



SQA-V LIS Interface Guide

For All Versions of SQA-V / V-Sperm

July 2018

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QwikLink™ LIS

SECTION 1: General Description

1.1. Background

The QWIKLINK™ LIS Interface is a Windows application, stand alone module that is activated upon start-up and continues to run in the background of the SQA-V/V-Sperm Gold system. The program retrieves data from the V-sperm data base and sends it to an external host via an RS232 connection.

1.2. Concept

The program, installed in the V-Sperm Gold folder, accesses the V-Sperm Gold database. The program searches for the text file: LMSPAR.TXT that is located in the application folder. This text file contains each and every parameter that can be retrieved from the data base.

The interval time for running the LIS Interface is set by the user. The default is five minutes. An icon will indicate when the program is running and when it is idle. The program will generate an error log file (error.log) when appropriate.

1.3. Document Overview

This document provides instructions for loading the LIS software, setting up the system defaults and installing the RS232 drivers.

SECTION 2: Installation

Phase 1: Communication cable:

RS232 connection

Connect one end of the RS232 communication cable to the V-Sperm computer and the other end of the cable to the Host computer as shown.

RS232 computer connection

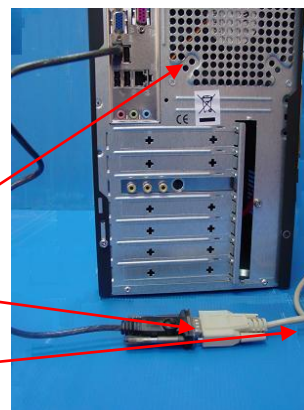


USB to RS232 Converter Cable

If there is no free RS232 port, use the USB to RS232 Converter Cable:

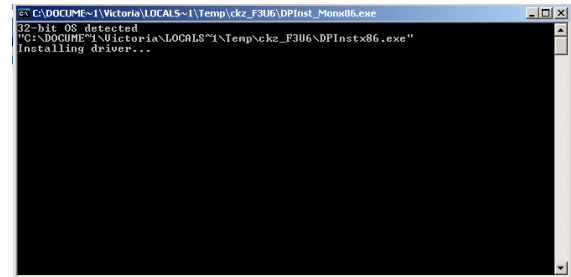
- Connect the other end of the USB to RS232 converter cable to the RS232 data cable that is connected to the Host computer, as shown below. (See Phase 1.1 for the USB to RS232 Converter installation instructions).

USB computer connection
USB to RS232 Converter Cable
RS232 Data Cable
(Connects to the Host Computer)



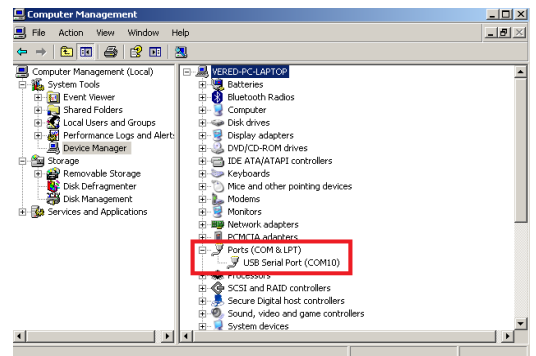
Phase 1.1: USB to RS232 Converter Cable Installation

1. Close all open programs.
2. Insert the **USB to RS232 FTDI Drivers CD** into the PC CD-ROM. Insert the USB Driver CD into the PC CD-ROM.
3. From the PC click: **START > RUN** and type in:
X:\Win200-XP-Vista\CDM 2.04.06.exe (X = letter of PC CD-ROM 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.



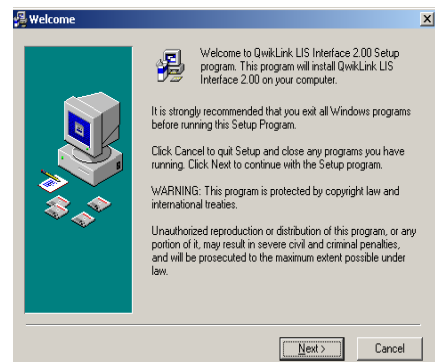
Verifying Proper Installation

6. Click on **START > RUN**
7. Type: **devmgmt.msc** and click **ENTER** in order to open the Device Manager.
8. Verify that the driver is installed (check to see the driver in the red boxed area displayed above).



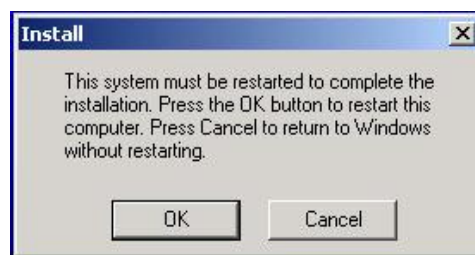
Phase 2: Software Installation:

1. Close all programs that are open and Re-boot the computer.
2. Insert the **QwikLink LIS Interface CD** into the PC CD-ROM. Installation will begin automatically. If installation fails to start automatically, Press Start->Run x:\Setup.exe (X is the letter of the PC CD-ROM drive).
3. The screen will display: **Initializing Wise Installation Wizard**
4. When the welcome screen is displayed, click **NEXT** to proceed.
5. Click **NEXT** to begin copying files.

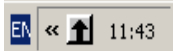


Phase 3: Installation Complete

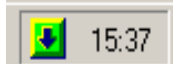
- Click **OK** to re-start the computer to complete the QWIKLINK™ LIS software installation.
- After re-start, the QWIKLINK™ LIS Interface Icon will appear indicating the software is running.
- See PHASE 5.1 below for settings.



A **gray** icon indicates the system is idling (not transferring data).



A **green** icon indicates the system is running and transferring data to the host computer.



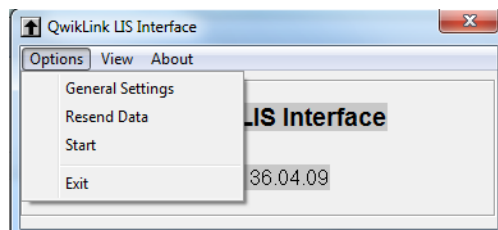
A **RED** icon indicates that an error occurred while transferring data. The system continues to transfer data but some data might be missed. For more details go to **View->Log Files -> Information**



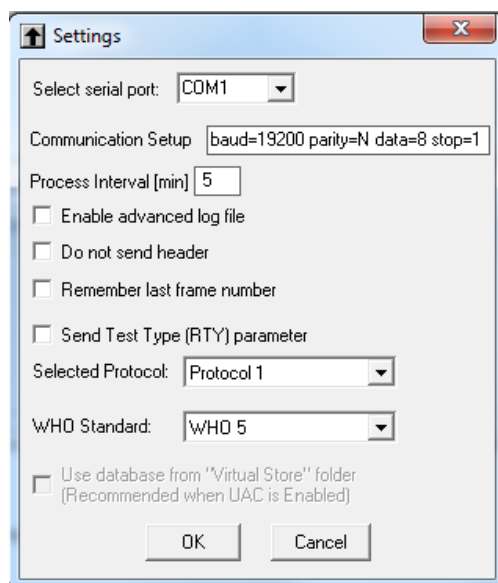
The 'General' settings screen opens after installation in order to provide an option to change the default settings.

Phase 4.1: General Settings

1. Right Click on the LIS Interface Icon to activate the drop down menu and click: **OPEN**
2. Select: **Options->General Settings**

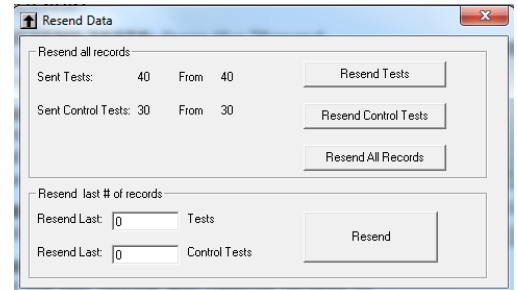


3. Select/Enter:
 - **COMMUNICATION PORT: DO NOT SELECT THE COM PORT THAT WAS DEFINED FOR V-SPERM.**
 - **PROCESS INTERVAL TIME:** Enter a number designating how often data should be transferred. The default is every 5 minutes.
 - **Enable advanced LOG FILE:** Enable/Disable the 'advanced' log file, which tracks transmitted data. The default is 'unselected'.
 - **SEND FACILITY HEADER:** Enable/ Disable 'facility data transmit'.
 - **REMEMBER LAST FRAME NUMBER:** Normally frame numbers restart from 0 in every session. It is optional to start each session with the last frame number used in the last session.
 - **SEND TEST TYPE (RTY) PARAMETER:** Enable/ Disable sending "Test Type" parameter(RTY). When changing to protocol 2 (Kaiser), the default option will be not to send this parameter.
 - **DATA TRANSFER PROTOCOL:** Select which protocol the data will be transferred; Default (Protocol 1) or Kaiser (Protocol 2). The manufacturer's default is Protocol 1.
 - **WHO STANDARD :** Select the WHO Standard for semen testing which matches the parameters transmitted. The default standard is WHO 5th.
 - **DATABASE LOCATION:** Enable using the data base "virtual store" location in case the computer UAC (User Account Control) settings is enabled.



Phase 4.2: Resend Data

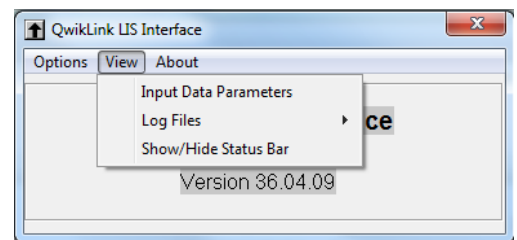
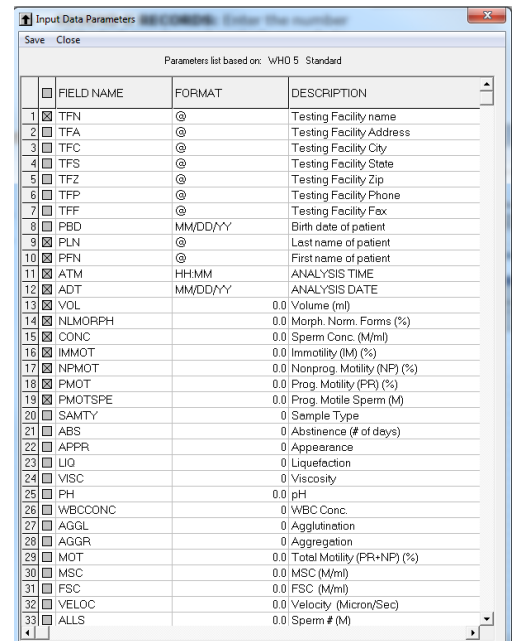
1. Select: **Options-> Resend Data**
2. Select/Enter:
 - **RESEND TESTS:** Press the "Resend Tests" button to resend all of the regular tests (not control tests).
 - **RESEND CONTROLS TESTS:** Press the "Resend Controls Tests" button to resend all of the controls tests (Without regular tests)
 - **RESEND ALL RECORDS:** Press "Resend All Records" to resend all records.
 - **RESEND LAST X OF RECORDS:** Enter the number of the last regular and controls records to retransmit. Then press the "Resend" button.



The screen RECORDS SETTINGS will close after pressing any of the resend buttons. Data will then be transferred automatically.

Phase 5.1: Input Data Parameters

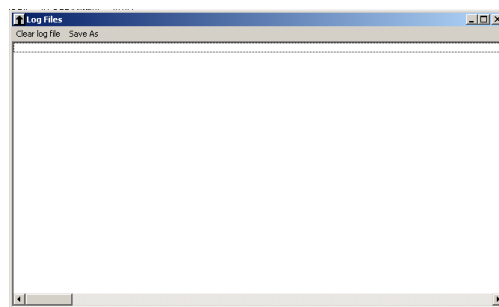
1. Right Click on the LIS Interface Icon to activate the drop down menu and click: OPEN
2. Select: **View->Input Data Parameters**
3. Select/Enter:
 - **INPUT DATA PARAMETERS TABLE :** Select/ deselect which parameter to transmit by pressing on the box to the left of the parameter row.

| FIELD NAME | FORMAT | DESCRIPTION |
|--|----------|--------------------------------|
| <input checked="" type="checkbox"/> 1 TFN | @ | Testing Facility name |
| <input checked="" type="checkbox"/> 2 TFA | @ | Testing Facility Address |
| <input checked="" type="checkbox"/> 3 TFC | @ | Testing Facility City |
| <input checked="" type="checkbox"/> 4 TFS | @ | Testing Facility State |
| <input checked="" type="checkbox"/> 5 TFZ | @ | Testing Facility Zip |
| <input checked="" type="checkbox"/> 6 TFP | @ | Testing Facility Phone |
| <input checked="" type="checkbox"/> 7 TFF | @ | Testing Facility Fax |
| <input checked="" type="checkbox"/> 8 PBD | MM/DD/YY | Birth date of patient |
| <input checked="" type="checkbox"/> 9 PLN | @ | Last name of patient |
| <input checked="" type="checkbox"/> 10 PFN | @ | First name of patient |
| <input checked="" type="checkbox"/> 11 ATM | HHMM | ANALYSIS TIME |
| <input checked="" type="checkbox"/> 12 ADT | MM/DD/YY | ANALYSIS DATE |
| <input checked="" type="checkbox"/> 13 VOL | | 0.0 Volume (ml) |
| <input checked="" type="checkbox"/> 14 NLMORPH | | 0.0 Morph. Norm. Forms (%) |
| <input checked="" type="checkbox"/> 15 CONC | | 0.0 Sperm Conc. (M/ml) |
| <input checked="" type="checkbox"/> 16 IMMOT | | 0.0 Immotility (IM) (%) |
| <input checked="" type="checkbox"/> 17 NPMOT | | 0.0 Nonprog. Motility (NF) (%) |
| <input checked="" type="checkbox"/> 18 PMOT | | 0.0 Prog. Motility (PR) (%) |
| <input checked="" type="checkbox"/> 19 PMOTSPE | | 0.0 Prog. Motile Sperm (M) |
| <input type="checkbox"/> 20 SAMTY | | 0 Sample Type |
| <input type="checkbox"/> 21 ABS | | 0 Abstinence (# of days) |
| <input type="checkbox"/> 22 APPR | | 0 Appearance |
| <input type="checkbox"/> 23 LIQ | | 0 Liquefaction |
| <input type="checkbox"/> 24 VISC | | 0 Viscosity |
| <input type="checkbox"/> 25 PH | | 0.0 pH |
| <input type="checkbox"/> 26 WBCCONC | | 0 WBC Conc. |
| <input type="checkbox"/> 27 AGGL | | 0 Agglutination |
| <input type="checkbox"/> 28 AGGR | | 0 Aggregation |
| <input type="checkbox"/> 29 MOT | | 0.0 Total Motility (PR+NF) (%) |
| <input type="checkbox"/> 30 MSC | | 0.0 MSC (M/ml) |
| <input type="checkbox"/> 31 FSC | | 0.0 FSC (M/ml) |
| <input type="checkbox"/> 32 VELOC | | 0.0 Velocity (Micron/Sec) |
| <input type="checkbox"/> 33 ALLS | | 0.0 Sperm # (M) |

Phase 5.3: Information Log File

1. Select: **View->Log Files->Information**
 - **INFORMATION LOG FILE** : Displays information about user usage

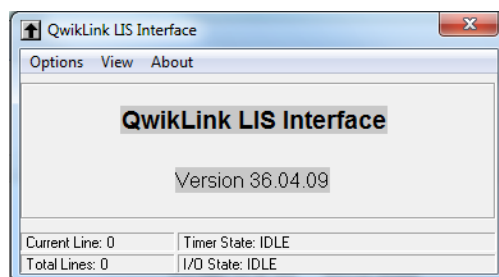


Phase 5.4: Transferred Data Log File

1. Select: **View->Log Files->Transferred data**
 - **ENABLE ADVANCED LOG FILE** : If checked in the "General Settings", the transmitted data will be shown.

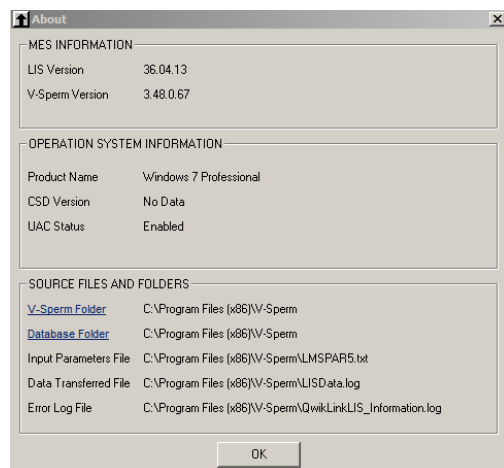
Phase 5.5: Show/Hide Status Bar

1. Select: **View->Show/Hide Status Bar**
 - **TRANSMITTED LINE NUMBER**: Shows the current and total number of lines that will be transmitted.
 - **SOFTWARE INTERNAL STAGES**: Displays information (for technical support) about the internal stages of the timer and the I/O.



Phase 6: About

1. Select: **About**
 - **MES INFORMATION**: Display the version of the current V-Sperm and Qwiklink LIS.
 - **OPERATION SYSTEM INFORMATION**: Displays details about the current PC (type, CSD version and UAC status).
 - **SOURCE FILES AND FOLDERS**: Display the location of various files and folders related to V-Sperm and Qwiklink LIS (press the "V-Sperm Folder" or "Database Folder" to open them).



SECTION 3: QwikLink LIS Interface

Phase 1: QwikLink LIS Concept Review

- ✦ The QwikLink LIS is installed in the V-Sperm Gold folder and accesses the V-Sperm Gold database.
- ✦ The program searches for the text file: LMSPAR.TXT that is located in the application folder. This text file contains each and every parameter that can be retrieved from the data base.
- ✦ The interval time for running the LIS Interface is set by the user. The default is five minutes.
- ✦ An icon will indicate when the program is running and when it is idle.
- ✦ The program will generate an error log file (QwikLinkLIS_Information.log) when appropriate.

Phase 2: Dependencies

- ✦ MES V-Sperm Gold software 3.49/3.48/3.60 is required

Phase 3: Development Environment

- ✦ Visual Basic

Phase 4: Error Messages

ERROR 1

- No response to the enquiry sent to the HOST indicating a communication error
- The program will be closed

ERROR 2

- The checksum calculated by the HOST does not match the SQA-V five consecutive times indicating a data transfer problem.
- The program will be closed

ERROR 3

- The HOST does not acknowledge that the transfer is complete indicating a communication error
- The program will set the status to IDLE

ERROR 4

- Wrong character at the beginning acknowledged from the HOST indicating a problem with data transfer
- The program will set the status to IDLE

ERROR 5

- Wrong character at the end acknowledged from the HOST indicating a problem with data transfer
- The program will set the status to IDLE

ERROR 99

- Internal function problem
- Write 99 in the log and document the name of the function
- The program will be closed



Phase 5: Input Parameter File

File name: LMSPAR3/4/5.TXT (Appendix 1.0)

This parameter file is a CSV format text file. Each parameter contained in this file is further described/defined by the following five fields.

- TRANSFER OPTIONS to the HOST - mark each parameter with the following indicator:
 - [1] Indicates that the parameter is to be transferred.
 - [0] Indicates that the parameter will not be transferred.
- FIELD CODE
- FIELD DATABASE SOURCE
- FIELD FORMAT
- FIELD DESCRIPTION
- MESSAGE TYPE INDICATOR – each parameter is marked with the following indicator:
 - [H] Indicates a Facility Data parameter.
 - [P] Indicates a Patient Data parameter.
 - [O] Indicates a Test Data parameter.
- GROUP TYPE INDICATOR – each parameter is marked with the following indicator:
 - [0] Header Parameters
 - [1] Archive Parameters
 - [2] Controls Parameters

Phase 6: User Interface

Settings

- Serial Port*
- Process Interval

*The serial port definitions are set to: Baud Rate = 19200; Data Bits =8; Parity = None; Stop Bits = 1; Flow Control = None

Start (Initiate data-transfer process)

Exit

Phase 7: Tray Menu

Open

Exit



Appendix 1.0 – Field List

| Transfer Flag | Field Code | Field Name in MES Data Base | Format | Description | Msg Type | Rec. Type | WHO Type |
|-------------------------------------|------------------------|-----------------------------|----------|---|----------|-----------|----------|
| Facility Data | | | | | | | |
| AUTOMATIC | | MESSQALISV2.0 | | Header | H | 0 | 3/4/5 |
| AUTOMATIC | FIC | Fields count | 0 | # Fields in 1 record transferred to LIS | H | 0 | 3/4/5 |
| 1 or 0 | TFN¹ | TF_Name | String | Testing Facility name | H | 0 | 3/4/5 |
| 1 or 0 | TFA | Address | String | Testing Facility address | H | 0 | 3/4/5 |
| 1 or 0 | TFC | City | String | Testing Facility City | H | 0 | 3/4/5 |
| 1 or 0 | TFS | State | String | Testing Facility State | H | 0 | 3/4/5 |
| 1 or 0 | TFZ | ZIP | String | Testing Facility ZIP | H | 0 | 3/4/5 |
| 1 or 0 | TFP | Phone | String | Testing Facility Phone | H | 0 | 3/4/5 |
| 1 or 0 | TFF | Fax | String | Testing Facility Fax | H | 0 | 3/4/5 |
| Patient Data | | | | | | | |
| AUTOMATIC | PID | PatientID | String | Number identifying the patient | P | 1 | 3/4/5 |
| AUTOMATIC | RTY | Record Type | 0 | Record Type: 0 –Test 1 – Control | P | 1 | 3/4/5 |
| AUTOMATIC | FIC | Fields count | 0 | # Fields in 1 record transferred to LIS | P | 1 | 3/4/5 |
| 1 or 0 | PFN | FirstName | String | First name of patient | P | 1 | 3/4/5 |
| 1 or 0 | PLN | LastName | String | Last name of patient | P | 1 | 3/4/5 |
| 1 or 0 | PBD | BirthDate | String | Birth date of patient | P | 1 | 3/4/5 |
| Test/Sample Identifying Data | | | | | | | |
| AUTOMATIC | SN# | Serial_Number | String | SQA-V system serial number | O | 1 | 3/4/5 |
| AUTOMATIC | SID | SampleID | String | Semen sample identification number | O | 1 | 3/4/5 |
| AUTOMATIC | FIC | Fields count | 0 | # Fields in 1 record transferred to LIS | O | 1 | 3/4/5 |
| 1 or 0 | ATM | TestTime | HH:MM | Time the test was run | O | 1 | 3/4/5 |
| 1 or 0 | ADT | TestDate | MM/DD/YY | Date the test was run | O | 1 | 3/4/5 |
| 1 or 0 | TOP | OrderingPhysician | String | Name of the MD ordering the test | O | 1 | 3/4/5 |
| 1 or 0 | TAS | Authoring | String | Lab person authorizing test results | O | 1 | 3/4/5 |
| 1 or 0 | TPB | PersonPerformTest | String | Lab person performing the test | O | 1 | 3/4/5 |
| 1 or 0 | ABS | Abstinence | 0 | Abstinence (# of days) | O | 1 | 3/4/5 |
| 1 or 0 | VOL | Volume | 0.0 | Volume of the semen sample | O | 1 | 3/4/5 |
| 1 or 0 | COLLDATE | Collected_Date | MM/DD/YY | Date Sample Collected | O | 1 | 3/4/5 |
| 1 or 0 | COLLTIME | Collected_Date | HH:MM | Time Sample Collected | O | 1 | 3/4/5 |
| 1 or 0 | RECEDATE | Received_Date | MM/DD/YY | Date Sample Received | O | 1 | 3/4/5 |
| 1 or 0 | RECETIME | Received_Date | HH:MM | Time Sample Received | O | 1 | 3/4/5 |
| 1 or 0 | SAMTY | SampleIndex | 0 | Normal, Washed, Frozen, Post-Vasectomy | O | 1 | 3/4/5 |
| 1 or 0 | COMMEN | Comments_m | String | Comments from the lab | O | 1 | 3/4/5 |
| 1 or 0 | MORPHINDEX | MorphologyCriteriaIndex | 0 | Morphology Type | O | 1 | 3/4 |
| 1 or 0 | APPR | Appearance | 0 | Appearance | O | 1 | 3/4/5 |

¹ The Transfer-Flag of the highlighted parameters is set to 1 by default.



| Transfer Flag | Field Code | Field Name in MES Data Base | Format | Description | Msg Type | Rec. Type | WHO Type |
|---|-------------|-----------------------------|--------|--|----------|-----------|----------|
| 1 or 0 | LIQ | Liquefaction | 0 | Liquefaction | O | 1 | 3/4/5 |
| 1 or 0 | VIS | Viscosity | 0 | Viscosity | O | 1 | 3/4/5 |
| 1 or 0 | AGGL | AgglutinationIndex | 0 | Agglutination | O | 1 | 3/4/5 |
| 1 or 0 | AGGR | AggregationIndex | 0 | Aggregation | O | 1 | 3/4/5 |
| 1 or 0 | STAND | Chamber | 0 | Sperm Conc. Chamber Standard | O | 1 | 3/4/5 |
| Automated Test Data | | | | | | | |
| 1 or 0 | NLMORPH | Morphology | 0.0 | % Normal Morphology (WHO 5th) | O | 1 | 3/4/5 |
| 1 or 0 | CONC | TSC | 0.0 | Total Sperm Concentration (M/ml) | O | 1 | 3/4/5 |
| 1 or 0 | MSC | MSC | 0.0 | Motile Sperm Concentration | O | 1 | 3/4/5 |
| 1 or 0 | MOT | Motility | 0.0 | Total Motility (PR+NP) (%) | O | 1 | 3/4/5 |
| 1 or 0 | PMOT | PMOTA | 0.0 | Progressive Motility (PR) | O | 1 | 5 |
| 1 or 0 | RPMOT | PMOTA | 0.0 | % Rapid Progressive Motile Sperm (a) | O | 1 | 3/4 |
| 1 or 0 | SPMOT | PMOTB | 0.0 | % Slow Progressive Motile Sperm (b) | O | 1 | 3/4 |
| 1 or 0 | NPMOT | Nonprog_Motility | 0.0 | Nonprogressive Motility (%) | O | 1 | 3/4/5 |
| 1 or 0 | IMMOT | Immotility | 0.0 | Immotility (%) | O | 1 | 3/4/5 |
| 1 or 0 | FSC | FSC | 0.0 | Functional Sperm Concentration | O | 1 | 3/4/5 |
| 1 or 0 | PMSCA | PMSCA | 0.0 | Progressively Motile Sperm Conc (M/ml) | O | 1 | 3/4/5 |
| 1 or 0 | PMSCB | PMSCB | 0.0 | Progressively Motile Sperm Conc (b) M/ml | O | 1 | 3/4 |
| 1 or 0 | VELOC | Average_Velocity | 0.0 | Velocity of the Sperm (Micron/Sec) | O | 1 | 3/4/5 |
| 1 or 0 | ALLS | All_Sperm | 0.0 | Sperm # (M) | O | 1 | 3/4/5 |
| 1 or 0 | MOTSPE | Motile_Sperm | 0.0 | Motile Sperm (M) | O | 1 | 3/4/5 |
| 1 or 0 | PMOTSPE | Prog_Motile_Sperm | 0.0 | Prog. Motile Sperm (M) | O | 1 | 3/4/5 |
| 1 or 0 | FUNCSPE | Functional_Sperm | 0.0 | Functional Sperm (M) | O | 1 | 3/4/5 |
| 1 or 0 | TMORPH | Total_Morph | 0.0 | Morph. Normal Sperm (M) | O | 1 | 3/4/5 |
| 1 or 0 | SMI | SMI | 0.0 | Sperm Motility Index | O | 1 | 3/4/5 |
| 1 or 0 | PH | PH | 0.0 | PH of the semen | O | 1 | 3/4/5 |
| 1 or 0 | WBCCONC | WBC_Concentration | 0 | WBC Concentration in the semen | O | 1 | 3/4/5 |
| Post-Vasectomy Automated Test Data | | | | | | | |
| 1 or 0 | HSMOT | HS_Motile | 0.0 | # Motile Sperm (PV) | O | 1 | 3/4/5 |
| 1 or 0 | HSIMM | HS_Immotile | 0.0 | # Immotile Sperm (PV) | O | 1 | 3/4/5 |
| 1 or 0 | HSTOTMOT | HS_Total_Motile | 0.0 | # Motile Sperm/Vol M/Vol (PV) | O | 1 | 3/4/5 |
| 1 or 0 | HSTOTMOTIMM | HS_Total_Motile_Immotile | 0.0 | # Total Sperm/Vol M/Vol (PV) | O | 1 | 3/4/5 |
| 1 or 0 | HSTOTIMM | HS_Total_Immotile | 0.0 | # Immotile Sperm/Vol M/Vol (PV) | O | 1 | 3/4/5 |
| 1 or 0 | HSTOTSPE | HS_Total_Sperm | 0.0 | # Total Sperm (PV) | O | 1 | 3/4/5 |
| Manual Test Data | | | | | | | |
| 1 or 0 | AGLUC | a_glucos_m | 0.0 | a-glucosidase (mU) | O | 1 | 3/4/5 |
| 1 or 0 | FRUC | FructSemPlas_m | 0.0 | Fructose (mmol/ejac.) | O | 1 | 3/4/5 |
| 1 or 0 | ZINC | Zinc_m | 0.0 | Zinc (mmol/ejac.) | O | 1 | 3/4/5 |
| 1 or 0 | NORFOR | Normal_Forms_m | 0.0 | Morphology % Normal Forms (%) | O | 1 | 3/4/5 |
| 1 or 0 | HEADDEF | Head_Defects_m | 0.0 | Morphology Head Defects (%) | O | 1 | 3/4/5 |
| 1 or 0 | NEAKMID | Neck_Midpiece_Defects_m | 0.0 | Morphology Neck/Midpiece (%) | O | 1 | 3/4/5 |
| 1 or 0 | TAILDEF | Tail_Defects_m | 0.0 | Morphology Tail Defects (%) | O | 1 | 3/4/5 |
| 1 or 0 | CYTOP | Cytop_drop_m | 0.0 | Morphology Cytoplasmic Droplets (%) | O | 1 | 3/4/5 |
| 1 or 0 | PINHEAD | Pinheads_m | 0.0 | Morphology Pinheads (%) | O | 1 | 3/4/5 |
| 1 or 0 | ROUNCELL | Round_cells | 0.0 | Round cells (M/ml) | O | 1 | 3/4/5 |
| 1 or 0 | VIAB | Vitality | 0.0 | Viability (%) | O | 1 | 3/4/5 |
| 1 or 0 | RBC | RBC | 0.0 | Red Blood Cells (M/ml) | O | 1 | 3/4/5 |
| 1 or 0 | OTH | Other_m | 0.0 | Other | O | 1 | 3/4/5 |



| Transfer Flag | Field Code | Field Name in MES Data Base | Format | Description | Msg Type | Rec. Type | WHO Type |
|--------------------------|------------|-----------------------------|----------|--|----------|-----------|----------|
| Main Control Data | | | | | | | |
| AUTOMATIC | SID | Serial_Number | String | Number identifying the device | P | 2 | 3/4/5 |
| AUTOMATIC | RTY | Record Type | 0 | Record Type: 0 –Test 1 – Control | P | 2 | 3/4/5 |
| AUTOMATIC | FIC | Fields count | 0 | # Fields in 1 record transferred to LIS | P | 2 | 3/4/5 |
| Controls Data | | | | | | | |
| AUTOMATIC | FIC | Fields count | 0 | # Fields in 1 record transferred to LIS | O | 2 | 3/4/5 |
| 1 or 0 | CTM | QC_DateTime | HH:MM | Time the control test was run | O | 2 | 3/4/5 |
| 1 or 0 | CDT | QC_DateTime | MM/DD/YY | Date the control test was run | O | 2 | 3/4/5 |
| 1 or 0 | CLE | Control_Level | 0 | Control Level: 1 – Level 1 2 – level 2 3 – Negative Control | O | 2 | 3/4/5 |
| 1 or 0 | CTY | Control_Type | 0 | Control Type: 0 - Latex-beads 1 - Stabilized Sperm CAP 2 - Stabilized Sperm MES | O | 2 | 3/4/5 |
| 1 or 0 | LOT | Lot | String | Lot Number | O | 2 | 3/4/5 |
| 1 or 0 | EXD | Exp_Date | MM/YY | Expire Date | O | 2 | 3/4/5 |
| 1 or 0 | TAR | Target_Val | 0.0 | Target Value | O | 2 | 3/4/5 |
| 1 or 0 | RAN | Target_Perc | 0.0 | Range +/- | O | 2 | 3/4/5 |
| 1 or 0 | CTS | Control_TSC | 0.0 | Conc. Results | O | 2 | 3/4/5 |
| 1 or 0 | RST | Over_Range | 0 | Range Status Empty-Normal 0-High 1- Low | O | 2 | 3/4/5 |
| 1 or 0 | COA | Correction | 0.0 | Corrective Action | O | 2 | 3/4/5 |
| 1 or 0 | CMSC | MSC | 0.0 | MSC | O | 2 | 3/4/5 |



Appendix 2.0 – Data Flow Protocol

Once the system is installed, the host computer acts as a “listener” and responds to messages sent from the SQA-VISION computer. The “listener” responds with an “acknowledge” to confirm whether the data was accepted correctly.

Phase 1: Message structure

Three types of messages, with unique fields, can be sent to the host computer:

1. Facility Data [H]
2. Patient Data [P]
3. Test Data [O] for a specific Patient

A message is composed of several delimited components. Two levels of delimiter are used – vertical bar (|) as the primary, and caret (^) as the secondary. The primary delimiter (|) comes before the parameter name, and the secondary delimiter (^) comes before and after the parameter value i.e. |SID^123456789^

Phase 1.1: Protocol 1

The message structure contains the following items:

1. [STX]
2. Frame number: 0-7
3. Message type indicator: (H) for Facility Data, (P) for Patient Data, (O) for Test Data.
4. List of fields and values, separated by primary (|) and secondary (^) delimiters. As indicated before, each type of message has it’s own unique fields (See Appendix 1.0 – Field list).
5. [ETX]
6. Check Sum number.
7. [CR]
8. [LF]

ASCII Values:

[STX] = 2, [ETX] = 3, [ACK] = 6, [LF] = 10, [CR] = 13, [NAK] = 21

Example: [STX]20|SN#^52^|SID^6^|FIC^1^|ATM^08:10^[ETX]8D[CR][LF]

| Primary / Secondary Piece | Description | Example |
|---------------------------|--|------------|
| 1 | [STX] – marks the beginning of the message | STX |
| 2 | Frame Number | 2 |
| 3 | Message type indicator | O |
| 4 | Parameter Name: Serial Number Field Code: SN# Field value: 52 | SN#^52^ |
| 5 | Parameter Name: Sample Number Field Code: SID Field value: 6 | SID^6^ |
| 6 | Parameter Name: field count -Number of result fields to follow Field Code: FIC Field value: 1 | FIC^1^ |
| 7 | Parameter Name: Test Time Field Code: ATM Field value: 08:10 | ATM^08:10^ |
| 8 | [ETX] – marks the end of the fields list | ETX |
| 9 | Check Sum Number(HEX) | 8D |
| 10 | [CR] | CR |
| 11 | [LF] | LF |



Phase 1.1.1: Host Response

The host must respond with [ACK] character to confirm that the data was accepted correctly and with a [NAK] in cases where erroneous data is received.

Phase 1.1.2: Message Order

The order in which the messages are sent to the computer is as follows:

1. First, the **Facility Data** [H].
2. Second, the **Patient Data** [P].
3. Last, the **Test Data** [O] relevant to the first patient and all subsequent patients in the queue is sent until all of the Test Data messages for all of the Patients are successfully transferred to the LIS.

Phase 1.1.3: Frame Number

For each message, the first character after the [STX] is a number between 0 and 7. This number is the Frame Number. The Frame Number is increased by 1 each time a message is successfully sent. When the Frame Number reaches the value of 7, the Frame Number will reset to 0.

If the message has not been sent successfully (Received [NAK] from Host) it will be resent with the same Frame Number. As stated above (section 9.2) after five consecutive [NAK] are sent, the MES V-Sperm Gold Computer discards the transaction to prevent an endless loop.

Phase 1.1.4: Example

Below is an example of the MES V-Sperm and Host computer communication:

MES V-Sperm Gold Computer:

[STX]0H|MES SQA-V|FIC^2^|TFN^Keiser^|TFC^New York^[ETX]52[CR][LF]

HOST:

[ACK]

MES V-Sperm Gold Computer:

[STX]1P|PID^173^|RTY^0^|FIC^1^|PBD^07/08/78^[ETX]19[CR][LF]

HOST:

[ACK]

MES V-Sperm Gold Computer:

[STX]2O|SN#^52^|SID^6^|FIC^5^|ATM^08:07^|ADT^10/26/06^|VOL^6.0^|
NLMORPH^^|CONC^114.8^[ETX]A1[CR][LF]

HOST:

[ACK]

MES V-Sperm Gold Computer:

[STX]3O|SN#^52^|SID^7^|FIC^5^|ATM^09:20^|ADT^10/26/06^|VOL^6.0^|
NLMORPH^^|CONC^321.8^[ETX]40[CR][LF]

HOST:

[ACK]

MES V-Sperm Gold Computer:

[STX]4P|SID^15^|RTY^1^|FIC^0^[ETX]A6[CR][LF]

HOST:

[ACK]

MES V-Sperm Gold Computer:

[STX]5O|FIC^8^|LOT^1^|EXD^01/00^|TAR^1.0^|RAN^1.0^|CTS^5.3^|RST^1^|COA^1^|
CMSC^^ETX33[CR][LF]

HOST:

[ACK]



Phase 1.2: Protocol 2 (Kaiser)

This specification has been updated to eliminate the initial [ENQ] / [ACK] sequence because it is not required. Whenever the LMS interface program is running it will be ready to receive data.

ASCII Values:

[STX] = 2, [ETX] = 3, [ACK] = 6, [LF] = 10, [CR] = 13, [NAK] = 21

| Primary / Secondary Piece | Description | Example Data |
|---------------------------|--|---------------------------------|
| 1 | Interface software version – used to verify that our software is written for the correct version of your interface. | MES SQA-V |
| 2 | Instrument Identifier – Used to uniquely identify the instrument in case in the future, the interface can send data from multiple instruments. | SN# 10550 |
| 3 | Test Type | 0 - Normal Test 1- Control Test |
| 3 | Specimen number | 123456789 |
| 4 | Number of result fields to follow | 10 |
| 5 | Result Field 1 | ATM^14:20^ |
| 5/1 | Assay Code | ATM |
| 5/2 | Result Value | 14:20 |
| 5/3 | Flag (for future use) | |
| 6-nn | Result Field 2 – Same as 5 | VOL^1.5^ |

Phase 1.2.1: Example

MES V-Sperm Gold Computer:

```
[STX]MES SQA V1.2|SN# 10550|
RTY^0^|123456789|9|ATM^14:20^|VOL^1.5^|NLMORPH^25^|CONC^20.5^|
NPMOT^14^|SPMOT^31^|RPMOT^77^|TPCOUNT^31^[ETX]96[CR][LF]
```

HOST:

```
[ACK]
```

Phase 2: Check Sum Calculation

Example:

```
[STX]10|SN#^52^|SID^3^|FIC^5^|ATM^07:41^|ADT^10/26/06^|VOL^5.0^|
|NLMORPH^^|CONC^125.3^[ETX]96[CR][LF]
```

A standard ASTM checksum calculation is used. The checksum calculation for the example above is displayed below:

1. Set $chksum = mod(chksum, 256)$; Extract the least significant 8 bits
2. Set $A = mod(chksum, 16)$; Extract the least significant 4 bits
3. Set $B = int(chksum / 16)$; Extract the most significant 4 bits

Based on the conditions below...

- The values of A and B are converted to HEX format
- The numbers 0 through 9 are unchanged
- The numbers 10 through 16 (decimal format) are converted to A through F (HEX format) resulting in 2 single-byte values.

...the Check Sum of the ASCII values is 6038

- The value associated with #1 (above) is 150 (the least significant 8 bits)
- The value associated with #2 (above) is 6 (the least significant 4 bits)



- The value associated with #3 (above) is 9 (the most significant 4 bits)

Comments:

1. The [STX], [CR] and [LF] values are not included in the checksum calculation
2. The check sum calculation used the [ETX] value as 3