Taft	1/1/03 4:26:00 PM	53847594394845753948
<input type="checkbox"/>	82030938426394839447	Elizabeth	Harrison	1/1/03 8:11:00 PM	4857655764933049489
<input type="checkbox"/>	82834769725376476276	Jenny	Gore	1/1/03 8:56:00 PM	93847564373484763845
<input type="checkbox"/>	82834769725376476276	Jenny	Gore	1/1/03 9:00:00 PM	73848564764758584735
<input type="checkbox"/>	8283923945884738475	Nelly	Monroe	1/1/03 1:00:00 PM	28374548458593945843
<input type="checkbox"/>	82838475638485789384	Frozen	Tyler	1/1/03 3:00:00 PM	73747458348484858880
<input type="checkbox"/>	83726374886374765848	Alison	Carter	1/1/03 1:09:00 PM	293847568594585348456
<input type="checkbox"/>	83746372837488237834	Karen	McKinley	1/1/03 4:12:00 PM	9485763487647465732
<input type="checkbox"/>	837463628374676384	Julie	nWilson	1/1/03 4:35:00 PM	73485948374658483925
<input type="checkbox"/>	83749584736239473624	Mary	Truman	1/1/03 12:15:00 PM	84736253748549348592
<input type="checkbox"/>	83848372638437487476	Nicole	Grant	1/1/03 3:39:00 PM	82738485837482838475
<input type="checkbox"/>	84758838475838482847	Anabel	Ford	1/1/03 11:59:00 AM	93847563848585958472

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:

Import **Control** test results from the SQA-V (See Import Test sections).

Running a Control Test Report:

- Click the **CONTROL** navigation button.
- From the Control Set-up screen select:
 - Test Method**–Manual or Automated
 - Control Media**–Latex Beads or Stabilized Sperm
 - 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.

Test Method
☒ Automated
☐ Manual

Control Media
☒ Latex Beads
☐ Stabilized Sperm

Control Level
☒ Level 1
☐ Level 2
☐ Negative Control

Date Range
☒ All
 From: 21/02/2005 To: 21/02/2005

Run Report Cancel

Control Set-up

Controls									
Automated/Latex Beads/Level 1									
✓	Date	Lot Number	Exp Date	Target Value	Range +/-	Conc. Results	In Range	Out of Range	
<input checked="" type="checkbox"/>	01/02/2005 16:26	080000001	0406	39	5.5	27.1			Li
<input checked="" type="checkbox"/>	01/02/2005 16:22	080000001	0406	39	5.5	27.1			Li
<input checked="" type="checkbox"/>	01/02/2005 16:19	080000001	0406	39	5.5	12.2			Li
<input checked="" type="checkbox"/>	01/02/2005 16:16	080000001	0406	39	5.5	29.3			Li
<input checked="" type="checkbox"/>	01/02/2005 16:14	080000001	0406	39	5.5	63.4			H
<input checked="" type="checkbox"/>	01/02/2005 16:12	080000001	0406	39	5.5	46.5			H
<input checked="" type="checkbox"/>	05/07/2005 10:44	080000001	0406	39	5.5	39.2			Normal
<input checked="" type="checkbox"/>	05/07/2005 10:42	080000001	0406	39	5.5	39			Normal

Control Test Results Table

- 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.

Corrective Action		
Code	Reason of corrective action	Corrective action required
CLEAN	SQA-V measurement compartment requires cleaning	Clean the SQA-V measurement compartment and re-run the test
MIX	QC material not homogeneously mixed	Properly mix control material
SET-UP	Target value and/or +/- range entered incorrectly in set-up	Re-enter values and re-run the test
STORAGE	Control material not properly stored	Use new control material and re-run the test
EXPIRED	Control material expired	Use new control material and re-run the test
NON-ASSAYED	Cannot run as an assayed control	Follow user guide instructions for running a non-assayed control and
OTHER	Other (specify)	

Menu of Corrective Actions

Spermalite/SQA-V Control Test Results

Control: Latex Beads
Automated SQA-V Level: 1
Date of Report: 3/1/2005 3:45:42 PM
Date Range: All

Date Test Performed	Lot #	Exp. Date	Concentration	Target Range +/-	Conc. Results	In Range	Out of Range	Corrective Action	SQA-V Stat
2/6/2005 09:59	120904001	05/05	43	6.1	5.1	Low			334
2/6/2005 09:51	120904001	05/05	43	6.1	38.3	Normal			334
2/6/2005 09:52	120904001	05/05	43	6.1	4.4	Low			334
2/6/2005 09:14	120904001	05/05	43	6.1	48.1	Normal			334
2/6/2005 09:21	120904001	05/05	43	3.2	53.1	High			334
2/6/2005 09:53	120904001	05/05	43	6.1	5.1	Low			334
2/6/2005 09:54	120904001	05/05	43	6.1	38.3	Normal			334
2/6/2005 09:55	120904001	05/05	43	6.1	4.4	Low			334
2/6/2005 02:57	120904001	05/05	43	6.1	48.1	Normal			334
2/6/2005 02:14	120904001	05/05	43	3.2	53.1	High			334
2/6/2005 03:55	120904001	05/05	43	6.1	38.3	Normal			334
2/6/2005 03:51	120904001	05/05	43	6.1	4.4	Low			334
2/6/2005 03:13	120904001	05/05	43	6.1	48.1	Normal			334
2/6/2005 04:25	120904001	05/05	43	3.2	53.1	High			334
2/6/2005 04:52	120904001	05/05	43	6.1	5.1	Low			334
2/6/2005 04:53	120904001	05/05	43	6.1	38.3	Normal			334
2/6/2005 04:54	120904001	05/05	43	6.1	4.4	Low			334
2/6/2005 04:56	120904001	05/05	43	6.1	48.1	Normal			334

Control Test Report



Click this icon to print a copy of the report.

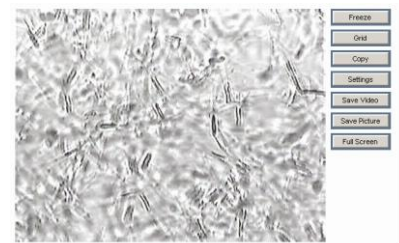
Control Test Report

- Use the **PAGE BAR** to move between pages (if necessary).
- Use the **ZOOM** function to maximize/minimize the 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.
- **Video Settings** – select grid size, color and video device
 - The appropriate video device settings are described in the video device installation procedure supplied with the video device hardware



Click **REAL TIME VIDEO** and seven 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 if the ZOOM on the SQA-V is set to X300. 20 squares are displayed for ease of counting – each sperm cell visualized in the entire grid = 1M/ml.
- **Copy** – Captures a picture that can be saved 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.

Import Test

Import/Export

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.

- **Save Picture** – Captures and saves a picture to an external file.
- **Full Screen** – Maximizes the image to full screen. Click the mouse to return to normal size.

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

Importing SQA-V test results to V-Sperm

Patient and control test results can be imported individually (Import Test), while Test Results can be imported in batches (Import/Export) from the SQA-V to V-Sperm. In order to import test results the computer must be connected to the SQA-V and V-Sperm software must be running:

Import a single test:

- After running a test on the SQA-V a screen will appear on the SQA-V instructing the user: **TO TRANSFER TEST RESULTS TO V-SPERM: PRESS IMPORT TEST BUTTON IN V-SPERM.**

Import the SQA-V archive of tests:

- The **SERVICE DATA** screen of the **SQA-V** must be displayed. To activate this screen go to: **MAIN MENU>SERVICE>SERVICE DATA.**
- From the **V-Sperm** main screen select: **IMPORT/EXPORT>IMPORT DATA.**
- Select **IMPORT ARCHIVE** (Patient Data).
- Click **CONTINUE** on the 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

Patient Data

Controls

Video

Import Test

Import/Export

Set-up

Utilities

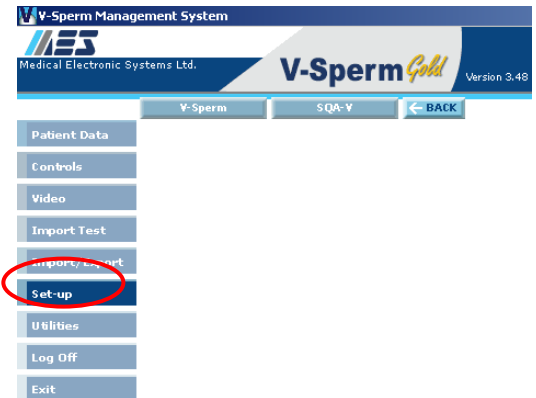
Log Off

Exit

Set-Up

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

- V-Sperm (System and Controls)
- SQA-V (System Defaults and Controls)



V-Sperm

Authorized Users

V-Sperm Set Up:

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.

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

Apply Cancel

NOTE: Enter new users by clicking an open cell under the "Title" column. 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.



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**

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.

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.

Testing Facility

• LANGUAGE

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.

Test Parameter	Description
<input checked="" type="checkbox"/> # Immotile Sperm (P)	The number of Immotile Sperm - Postvasectomy(P)
<input checked="" type="checkbox"/> # Immotile Sperm/Vol (P/Vol)	The number of Immotile Sperm in the whole sample - Postvasectomy(P)
<input checked="" type="checkbox"/> # Motile Sperm (P)	The number of Motile Sperm - Postvasectomy(P)
<input checked="" type="checkbox"/> # Motile Sperm/Vol (P/Vol)	The number of Motile Sperm in the whole sample - Postvasectomy(P)
<input checked="" type="checkbox"/> # Total Sperm (P)	The number of Total Sperm - Postvasectomy(P)
<input checked="" type="checkbox"/> # Total Sperm/Vol (P/Vol)	The number of Total Sperm in the whole sample - Postvasectomy(P)
<input checked="" type="checkbox"/> % Normal Forms (C)	Manual Entry of Normal Forms
<input checked="" type="checkbox"/> Abstinence (P of days)	Number of days since last ejaculation
<input checked="" type="checkbox"/> Agglutination	Degree of spermatozoa agglutination (+/++/+++)
<input checked="" type="checkbox"/> Spermatozoa (P/C)	Manual Entry of spermatozoa
<input checked="" type="checkbox"/> A1 Sperm (M)	Total of Sperm in sample (Millions)
<input checked="" type="checkbox"/> Appearances	Normal - Only, appearance experience
<input checked="" type="checkbox"/> Comments	Manual Entry of comments regarding the test, sample or results
<input checked="" type="checkbox"/> Comments - Duplicate (C)	Manual Entry of Comments - Duplicate
<input checked="" type="checkbox"/> Date Sample Collected	The date the sample was collected
<input checked="" type="checkbox"/> Date Sample Received	The date the sample was received
<input checked="" type="checkbox"/> Date Test Performed	Date test performed
<input checked="" type="checkbox"/> Fructose (mmol/L)	Manual Entry of Fructose in seminal plasma
<input checked="" type="checkbox"/> FSC (M/L)	Functional Sperm Concentration - Progressively Motile sperm with normal morphology (M/M)
<input checked="" type="checkbox"/> Functional Sperm (M)	Total of Functional Sperm in sample (Millions)
<input checked="" type="checkbox"/> Head Defects (C)	Manual Entry of Head Defects
<input checked="" type="checkbox"/> Immotility (C)	Normal - Sample liquefied within 1 hour of collection @ room temperature
<input checked="" type="checkbox"/> Location	% Normal Morphology (FSC 30 or 40°C, 40 (30°C))
<input checked="" type="checkbox"/> Motile - % Normal Forms (C)	Total of Motile Sperm in sample (Millions)
<input checked="" type="checkbox"/> Motile Sperm (M/Vol)	Motile (C)
<input checked="" type="checkbox"/> Motile Sperm/Vol (C)	Motile Sperm Concentration (M/M)
<input checked="" type="checkbox"/> MSC (M/L)	Manual Entry of Motile Sperm Defects
<input checked="" type="checkbox"/> Non-progressive Motility (C)	Non-progressive Motility (C)
<input checked="" type="checkbox"/> Non-progressive Motility (C)	The name of the physician entering the semen test
<input checked="" type="checkbox"/> Other	User input

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 (\geq , $<$, $=$, etc.).
- Enter the desired value.
- Click **APPLY** to enter.



System	Normal Range	
# Immot. Sperm/Vol		
# Immotile Sperm		
# Motile Sperm		
# Motile Sperm/Vol		
# Total Sperm		
# Total Sperm/Vol		
Abnormal Forms		
Abstinence		
Acrosome Test		
All Sperm	≥ 40	
Anti-Sperm Ab		
Collect to Test Time		
Cyto Droplets		
Fructose		
FSC	≥ 7	
Functional Sperm	≥ 14	
Head Defects		
Immature Cells		
Immotility		
Immunobead		

Normal Range Settings

Field: All Sperm (M) Symbol: \geq Number: 40

Apply Cancel

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.

Testing Facility: University Hospital City:

Address: 1234 Washington Blvd State:

Zip:

Phone Number: Fax Number:

☒ Show in Report

Apply Cancel

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.

SQA-V

SQA-V Set-up through V-Sperm (SQA-V version 2.48):

Two options are available from the Set-up > SQA-V buttons:

- **SQA-V Defaults:** Both the SQA-V system and control defaults can be set-up as follows:
 - Activate and connect both the SQA-V and V-Sperm
 - Go to the SQA-V **MAIN MENU** and select: **SERVICE >SERVICE DATA.**
- Click on: **SET-UP>SQA-V>SQA-V DEFAULTS** 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 Defaults

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**

- **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 for more information)
 - LES setting – use '1' if you operate in the U.S. or '2' if the system will be operating outside of the U.S.
 - Morphology Criteria (**WHO 3rd** or WHO 4th Strict)
 - Printing options: **automatically print test results/self test report on start-up.**
 - Printer type: Set only to **INK**

IVD

CE

data transfer may take several minutes!
Please wait.....

NOTE: Factory default settings are listed in **RED**.

Utilities

Self-Test Data

- **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.

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**

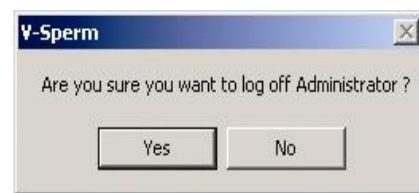
Motility Channel		Conc. Channel	
REF1	205 mV	REF2	2880 mV
LED CUR. 1	12 mA	LED CUR. 2	20.5 mA
AMPLITUDE	63 mV	CONC 1	0 M/ml
SMI	33	CONC 2	105.3 M/ml
ZERO LEVEL	520	CONC 3	449.8 M/ml

Algorithm				
MSC	66.1	M/ml	AREA	64
Conc.	449.8	M/ml	Motility	14.7 %
N. Morph	18.4	%	FSC	10.1 M/ml
Velocity	4	mic/sec	Number of Spike	61

SECTION 10: Log-Off

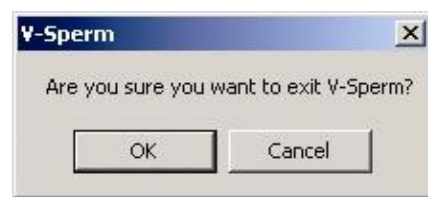
LOG-OFF V-Sperm by clicking the navigation button and confirming with a click.

- 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

To Exit – Click on the OK button.



SECTION 12: Install Software and Hardware

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

Phase 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.

Phase 3: Software Installation

- Step 1:** Insert the **V-Sperm** DOK into the PC → Double click on the installation file.
- 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.
- Step 5:** When the installation program is finished click **YES** to proceed.

Phase 4: MDAC Installation

- 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:** The computer will re-start and automatically begin installation.
- Step 5:** Click **YES** to proceed.



Phase 5: Collecting Information

- Step 1:** When the Welcome screen is displayed, click **Next** to proceed.
- Step 2:** The message "**Please wait, installation is looking for a previous version**" will be displayed.
- Step 3:** If a previous version is on the computer please proceed to "Phase 6: Import Data from a Previous Installation."
- Step 4:** Click **NEXT** when the default directory for V-Sperm is displayed.
- Step 5:** Click **NEXT** when the default name for V-Sperm is displayed.
- Step 6:** Click **Next** to begin copying files (all information required for installation has been gathered).

NOTE: Refer to the "System Requirements" section for details regarding the minimum requirements for running V-Sperm.

NOTE: Skip to Phase 3 if the MDAC message is not displayed

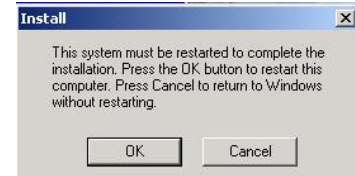
NOTE: It is highly recommended to use the manufacturer's automatic default settings.

Phase 6: Installation Process

- 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.

Phase 7: Installation Complete

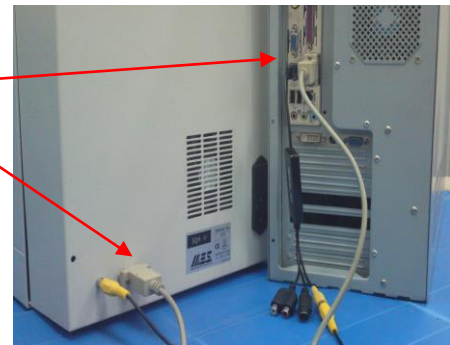
Click **OK** to restart the PC and complete the software installation.



NOTE: The RS232 communications cable is supplied with the SQA-V.

SQA-V Communications Cable

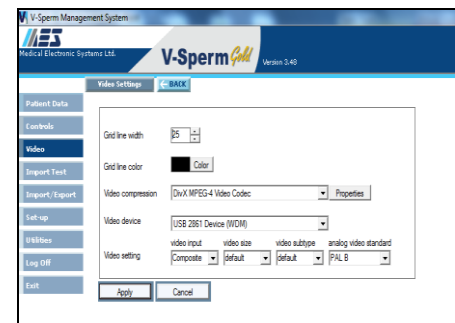
- Connect one end of the RS232 communications cable to the PC.
- Connect the other end of the RS232 communications cable to the SQA-V.



Communication cable connected

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.**



V-Sperm Video Settings Screen

WARNING: Close V-Sperm and any other open programs before beginning the uninstall process.

- 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 in order to fit the preferences of every individual.

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 that 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 the process is complete.

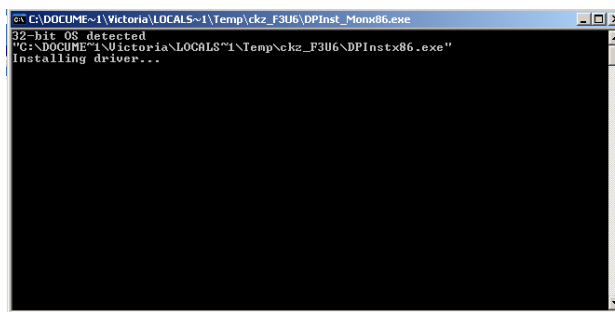
SECTION 14: Installation Instructions: USB to RS232 Converter General Description

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 the appropriate driver is automatically installed.

USB to RS232 Device Driver Installation

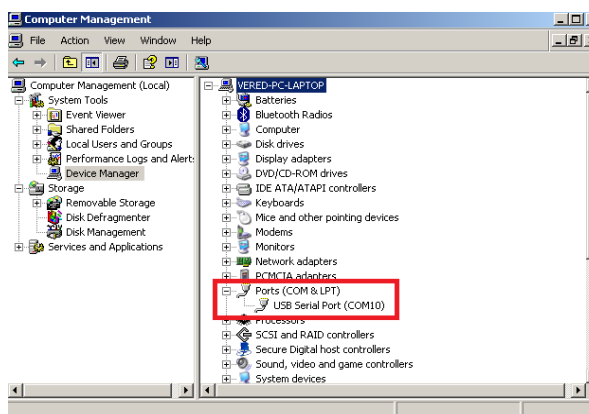
1. Close all open programs.
2. Insert the **USB to RS232 FTDI Drivers DOK** into the PC.
3. Double click on the installation file.
4. Wait a few seconds until the installation process is completed (the DOS window displayed below will disappear)



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).