



LIS Interface Guide

Version 2.00.8
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QwikLink™ LIS

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.

2. Installation

NOTE: All cables are supplied in the QwikLink kit.

Phase 1: Communication cable:

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 connection

RS232 computer connection



USB to RS232 Converter Cable

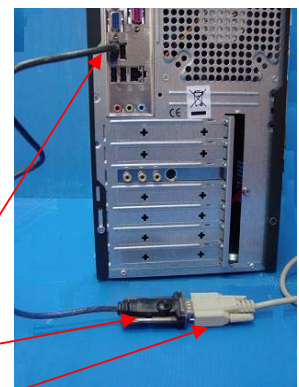
If there is no free RS232 port, use the USB to RS232 Converter Cable:

- Connect the USB end of the cable to the V-Sperm computer
- 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

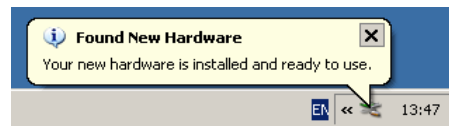
Windows XP

Windows XP Operating System

1. Close all programs that are open or running.
2. Insert the USB Driver CD into the PC CD-ROM.
3. Plug the USB to RS232 Converter Cable into a free USB port.
4. Now the "Welcome to the Found New Hardware" Wizard will appear, select "**No, not this time**", and click **NEXT**.
5. Choose "**Install the software automatically (Recommended)**" and click **NEXT**.
6. Click the "**Continue Anyway**" Button and when the "**Completing the Found New Hardware Wizard**" window is displayed, click **FINISH**



7. Check the bottom right corner of the screen – a message should appear "**Your new hardware is installed and ready to use**".



Windows 2000

Windows 2000 Operating System

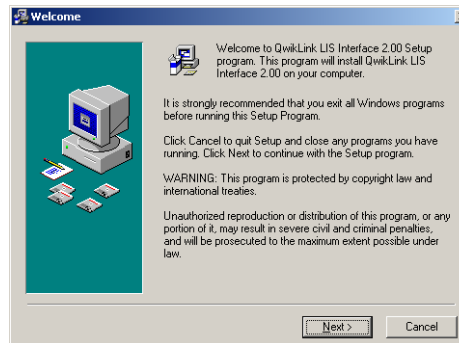
1. Close all programs that are open or running.
2. Insert the USB Driver CD into the PC CD-ROM.
3. Plug the USB to RS232 Converter Cable into a free USB port.
4. The "**Welcome to the Found New Hardware**" window will now appear, click **NEXT**.
5. Choose the "**Search for a suitable driver for my device (Recommended)**" option, and click **NEXT**.
6. The "**Locate Driver Files**" window is now displayed:
 - Check **only** the "CD-ROM drives" checkbox
 - Uncheck all other options
 - Confirm that the **USB Driver CD** is in the PC CD-ROM and click **NEXT**.
7. On the "**Driver Files Search Results**" click **NEXT**.
8. When the message "**Completing the Found New Hardware Wizard**" window is displayed, click **FINISH**.

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.**



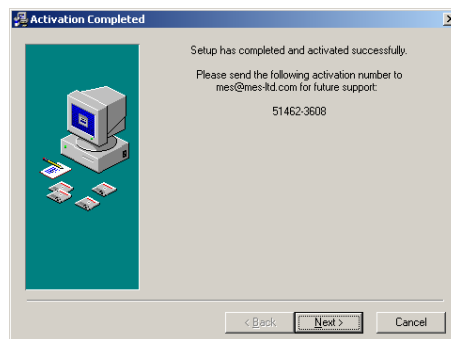
4. When the welcome screen is displayed, click **NEXT** to proceed.



5. Click **NEXT** to begin copying files.

Phase 3: Activation Completed

Each copy of QWIKLINK™ LIS is assigned a unique activation number specific to the computer it is installed on. Please note the activation number displayed and click **NEXT**. The activation number should be sent to mes@mes-ltd.com for future support.



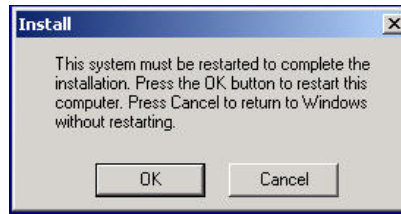
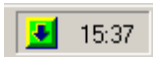
Phase 4: Installation Complete

Click **OK** to re-start the computer and complete the QWIKLINK™ LIS Interface software installation.

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



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

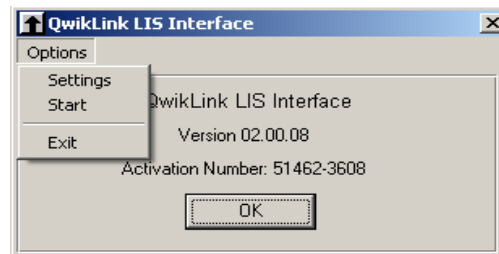


Once the system has been successfully re-started, the QWIKLINK™ LIS Interface Icon will appear on the Tray Icon indicating the software is running and its status.

The system will initiate a data transfer based on the interval timing that was defined in the program settings (see Phase 4).

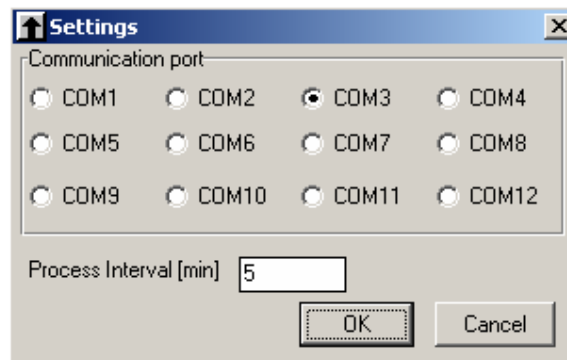
Phase 5: Setting the Communication Port

1. Right Click on the LIS Interface Icon located on the tray Icon to activate the drop down menu and click: **OPEN**



Attention:
 Do not select COM1 – this port is the default for V-Sperm

2. Navigate through the window menu to **Options->Settings**
3. Choose a COMMUNICATION PORT from the options displayed on the screen displayed below. **DO NOT SELECT COM1** because this is the V-Sperm port.
4. Enter the Process Interval time you would like (default is 5 minutes)





3. QwikLink LIS Interface

Phase 1: QwikLink LIS Concept Review

- The QwikLink LIS Interface 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 (error.log) when appropriate.

Phase 2: Dependencies

- MES V-Sperm Gold software 3.49/3.48 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: LMSPAR.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.

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
Facility Data					
AUTOMATIC		MESSQALISV2.0		Header	H
AUTOMATIC	FIC	Fields count	0	# Fields in 1 record transferred to LIS	H
1 or 0	TFN¹	TF_Name	String	Testing Facility name	H
1 or 0	TFA	Address	String	Testing Facility address	H
1 or 0	TFC	City	String	Testing Facility City	H
1 or 0	TFS	State	String	Testing Facility State	H
1 or 0	TFZ	ZIP	String	Testing Facility ZIP	H
1 or 0	TFP	Phone	String	Testing Facility Phone	H
1 or 0	TFF	Fax	String	Testing Facility Fax	H
Patient Data					
AUTOMATIC	PID	PatientID	String	Number identifying the patient	P
AUTOMATIC	FIC	Fields count	0	# Fields in 1 record transferred to LIS	P
1 or 0	PFN	FirstName	String	First name of patient	P
1 or 0	PLN	LastName	String	Last name of patient	P
1 or 0	PBD	BirthDate	String	Birth date of patient	P
Test/Sample Identifying Data					
AUTOMATIC	SN#	Serial_Number	String	SQA-V system serial number	O
AUTOMATIC	SID	SampleID	String	Semen sample identification number	O
AUTOMATIC	FIC	Fields count	0	# Fields in 1 record transferred to LIS	O
1 or 0	ATM	TestTime	HH:MM	Time the test was run	O
1 or 0	ADT	TestDate	MM/DD/YY	Date the test was run	O
1 or 0	TOP	OrderingPhysician	String	Name of the MD ordering the test	O
1 or 0	TAS	Authoring	String	Lab person authorizing test results	O
1 or 0	TPB	PersonPerformTest	String	Lab person performing the test	O
1 or 0	ABS	Abstinence	0	Abstinence (# of days)	O
1 or 0	VOL	Volume	0.0	Volume of the semen sample	O
1 or 0	COLLDATE	Collected_Date	MM/DD/YY	Date Sample Collected	O
1 or 0	COLLTIME	Collected_Date	HH:MM	Time Sample Collected	O
1 or 0	RECEDATE	Received_Date	MM/DD/YY	Date Sample Received	O
1 or 0	RECETIME	Received_Date	HH:MM	Time Sample Received	O
1 or 0	SAMTY	SampleIndex	0	Normal, Washed, Frozen, Post-Vasectomy	O
1 or 0	COMMEN	Comments_m	String	Comments from the lab	O
1 or 0	APPR	Appearance	0	Appearance	O
1 or 0	LIQ	Liquefaction	0	Liquefaction	O
1 or 0	VISC	Viscosity	0	Viscosity	O
1 or 0	AGGL	AgglutinationIndex	0	Agglutination	O
1 or 0	AGGR	AggregationIndex	0	Aggregation	O
1 or 0	STAND	Chamber	0	Sperm Conc. Chamber Standard	O
1 or 0	MORPHINDEX	MorphologyCriteriaIndex	0	Morphology: Kruger or WHO Standard	O

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
Automated Test Data					
1 or 0	NLMORPH	Morphology	0.0	% Normal Morphology	0
1 or 0	CONC	TSC	0.0	Total Sperm Concentration (M/ml)	0
1 or 0	MSC	MSC	0.0	Motile Sperm Concentration	0
1 or 0	MOT	Motility	0.0	% Motility (a+b+c)	0
1 or 0	RPMOT	PMOTA	0.0	% Rapid Progressive Motile Sperm (a)	0
1 or 0	SPMOT	PMOTB	0.0	% Slow Progressive Motile Sperm (b)	0
1 or 0	NPMOT	Nonprog_Motility	0.0	% Non Progressive Motile Sperm (c)	0
1 or 0	IMMOT	Immotility	0.0	% Immotile Sperm (d)	0
1 or 0	FSC	FSC	0.0	Functional Sperm Concentration	0
1 or 0	PMSCA	PMSCA	0.0	Progressively Motile Sperm Conc (a) (M/ml)	0
1 or 0	PMSCB	PMSCB	0.0	Progressively Motile Sperm Conc (b) (M/ml)	0
1 or 0	VELOC	Average_Velocity	0.0	Velocity of the Sperm (Micron/Sec)	0
1 or 0	PCOUNT	Prog_Motile_Sperm	0.0	Total # of Progressive Motile Sperm	0
1 or 0	ALLS	All_Sperm	0.0	Total # Sperm in the sample (M)	0
1 or 0	MOTSPE	Motile_Sperm	0.0	Motile Sperm (a+b+c) (M/Ejac.)	0
1 or 0	PMOTSPE	Prog_Motile_Sperm	0.0	Prog. Motile Sperm (a+b) (M)	0
1 or 0	FUNCSPE	Functional_Sperm	0.0	Functional Sperm (M)	0
1 or 0	SMI	SMI	0.0	Sperm Motility Index	0
1 or 0	PH	PH	0.0	PH of the semen	0
1 or 0	WBCCONC	WBC_Concentration	0	WBC Concentration in the semen	0
Post-Vasectomy Automated Test Data					
1 or 0	HSMOT	HS_Motile	0.0	# Motile Sperm (PV)	0
1 or 0	HSIMM	HS_Immotile	0.0	# Immotile Sperm (PV)	0
1 or 0	HSTOTMOT	HS_Total_Motile	0.0	# Motile Sperm/Vol M/Vol (PV)	0
1 or 0	HSTOTMOTIMM	HS_Total_Motile_Immotile	0.0	# Total Sperm/Vol M/Vol (PV)	0
1 or 0	HSTOTIMM	HS_Total_Immotile	0.0	# Immotile Sperm/Vol M/Vol (PV)	0
1 or 0	HSTOTSPE	HS_Total_Sperm	0.0	# Total Sperm (PV)	0
Manual Test Data					
1 or 0	AGLUC	a_glucos_m	0.0	a-glucosidase (mU)	0
1 or 0	FRUC	FructSemPlas_m	0.0	Fructose (mmol/l)	0
1 or 0	ZINC	Zinc_m	0.0	Zinc (mmol/l)	0
1 or 0	NORFOR	Normal_Forms_m	0.0	Morphology % Normal Forms (%)	0
1 or 0	HEADDEF	Head_Defects_m	0.0	Morphology Head Defects (%)	0
1 or 0	NEAKMID	Neck_Midpiece_Defects_m	0.0	Morphology Neck/Midpiece (%)	0
1 or 0	TAILDEF	Tail_Defects_m	0.0	Morphology Tail Defects (%)	0
1 or 0	CYTOP	Cytop_drop_m	0.0	Morphology Cytoplasmic Droplets (%)	0
1 or 0	PINHEAD	Pinheads_m	0.0	Morphology Pinheads (%)	0
1 or 0	ROUNCELL	Round_cells	0.0	Round cells (M/ml)	0
1 or 0	VIAB	Vitality	0.0	Viability (%)	0
1 or 0	RBC	RBC	0.0	Red Blood Cells (M/ml)	0
1 or 0	OTH	Other_m	0.0	Other	0



Appendix 2.0 – Data Flow Protocol

The data to be sent from the SQA-V V-Sperm Gold computer to the host computer must first be selected based on the instructions in section 5.2 TRANSFER OPTIONS TO THE HOST. A complete list of fields are listed in APPENDIX 1.0 FIELD LIST. A "0" or "1" will indicate which fields are selected.

Once the system is installed, the host computer acts as a "listener" and responds to messages sent from the V-Sperm Gold computer. The "listener" responds with an "acknowledge" to confirm whether the data was accepted correctly.

Phase 1: Message

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^

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]2O|SN#^52^|SID^6^|FIC^1^|ATM^08:10^[ETX]8D[CRLF]

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 2: 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 3: 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 4: 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 5: Message Communication

An example of the communication between the MES V-Sperm Gold Computer and the Host computer is displayed below:

MES V-Sperm Gold Computer:

```
[STX]0H|MESSQALISV2.0|FIC^2^|TFN^Keiser^|TFC^New York^[ETX]52[CR][LF]
```

HOST:

```
[ACK]
```

MES V-Sperm Gold Computer:

```
[STX]1P|PID^173^|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]
```

Phase 6: Check Sum Calculation

Example:

```
[STX]1O|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 $chksum = \text{mod}(chksum, 256)$; Extract the least significant 8 bits
2. Set $A = \text{mod}(chksum, 16)$; Extract the least significant 4 bits
3. Set $B = \text{int}(chksum / 16)$; 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



Appendix 3.0 – Getting Started Check List

Customer Required Information		Details	Done
1	Contact Information	Name, title, email, phone #	
2	Review Appendix 2.0 Section 9 and respond to MES contact:	<ul style="list-style-type: none"> ▪ RS232 connection supported? ▪ Will this protocol work? ▪ If no, please supply an alternative protocol 	
3	Review Appendix 1.0 Section 8 and select fields to be transferred to the LIS	<ul style="list-style-type: none"> ▪ Select fields by noting a "0" or "1" in the Transfer Flag column ▪ Determine if the MES lab values are the same as currently reported values (i.e. Progressive Motility) 	
MES Required Information			
1	Contact Information	<ul style="list-style-type: none"> ▪ Beni Cohen, Director R&D beni@mes-ltd.com Office: 011 972 4637-3981 Cell: 011 972 54-441-9484 ▪ Eric Carver, Manager Sales & Training eric@mes-llc.com Cell: 818 917-1074 Office: 310 557-9066 	
2	Completed Appendix 2.0	Protocol confirmed or revised written protocol received from customer	
3	Completed Appendix 1.0	All fields defined and selected	
ALL: Target Dates for Completion		Target Dates/Responsibility	
1	Phase 1: Final Data/Protocol Review		
2	Phase 2: Roles defined/Data selected		
3	Phase 3: Programming/Beta Testing		
4	Phase 4: Live Transfer		