BSE
B-Sperm™ & SQA-Vb

User Guide

Catalog # 7410

Version 2.0

May 2015

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Section 1: Overview

The SQA-Vb and B-Sperm™ bull BSE management software work together to provide an integrated system for bull breeding soundness evaluation (BSE).

Both the **physical examination and semen testing** elements of the BSE are included in the software and integrated into a final BSE report.

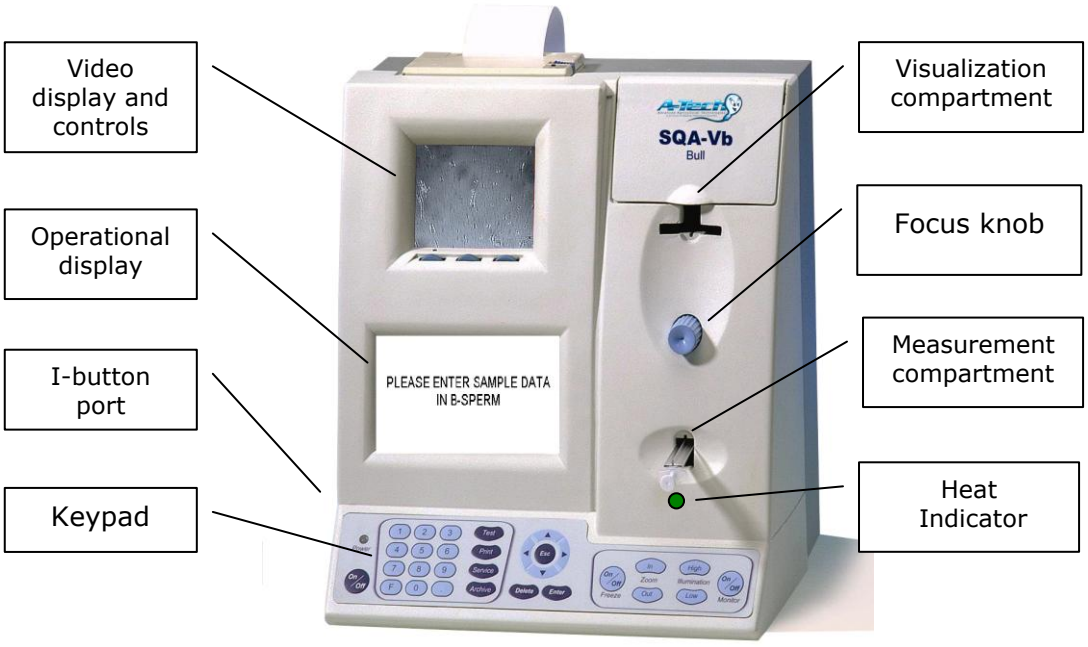
FRESH bull semen samples are prepared and aspirated into a multi-use, washable testing capillary. The capillary is inserted into the measurement compartment of the SQA-Vb where state of-the-art technology in electro-optics, computer algorithms and video microscopy produce rapid, accurate and precise analysis of the sample. Samples can be viewed using the on-board video visualization system with a magnification range of X300 through X500.

All bull/sample data entry, settings and reports are handled in the PC-based BSE management software. The following functions and features of the system are listed below:

- Rapid data entry that is updated during the testing process or from pre-set tables.
- Fast test results – Less than one minute is required to report all semen parameters. Perfect for high throughput.
- Easily assess morphology defects using the QwikClick™ feature.
- Herd data analysis (histograms).
- Numeric and graphical Bull information/reports.
- Bull semen samples can be viewed on a large PC screen (video or image) and images can be captured and stored with individual bull records.
- Report options: BSE, Test Report, Morphology (differential).

Section 2: SQA-Vb Overview

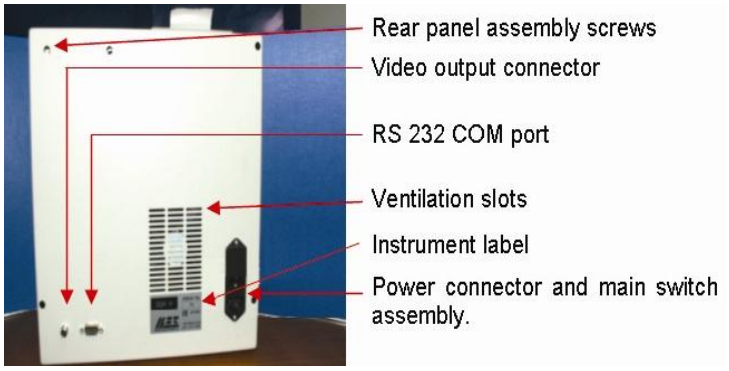
SQA-Vb



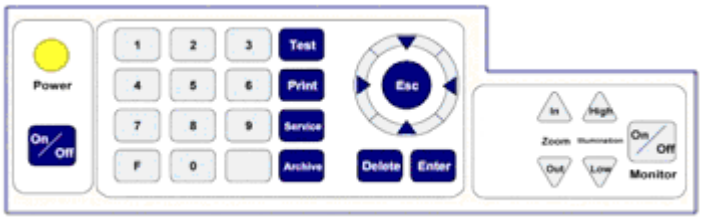
The Rear/Side Panel

I-button

The Rear Panel components are as follows:



Keypad and Navigation

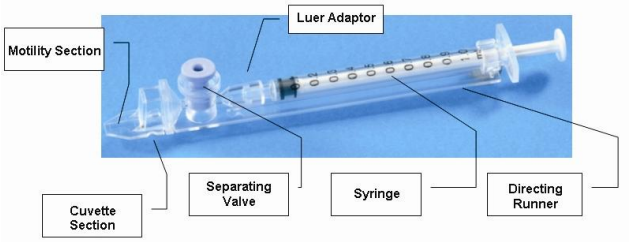


The SQA-Vb front panel Keypad is used for navigation of the SQA-Vb:

- Service Key = Opens the Service Menu.
- ARROW keys = To move within the Service Menu screen.
- ENTER = To select menu options and to move to the next screen.
- ESC = Return to a previous screen or row.
- ZOOM = Set the visualization magnification
- Other keys = Calibration/verification (for manufacturer's use only)

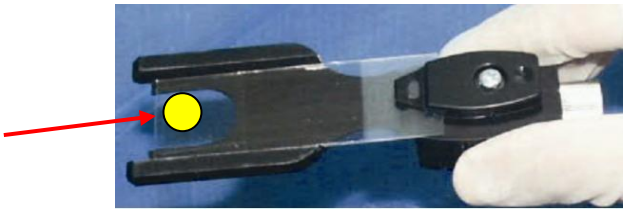
SQA-Vb Testing Capillary

The testing capillary consists of the following parts:



- Plastic, multi-use (animal use only), disposable.
- Can be used in either the SQA-Vb measurement or visualization chamber
- For capillary use/cleaning instructions, refer to the appendix section of this guide.

Slide Adaptor

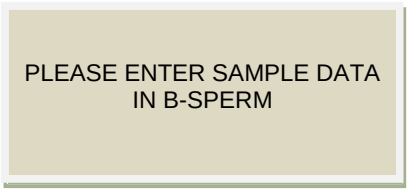


- Use a standard laboratory slide 76 x 25.6 mm and 22 x 22 mm cover-slip.
- Sample should be placed where indicated by the yellow dot.

Section 3: Start-up SQA-Vb

NOTE: Load I-button tests and set system date **PRIOR** to testing (see **SQA-Vb Service Menu** section for full instructions).

- Turn on the main switch on the rear panel of the SQA-Vb.
- Both the power and heater light on the front panel will illuminate.
- Press the On/Off key on the SQA-Vb keypad.
- The SQA-Vb will perform self-testing and then will display the **#** Tests Remaining
- When ready for testing samples, the SQA-Vb will display the following message:



Section 4: Start-up B-Sperm

WARNING: remember the new password or the system cannot be re-entered.

WARNING: Set-up system defaults prior to using B-Sperm

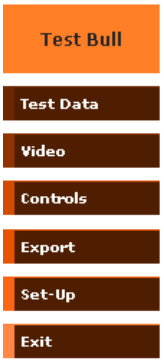
Click on the B-Sperm icon located on the PC desktop to enter the system.

- Enter the **temporary password: fertility** and then click OK.

- A screen for changing the password will appear, enter and confirm a new password.

Section 5: B-Sperm Navigation Overview

Seven navigation buttons allow easy access to the B-Sperm features.



Click one of SEVEN B-Sperm buttons to activate the features described below:

- **TEST BULL**: Initiate a new BSE report and test FRESH BULL SEMEN.
- **TEST DATA:** Activate and navigate from a grid that displays FRESH bull semen information such as test results, graphs, semen images/videos.
- **VIDEO**: View samples on the PC; and save sperm videos and pictures
- **CONTROLS**: Tests external quality control material, displays control data and reports.
- **EXPORT**: Export the test results and control archives to an Excel file.
- **SET-UP**: Define settings/content for the BSE Report, QwikClick™, sample cut-offs, semen normal ranges, languages, password and PC communication port.
- **EXIT:** Click to close B-Sperm.

Test Bull

Section 6: Test Bull

- Before testing for the first time or in the event of a change, update the default settings in B-Sperm (Please refer to the Set-up section).
- Turn on both the SQA-Vb and B-Sperm to begin BSE testing.

Click the **Test Bull** button and the screen below will be displayed:

ENTER:

- **OWNER NAME** and other information related to a given owner (first row).
- **BULL ID, NAME** (if required), **BIRTH DATE** (**AGE** will be calculated automatically) and **BREED**.

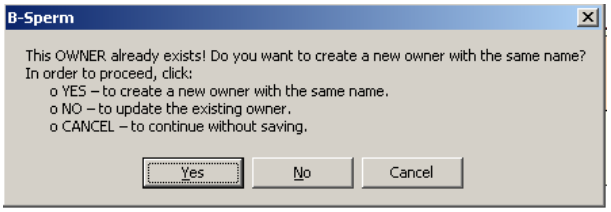
The bull information can be entered as each bull is tested OR in advance by entering all the bulls in this table.

DELETE:

- Bull records by selecting the record in the far left hand box and pressing the **DELETE** button.
- Owner by selecting the small square near the Owner Name and pressing the **DELETE** button. **All the bull records related to this owner will be deleted.**

Press the **PRINT** button to print the bull setting table for a given Owner.

If the **OWNER** (Name) is in there twice, the message below is displayed. Select one of the three options as explained in the message.



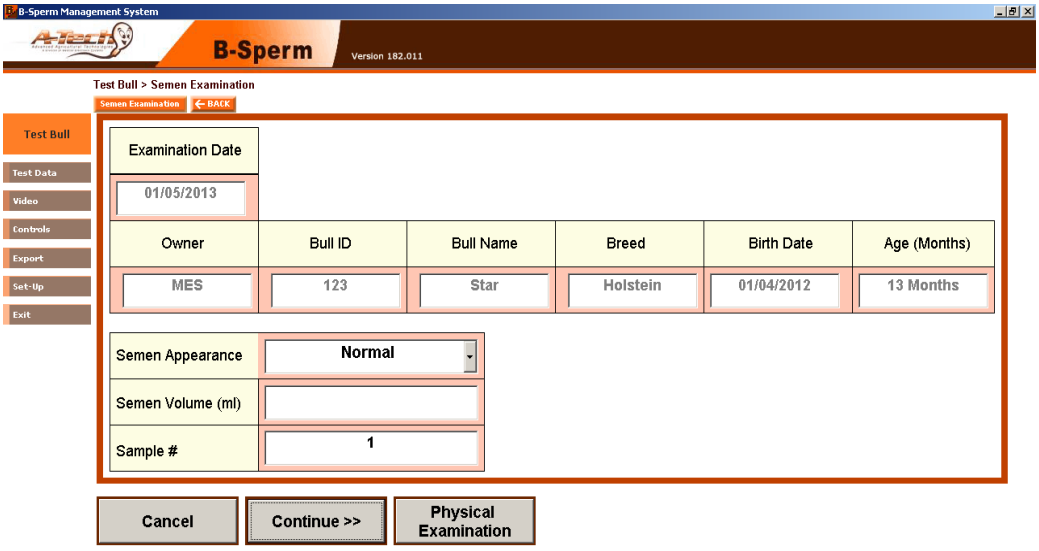
START TESTING:

- Select the desired **BULL** and click on **Semen Examination** or **Physical Examination** to start the testing process.

Semen Examination

SEMEN EXAMINATION:

Click **SEMEN EXAMINATION** to display the screen below:



Select/Enter:

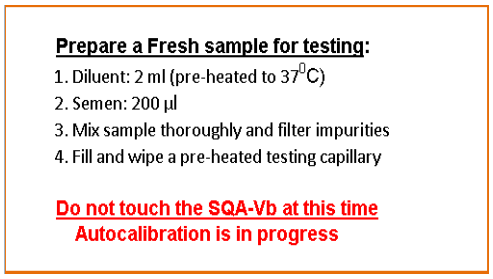
- **SEMEN APPEARANCE: Normal** or **Semi-Transparent (Thin)**.
- **SEMEN VOLUME (ml)**
- **SAMPLE #**

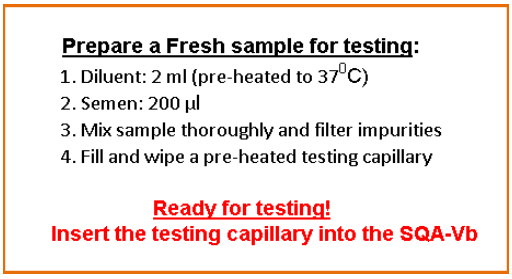
Click **CONTINUE>>** to begin testing or **CANCEL** to cancel the test.

Click **PHYSICAL EXAMINATION** to open the input screen for the BSE report.

FRESH SAMPLE PREPARATION AND TESTING:

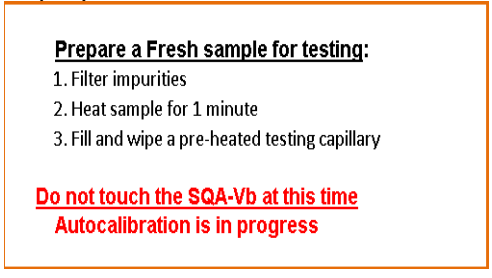
If **SEMEN APPEARANCE: Normal** is selected, after clicking **Continue>>**, the following sample preparation screens are displayed:





- Prepare a **FRESH** sample based on the instructions.
  - Prepare 2ml aliquots of diluent pre-heated to 37⁰C (98.6⁰F).
  - Pre-heat the testing capillaries to 37⁰C (98.6⁰F).
  - **DO NOT HEAT THE SAMPLE! ONLY THE DILUENT AND CAPILLARY** or motility will be impacted!

If **SEMEN APPEARANCE: Semi-Transparent (Thin)** is selected and the **SEMEN VOLUME => 1 ml**, after clicking **Continue>>** the sample preparation screens below are displayed:



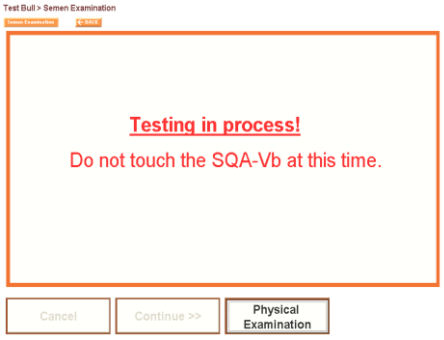
NOTE: When preparing **FRESH** samples **with Normal Appearance** for testing the diluent volume is always 2 milliliters.

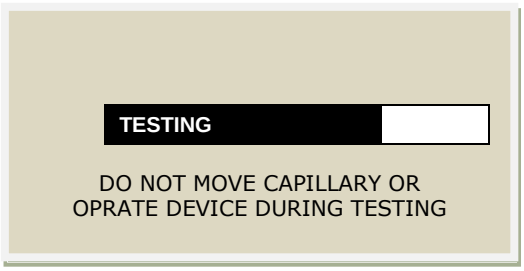
NOTE: **DO NOT pre-heat** the **FRESH** sample! Only pre-heat the diluent and the testing capillaries or motility will be impacted.

NOTE: **Pre-heat** the **FRESH** sample per onscreen instructions when run without dilution.

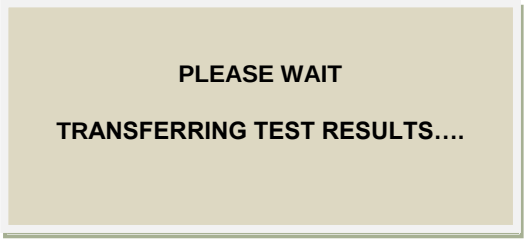
- Follow the screen instructions and do not touch the SQA-Vb or insert a testing capillary until instructed.
- Insert the prepared testing capillary into the SQA-Vb when the SQA-Vb 'beeps' and the message: **INSERT CAPILLARY INTO CHAMBER** is displayed.
- Testing will begin automatically and run for approximately 30 seconds.

B-Sperm **SQA-Vb**





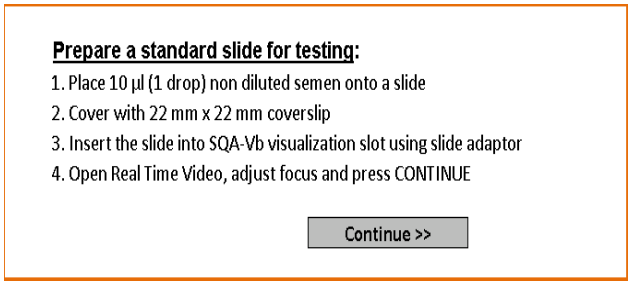
- A "beep" will be heard when the automated testing is finished and the test results will automatically be transferred to B-Sperm.

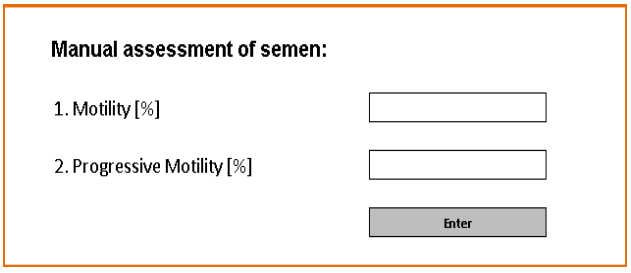


- Remove the testing capillary after testing (a message will be displayed).

If **SEMEN APPEARANCE: Semi-Transparent (Thin)** is selected and **SEMEN VOLUME < 1 ml**, after clicking **Continue>>** the following screen are displayed:

NOTE: Run the **FRESH** sample manually per onscreen instructions if it cannot be diluted and the semen volume is limited.





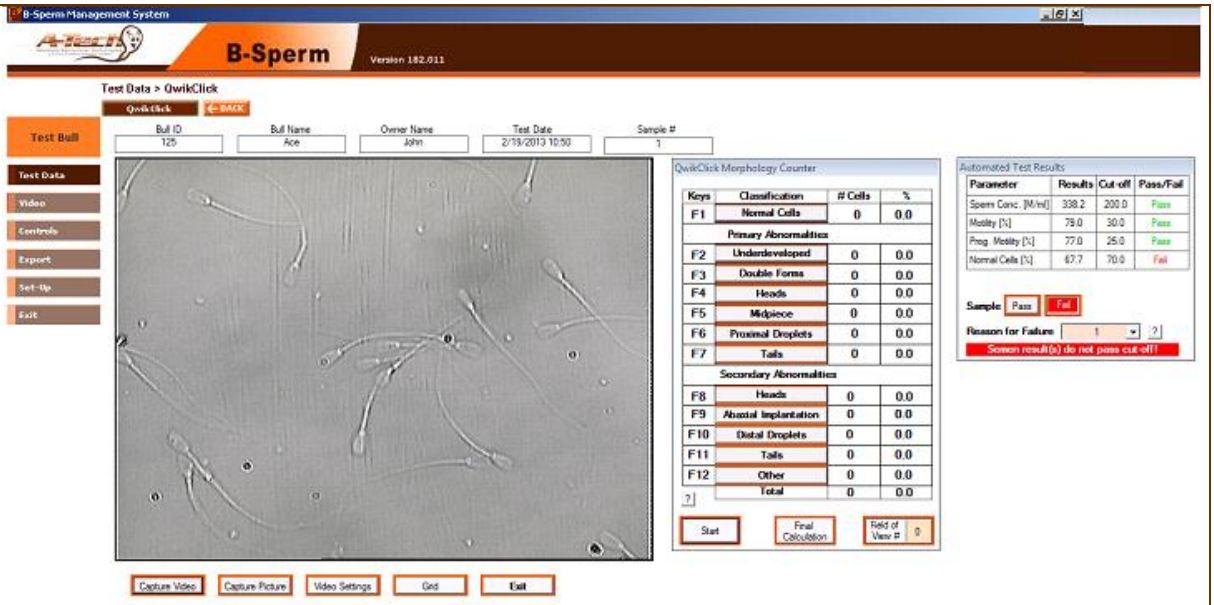
To assess the Motility and Progressive motility manually using the **Real Time Video**

- Prepare a standard slide per onscreen instructions
- Click **Video>Real Time Video** and press **Continue>>**

Enter the results into the manual assessment screen (shown above); press **Enter**.

- The results will be saved by the system.
- The QwikClick Morphology Counter can automatically be displayed (if this is pre-set). Alternatively it can be opened offline for each bull record when needed.

QwikClick

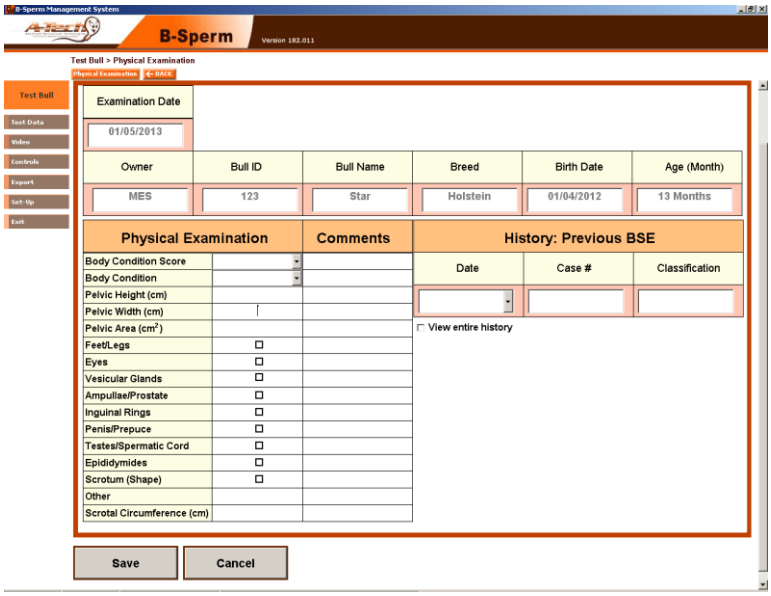


- The QwikClick screen is used for morphology assessment. It contains a video screen, the QwikClick™ Morphology Counter and the Automated Test Results tables.
- The **Sample Pass/Fail** indicator is at the bottom of the Automated Test Results table. Enter the reason for failure from a list of failure codes.
- Use the PC keyboard function (F) keys for counting morphology abnormalities.
- Click: **Final Calculation** when the morphology assessment is completed.
- For detailed information on how to use this feature, refer to the **QwikClick™** section of this user guide.
- Final morphology results will be saved with the bull/sample data in the B-Sperm database.

Physical Examination

PHYSICAL EXAMINATION:

Click: **Physical Examination** from any screen to display the table below:



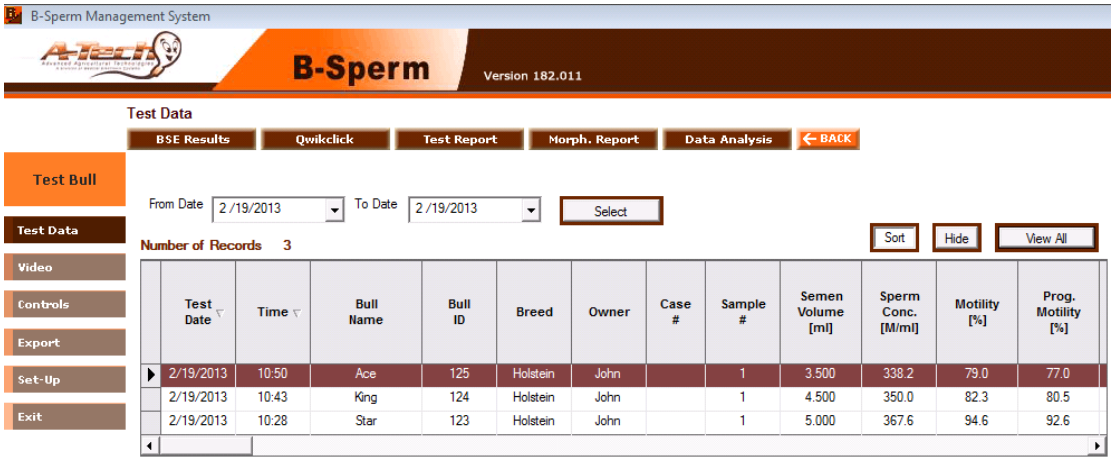
- The table displays the standard parameters recommended by the Society for Theriogenology. These parameters can be modified in the BSE Report settings.
- Use drop down menus and check boxes to quickly fill in the table.
- Click the box next to **View entire history** to view past BSE records for the bull.

- The History section data shows if the bull was classified as **Satisfactory or Unsatisfactory Potential Breeder** or classification was **Deferred**.
- Click: **SAVE** to store the results in the BSE archive.

Section 7: Test Data

Test Data

Click **Test Data** option from the main menu and the following grid will be displayed:



Click in the grey box of the first column to select one record or drag the arrow to select multiple records. The following information is displayed in the **Test Data** table:

Sample/Bull Information:

- **Date** – The date the sample was tested.
- **Time** – The time the sample was tested.
- **Bull Name** – Entered through the **Test Bull** data entry screen (not required).
- **Bull ID** – A unique bull identification # designated by the owner (required).
- **Breed** – The bull breed entered in the data entry screen.
- **Owner** – The name of the bull owner.
- **Case #** – A number designated by the user.
- **Sample #** – The sample number designated by the user.
- **Semen Volume** – The ejaculate volume (ml).

Test Results:

- **Semen parameters**: Sperm Concentration, Motility, Progressive Motility, % Normal Cells, % Primary Abnormalities and % Secondary Abnormalities.
- **Sample Information**: Sample Pass/Fail. If all parameters pass the pre-set cut-off, **Sample Pass** is indicated. The **Sample Fail** will be displayed if **at least** one parameter is below the cut-off. The **Sample Fail** can be changed to Sample Pass manually if desired.

Additional Information:

- A variety of the following icons indicate different features:

Graphs: This icon will appear when there are enough test results to graph. Click on the icon and select the parameter desired to produce a graph.

<> Test results out of normal range: This icon alerts the user that at least one test result is **out of the normal range.** Refer to the Set-up>Normal Ranges section for details).

Picture indicator: This indicates that images are attached to a record. Click to view images captured from stained morphology slides (can be attached to each test).

Video Indicator: This icon indicates a video clip has been attached to the record. Click to view. Only one video clip can be attached to each test record.

Three buttons appear at the bottom of the **Test Data** screen:

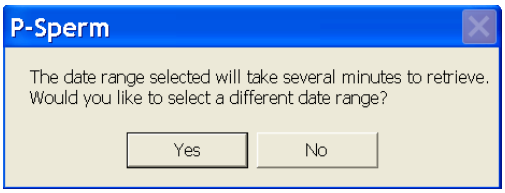
- **Clear All:** Click to deselect all selected records.
- **Select All:** Click to select all records.
- **Delete:** Click to delete selected record.

Three buttons are located in the upper right hand corner of the **Test Data** screen.

- Click: **SORT** and then click on the column header that contains the information to sort (Date, Bull ID, Sperm Conc., etc.).
- Click: **HIDE** and then select the columns to hide. The columns will disappear.
- Click**: VIEW ALL** to re-activate ALL of the hidden columns.

Five buttons and a date range setting are displayed at the top of the **Test Data** screen:

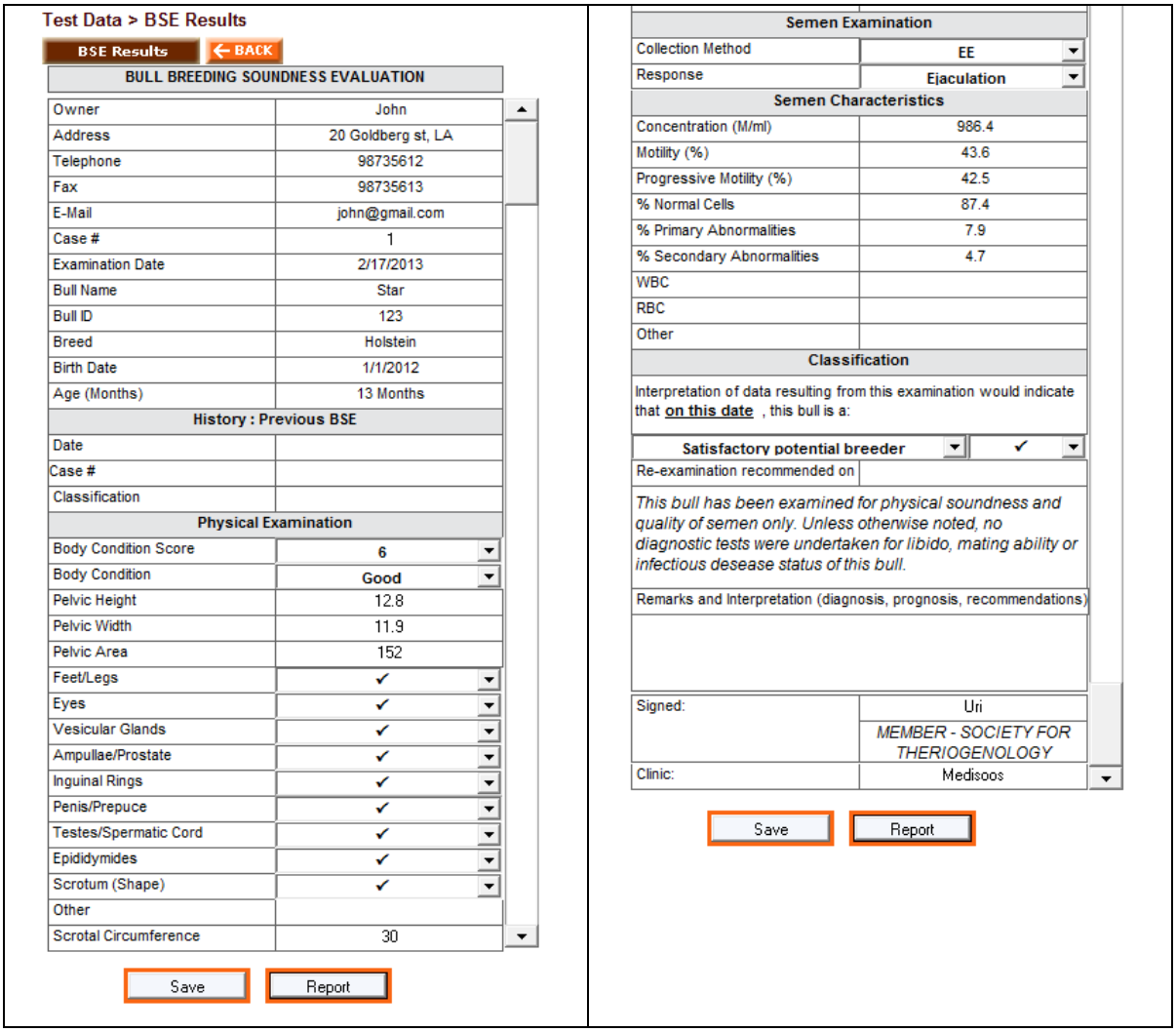
Set the date range to display data within that timeframe. The default is one month, however this can be re-set by the user. If the selected date range is too broad, the following message is shown:



BSE Results

BSE RESULTS:

Select the desired record and click **BSE Results** to display the following grid:



- Move the scrolling button on the right side **of** the grid to view all of the information.
- Owner and bull data, semen and physical examination results are displayed in the BSE grid. Additional data such as the bull classification, comments. etc. can be manually entered in the grid.
- Click: **SAVE** to retain the BSE results.
- Click: **Report** for the printable BSE Report.

Qwikclick

QWIKCLICK:

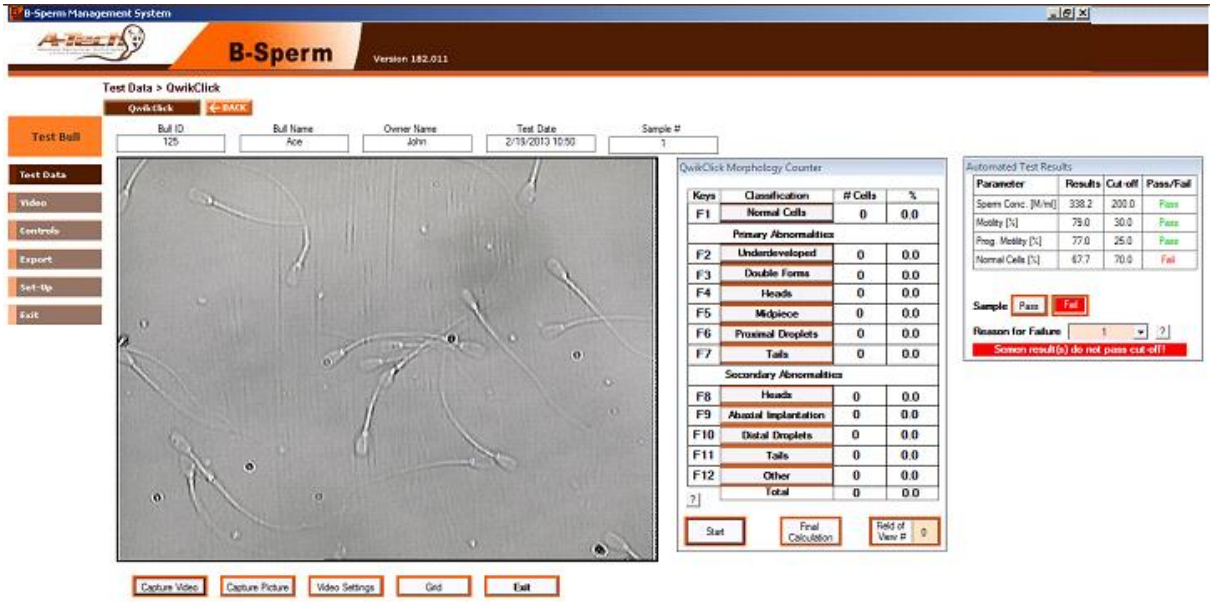
This section describes how to use the B-Sperm QwikClick™ Morphology Counter.

DEFINITIONS: The QwikClick™ feature has the following options for assessing bull morphology if the fully automated option is not preferable:

- **QwikClick™ Morphology Counter** (on-line right after the automated test)
- **QwikClick™ Morphology Counter** (off-line, access: **Test Data**>**QwikClick™**)

Note: To automatically open the QwikClick™ screen after sample testing, go to: **Set-up > QwikClick™ > Yes**.

The **QwikClick™ Morphology Counter** is displayed below:



The QwikClick™ screen has two sections:

- **QwikClick™ Morphology Counter**
- **Automated Test Results**

Two examples of **Automated Test Results** are displayed below.

- Cut-off criteria can be set-up by the user (see the **Set-Up > Defaults > Cut-Off Settings** section of this User Guide). If not set-up, the manufacturer default cut-offs will be used.

The sample will **PASS** if all of the semen parameters have passed the cut-offs. The sample will **FAIL** if at least one semen parameter fails. The user can manually change the automatic PASS/FAIL indication.

Automated Test Results

Parameter	Results	Cut-off	Pass/Fail
Sperm Conc. [M/ml]	986.4	0.0	Pass
Motility [%]	43.6	30.0	Pass
Prog. Motility [%]	42.5	25.0	Pass
Normal Cells [%]	87.4	70.0	Pass

Sample Pass Fail

Reason for Failure ?

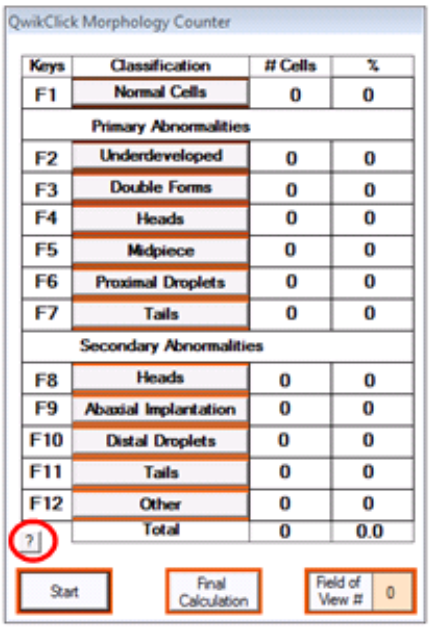
Automated Test Results

Parameter	Results	Cut-off	Pass/Fail
Sperm Conc. [M/ml]	1015.7	0.0	Pass
Motility [%]	29.7	30.0	Fail
Prog. Motility [%]	28.8	25.0	Pass
Normal Cells [%]	61.9	70.0	Fail

Sample Pass Fail

Reason for Failure ?

Semen result(s) do not pass cut-off!



To use the **QwikClick Morphology Counter** click ? icon to display instructions.

Note:

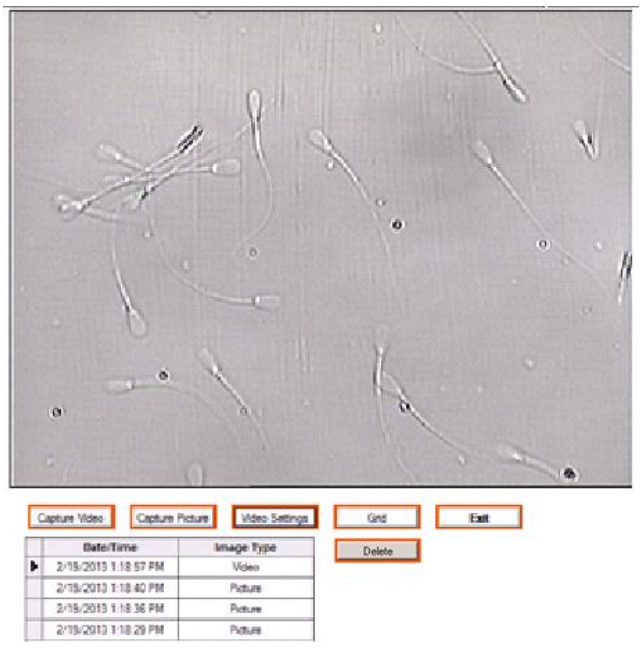
The function keys that correspond to morphological defects are set by the manufacturer, but can be re-set by the user in the B-Sperm set-up.

Procedure:

- Prepare a slide of non-motile sperm cells and place it into the SQA-Vb visualization compartment.
- Use the PC function keys (F1, F2, etc.) for counting normal cells and morphological abnormalities (one abnormality per spermatozoa).
- Click **Next Field** and move to another field of view by slightly turning the silver knob of the SQA-Vb slide holder.
- Click **FINAL CALCULATION** to save the results.

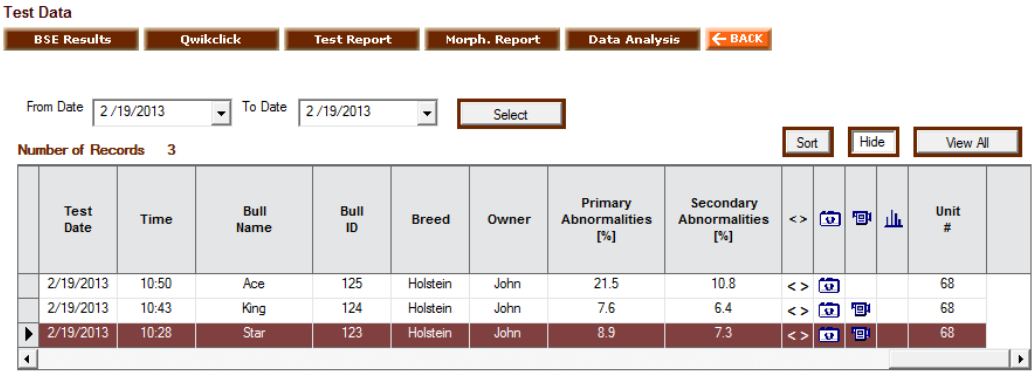
- A differential Morphology assessment can be performed using stained smears or captured images.
- If the user exits this screen without counting, the **% Normal Cells** will be calculated based on automated results.
- If a differential Morphology is performed and the **Final Calculation** button is pressed, the **% Normal Cells** will be calculated based on the manual assessment.
- Differential Morphology results will be seen in the BSE and Morphology Report.

Capture Picture or Video. To save a picture or video clip and attach it to a record:



- Insert a slide with a semen sample into the visualization system of the SQA-Vb.
- Highlight a record in the **Test Data** grid to attach the video/picture (not necessary if the QwikClick™ is opened on-line).

- Click the **Capture Picture** or **Capture Video** button at the bottom of the video screen and the image will be saved.
- Click: **Stop Capturing** to end the video capture process.
- Several pictures and one video can be saved and attached to the bull record.
- To **delete** a picture or video, select the desired image at the bottom table of the QwikClick screen (shown above) and click the **Delete** button.
- A picture or video can be deleted in the **Test Data** screen by clicking the picture or video icon in the **Test Data** grid and then clicking the Delete button (located at the bottom of the grid or video clip).



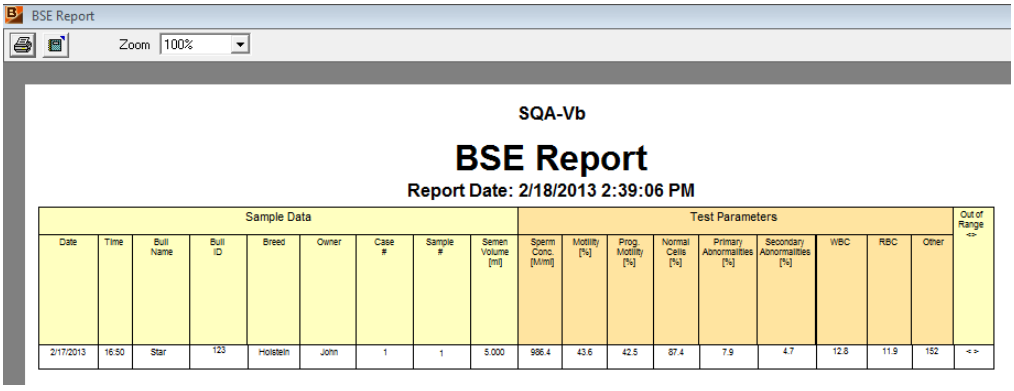
TEST REPORT:

Test Report

Click on this icon to print a copy of the report.

Click on this icon to export the semen analysis report to Excel file.

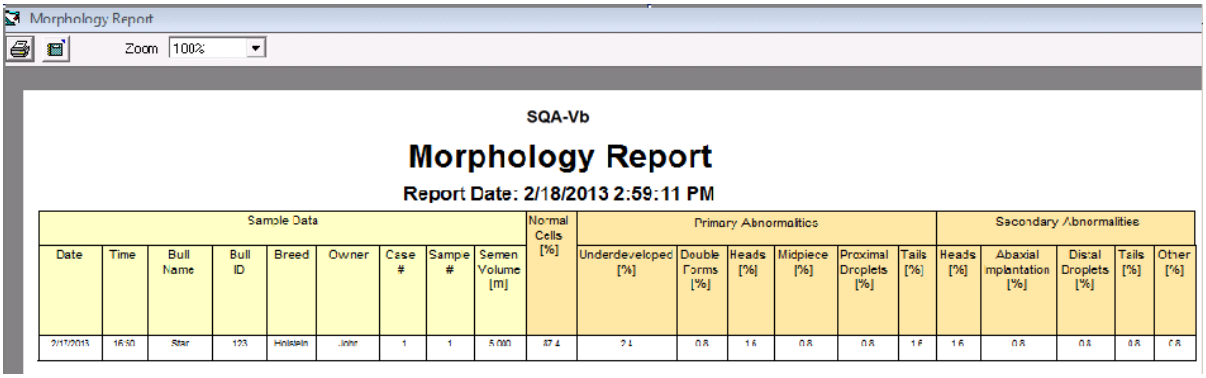
Click **Test Report** to view and print the following report displaying the bull data and semen analysis results for the selected period of time:



MORPHOLOGY REPORT:

Morph. Report

Click **Morphology Report** to view and print the Morphology report, which displays the Sample Data and QwikClick differential morphology results of the selected records:



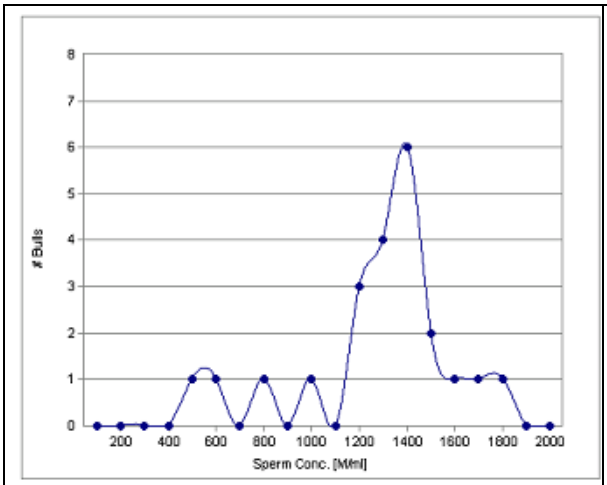
Data Analysis

DATA ANALYSIS:

Click the **Data Analysis** button and the grid below will open:

Test Date	Owner	Case #	Sperm Conc. AVG [M/ml]	Motility AVG [%]	Normal Cells AVG [%]
2/17/2013	John	1	986.4	43.6	87.4

- From the drop-down menu, select **Test Date**, **Owner** and **Case #**.
- The average values of the **Sperm Concentration**, **Motility** and **Normal Cells** of the bulls tested on selected date will be displayed automatically.
- Click on one of the average values, and a histogram showing the distribution of the selected semen parameter among the tested bulls will be displayed:



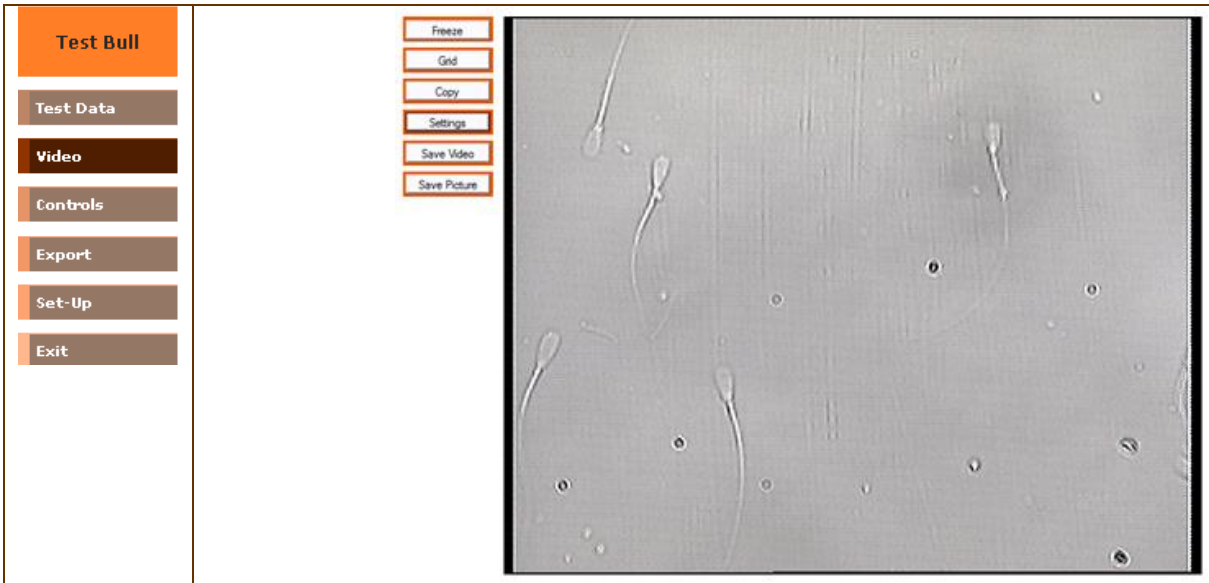
Sperm Conc. [M/ml]	# Bulls
0-100	0
100-200	0
200-300	0
300-400	0
400-500	1
500-600	1
600-700	0
700-800	1
800-900	0
900-1000	1
1000-1100	0
1100-1200	3
1200-1300	4
1300-1400	6
1400-1500	2
1500-1600	1
1600-1700	1
1700-1800	1
1800-1900	0
1900-2000	0
>2000	4
Total	26

Section 8: Video

Click the **VIDEO** navigation button to activate the:

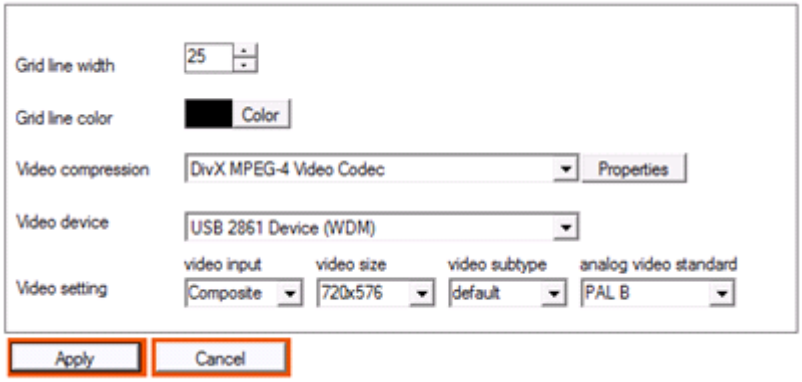
- **Real Time Video**: View samples "live" from the SQA-Vb visualization system.
- **Video Settings**: Customize the video set-up.

Click **REAL TIME VIDEO** and the following screen will be displayed:



- **FREEZE –** To freeze the dynamic image. Click the REAL TIME button (displayed after image freezing) to un-freeze.
- **GRID –** A grid can be added to the screen to make counting easier.
- **COPY –** Pictures can be copied by clicking the COPY button and then pasting the picture in an external file (WORD, Excel, etc.).
- **SETTINGS –** Video settings can be selected by the user.
- **SAVE VIDEO/PICTURE –** Save video clips (.avi format) and pictures (.bmp format) in a PC file.
- **FULL SCREEN** – Double click on the image to maximize it. Use F1 to freeze/unfreeze and Esc to minimize an image.

Click the **VIDEO SETTINGS** button to select grid line width, color and video settings. The appropriate video device settings are described in the video device installation procedure supplied with the video device hardware:



Section 9: Controls

Click **Controls** and three options are displayed: **Set-up**, **Test Results** and **Test Controls:**

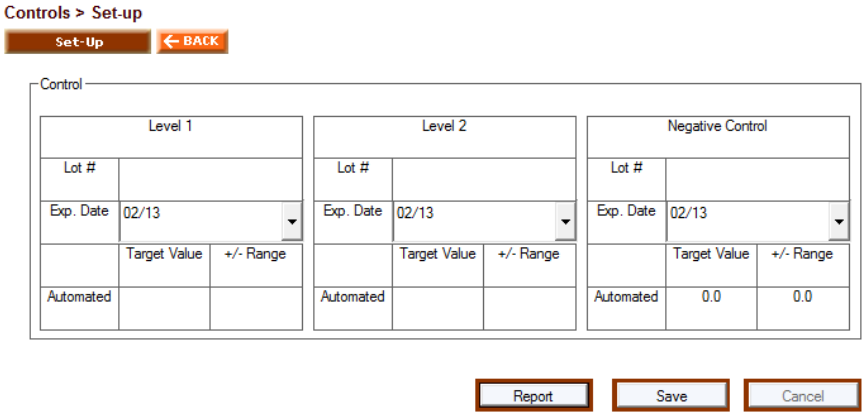
Click **Controls > Set-up** to view the screen below:

Controls Testing

QwikCheck™ beads are produced by Medical Electronic Systems: www.mes-global.com)

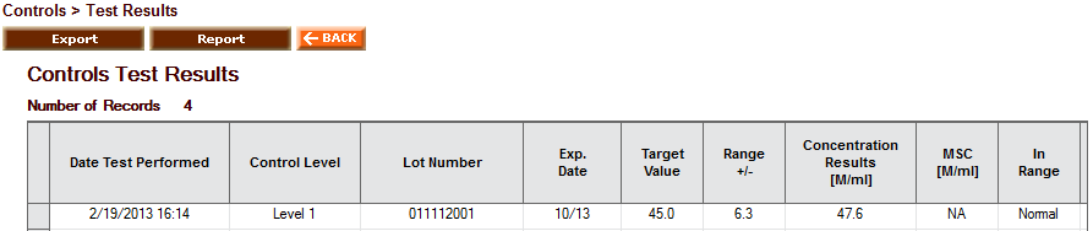
Please note: QwikCheck beads verify that the concentration channel of the SQA-Vb is optimally functioning before a problem impacts the test results.

NOTE: Remember to set-up Controls before running a new box of QwikCheck Beads.

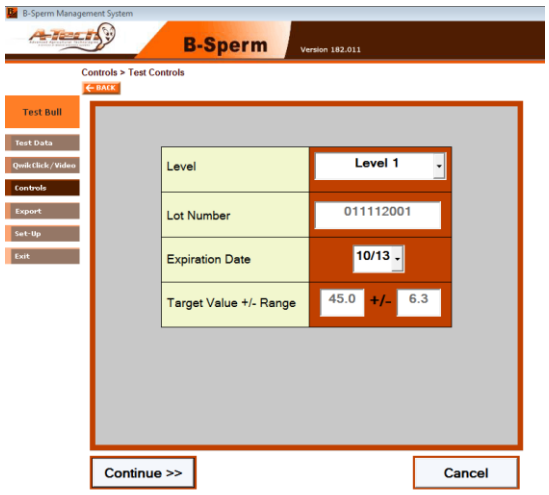


Enter the required information into the table. This information is on the QwikCheck™ beads box. Press **Report** to print out the settings. Press **Save** to apply the settings.

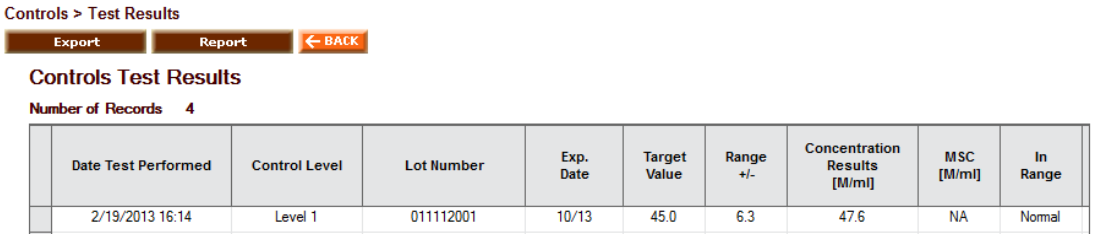
Click **Controls > Test Results** to view the control records:



Click the **Test Controls** button and the screen below will be displayed:



- Select the Control **Level**.
- The pre-set **Lot Number**, **Expiration Date** and **Target Value +/- Range** will be displayed automatically. Press **Continue** and follow the screen instructions.
- When testing is completed, the screen below will be displayed:



- Click the **Report** or **Export** buttons to print a report or export the control results to an Excel file.

Section 10: Export

Click Export button and two options will be displayed:

Activation **Export Test Results** feature allows transferring the entire archive of the test results to the Excel file (the user should specify the path with the name of the file).

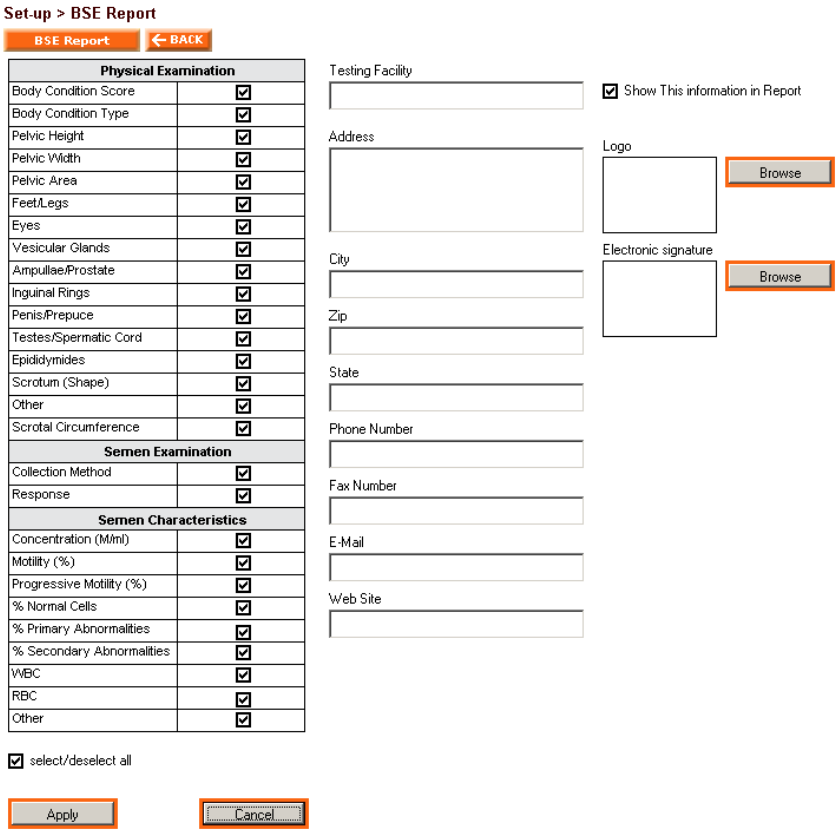
Activation **Export Controls** feature allows transferring the entire control archive to the Excel file (the user should specify the path with the name of the file).

Section 11: Set-up

Set-up section contains 7 sub-menus:

BSE Report setting

Click **BSE Report** to display the set-up grid for the BSE Report (shown below).



The **Physical** and **Semen Examination** parameters displayed in the BSE report are parameters recommended by the Society for Theriogenology. Parameters can be deselected (by clicking) so that they will not appear on the BSE report.

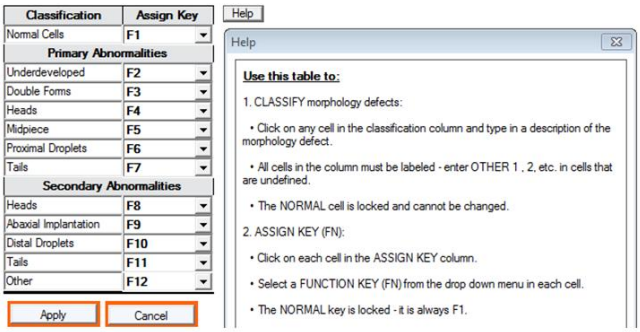
Press: **Apply** to save the settings or **Cancel** to not save the entries.

QwikClick setting

Select: QwikClick™ Setting: **Yes / No** to begin.

- If **Yes** is selected (No is the default), the QwikClick screen will automatically open each time after running a test.
- If **No** is selected the QwikClick screen will not be displayed and the automated morphology will be reported. (QwikClick™can be opened off-line to perform a morphology assessment. These results will then be displayed in the BSE report.

Set Morphology abnormalities using the following table:



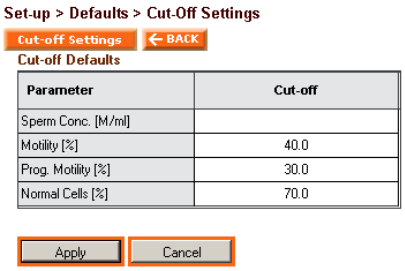
The classification of morphology defects and function (F) keys for counting the different morphological abnormalities are manufacturer defaults. They can be re-set by the user per Help instructions.

Defaults – Click this button and the sub-menu shown below will be opened:

Default setting

Cut-off settings

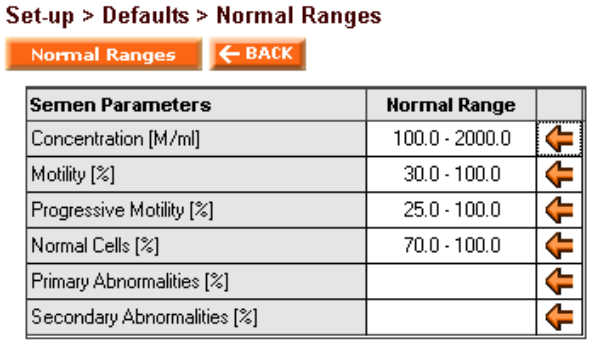
Cut-off Settings can be pre-set by entering (overwriting) the cut-off values in the table provided:



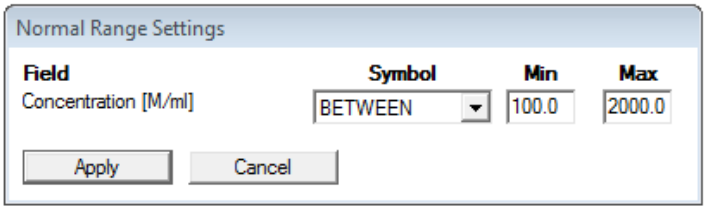
- **Sperm Concentration Cut-off (M/ml):** Enter the lowest acceptable Concentration (leave it empty if there is no cut-off).
- **Motility Cut-off (%):** Enter the lowest acceptable Motility.
- **Progressive Motility Cut-off (%):** Enter the lowest acceptable Progressive Motility.
- **Normal Cells Cut-off (%):** Enter the lowest acceptable % Normal Cells.

Normal Ranges setting

Normal Ranges – Set-up normal ranges for semen test results:



- Click on the ARROW ⇦ which points to the parameter to be set-up. The **Normal Range Settings** screen will appear. Enter a symbol (≤, ≥, =, BETWEEN, etc.) and the MIN/MAX values, press **Apply**.

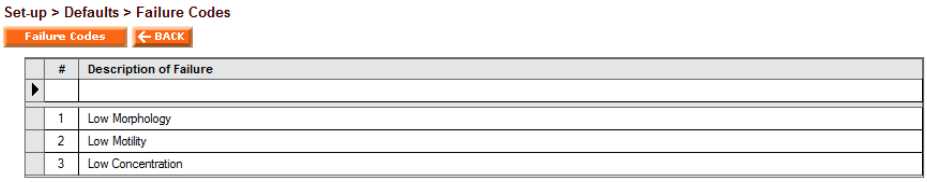


Conc. Standard setting

Concentration Standard – Click this button to set-up Concentration Standard 1 or 2. Standard 1 corresponds to Hemocytometer counting chamber and 2 to Nucleocounter.

Failure Codes setting

Failure Codes – Set the failure codes that best indicate the reason the sample failed.

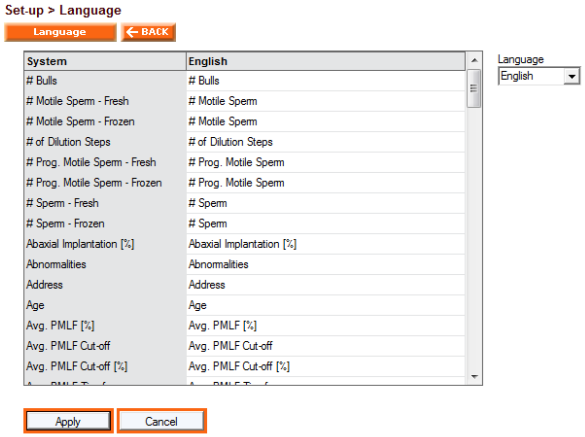


Archive Management setting

Archive Management: Click this button to view the screen below. It is best (because of the LARGE data base of bull information) to set records to be archived in MONTHS (rather than years – and as short a timeframe as possible).

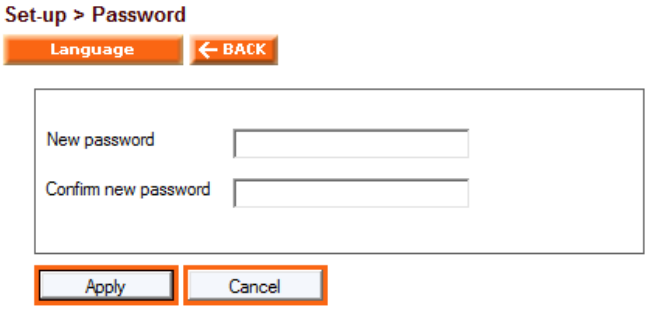
Language setting

Click: Language to customize the language used in B-Sperm Reports. Choose "Other" from the Language drop-down menu, fill-in the table as desired and click **Apply**.



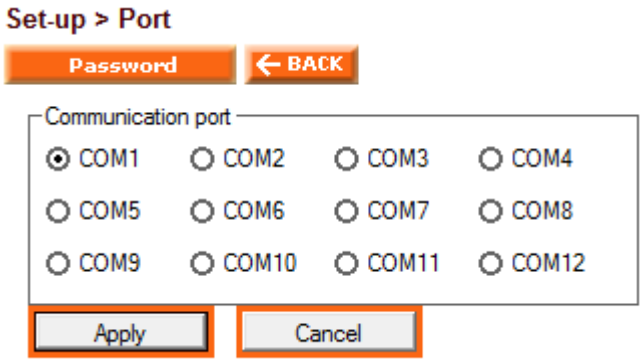
Password setting

Click **Password** to change to a new password. Enter and confirm the new password in the screen below. Click **Apply** to immediately re-set and save the new password.



Port setting

Port: Click this button to set the communication port for the PC:



SQA-Vb setting

SQA-Vb – Click this button and two options are displayed:

- Self-Test Data
- Verification

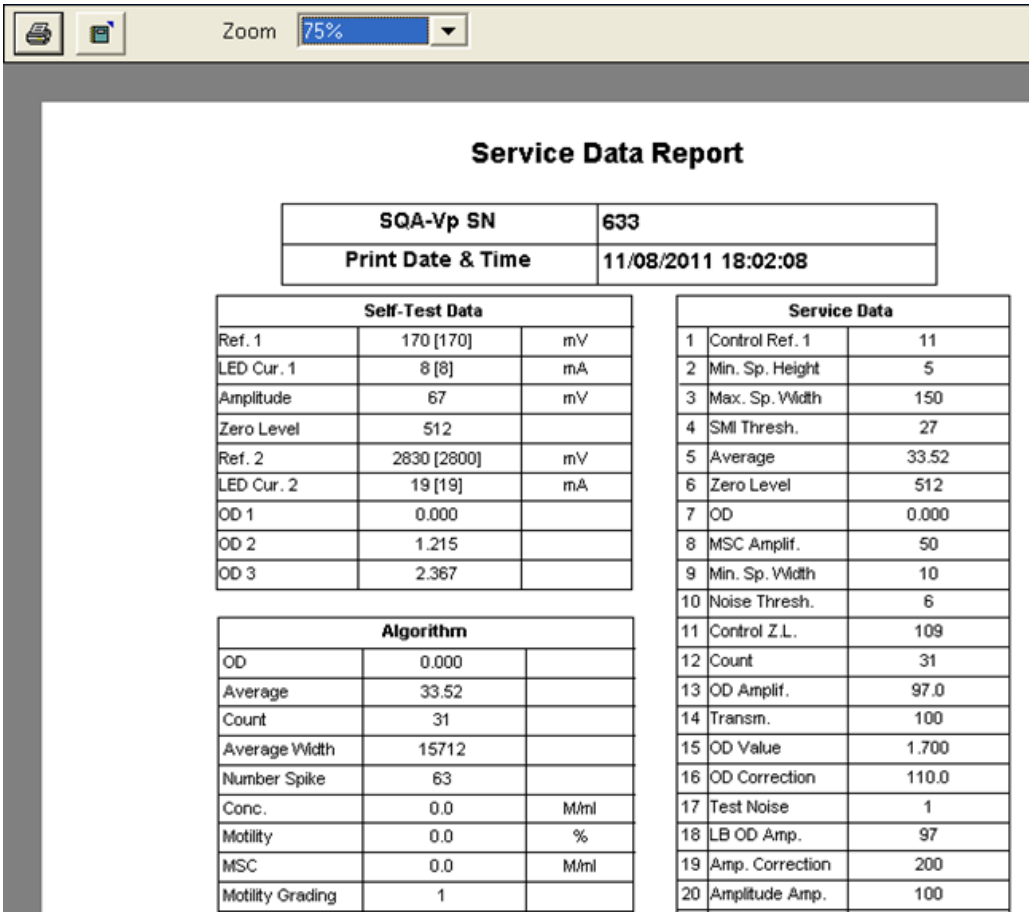
Click **Self-Test Data** and this information will be displayed:

Motility Channel			Conc. Channel		
REF. 1	170	mV	REF. 2	2800	mV
LED CUR. 1	8	mA	LED CUR. 2	19	mA
AMPLITUDE	67	mV	OD 1	0.0	M/ml
ZERO LEVEL	512		OD 2	1.2	M/ml
			OD 3	2.4	M/ml

Algorithm				
OD	0.0	CONC.	0.0	M/ml
AVERAGE	33.5	MOTILITY	0.0	%
COUNT	31.0	MSC	0.0	M/ml
AVERAGE WIDTH	15712.0	MOTILITY GRADE	1.0	
NUMBER SPIKE	63	MORPHOLOGY	NA	%

SQA-Vb setting

Print the **Service Data Report** which contains additional information:



The **Verification** function is for Service Personnel only.

Section 12: Exit

Click **Exit** to close the B-Sperm program. Confirm **YES** or **NO**.

Appendix I: Semen Sample Preparation

EQUIPMENT REQUIRED:

- Testing Media: QwikCheck™ Diluent for FRESH BULL semen
- Diluent Dispenser
- 10 ml Plastic Containers
- 25-micron filter
- 1 ml Pipette with tips
- SQA-Vb capillary
- Heating stage

Figure 1: Diluent Dispenser

FRESH SEMEN SAMPLES:

DILUENT/TESTING CAPILLARY PREPARATION (prior to testing the sample)

- Pre-heat testing capillaries to 37^{0}C / 98.6^{0}F for at least four minutes.
- Bring **QwikCheck™ Diluent for FRESH BULL semen** to room temperature (RT: 22^{0}C-26^{0}C or 72^{0}F-79^{0}F).
- Extract 2.0 ml of **QwikCheck™ Diluent for FRESH BULL semen** into a 10 ml plastic container using the dispenser (Fig. 1).
- Place 10 ml plastic container with the diluent into the heating device (see appendix section for how to operate). Pre-heat the **QwikCheck™ Diluent for FRESH BULL semen** at 37^{0}C / 98.6^{0}F for at least 4 minutes.

Figure 2: Sample Preparation

FRESH SAMPLE PREPARATION

1. Mix Fresh semen sample thoroughly.
2. Extract exactly 200 µl of semen using a pipette (Fig. 2).
3. Add the semen from the pipette to the 2.0 ml of **QwikCheck™ Diluent for FRESH BULL semen** in the plastic container (Fig 3).
4. Gently but thoroughly mix the sample for 10-20 seconds (Fig 4) to insure that the diluent and semen are homogeneously mixed.
5. Unplug 1 ml syringe from the capillary and fill it with 1 ml of diluted semen.
6. Pour semen from the syringe onto the 25-micron filter.
7. Open the filter cup, fill and wipe the testing capillary (pre-heated to 37^{0}C) per the instructions in the Appendix II section of this SQA-Vb User Guide.
8. The sample is now ready for testing.

Figure 3: Add semen to the diluent

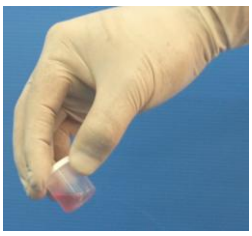
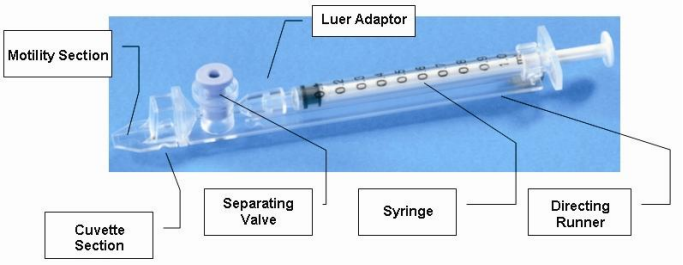


Figure 4: Mixing the sample

Note: If testing a non-diluted sample, follow the screen instructions for sample preparation.

Appendix II: Capillary Filling Instructions

SQA-Vb Testing Capillary



1. Push the syringe piston in fully. Place only the thin part of the capillary into the bottom of the diluted sample - Figure 1.
2. Placing two fingers below the piston head pull the piston back slowly while keeping the tip of the capillary well below the sample level and below any surface bubbles (Figure 1). Continue to aspirate the sample until it appears in the Luer adaptor.
3. Hold the capillary in a vertical position and visually confirm that the sample has completely filled the thin section and the cuvette section and appears in the Luer adaptor (Figure 2).
4. Tap on the syringe to make sure there are no air bubbles in the sample.
5. Quickly and thoroughly wipe both the top and bottom of the outer surface of the capillary with a tissue such as Kimwipes, etc. (Figure 3). Visually confirm that the capillary chambers are still full after wiping. If some of the sample has been depleted, a meniscus will be visible in the thin section of the capillary. If this is evident, push very slightly on the piston to re-fill the thin capillary section.
6. Slowly and carefully push-in the separating valve until it is level with the plastic. The capillary is now ready for testing (Figure 4)
7. Insert the capillary into the SQA-Vb (Figure 5)

Figure 1

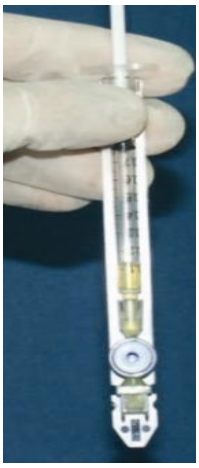


Figure 2

Figure 3

NOTE: If air bubbles are still present in the capillary after tapping on the syringe, dip the capillary into the semen sample again and aspirate a small quantity of semen to draw air bubbles into the syringe.

NOTE: It is important to remove all semen from the exterior of the capillary in order to prevent the SQA-Vb optical chamber from becoming clogged.

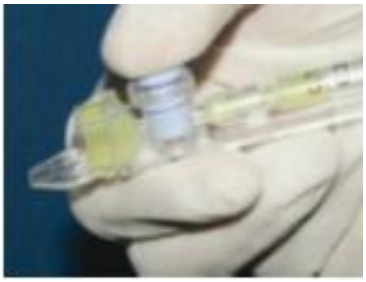


Figure 4

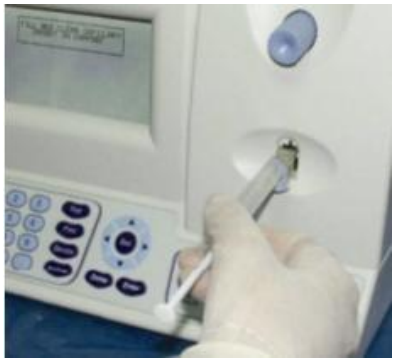


Figure 5

Appendix III: SQA-Vb Cleaning Instructions

When to clean:

- Daily or after every 25 tests
- If the system fails SELF-TEST

Cleaning kit components:

- Blue Dot capillaries (Fig. 1)
- Sponge-tipped drying capillaries (Fig. 2)
- Cleaning brush-wooden-handled (Fig. 4)
- Cleaning fluid

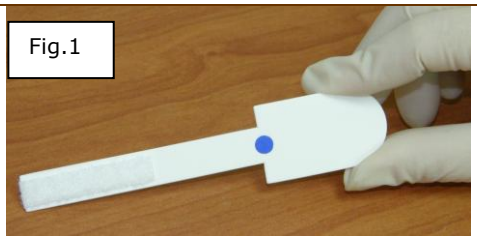


Fig.1

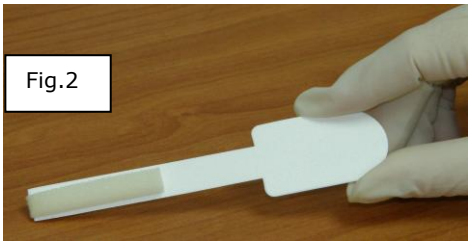


Fig.2

CLEANING: STEP 1

1. **TURN OFF** SQA-Vb and unplug it at main electrical outlet.
2. Select a **BLUE DOT cleaning** capillary (Fig. 1).
   - Moisten with **ONE** drop of cleaning fluid, shaking off excess fluid.
   - Insert into the measurement compartment - fibrous material facing up, and move back and forth a few times in the directional runner.
   - Repeat with fibrous material facing down
   - Select a sponge material capillary (Fig. 2) and insert it in the same compartment in order to dry the chamber (Fig. 3)


Fig.3


Fig.4

CLEANING: STEP II

Clean the channel that measures concentration using the cleaning brush (Fig. 4):

1. Insert the brush (bristle-side down) fully into the upper portion of the lower chamber of the SQA-Vb in same manner as a testing capillary (Fig. 5).
2. Pull the brush out of the chamber while sweeping or "dusting off" the LED (you will feel a step or shelf at the back and top of the chamber – this is the top of the LED) (Fig. 6).
3. Switch SQA-Vb unit **ON** and observe self-test results. The SQA-Vb should now PASS the self-test. If not, repeat cleaning procedure with the brush.


Fig.5

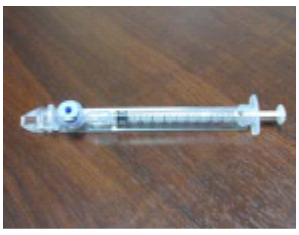

Fig.6

Appendix IV: Capillary Washing/Drying Instructions

Testing Capillary

Repositioning the blue valve with the jig

Removing the plunger



Reassembled capillary

Washing 10 ml sample collection cups

(For animal applications ONLY!)

Both testing capillaries and 10ml sample collection cups can be washed and re-used up to 5 times by following this EASY procedure:

Step 1 After running a test:

- Use the white capillary jig to re-position the blue capillary valve
- Expel semen by pumping the plunger a couple of times
- Soak the testing capillary in tap water until ready to wash

Step 2 Set-up: Fill with 1 liter/2 quarts of solution as follows:

- Bowl #1: Tap water (marked “TAP WATER”)
- Bowl #2: Distilled water (marked “DISTILLED WATER”)
- Bowl #3: Isopropyl Alcohol 70% - 100%

Step 3: Remove all liquid from the testing capillary:

- Pump the syringe plunger a couple of times to remove liquids.

Step 4: Capillary Washing – Follow this order:

- Bowl #1 Tap Water: Completely fill each capillary with tap water. Expel the solution into a hazardous waste container. **Repeat 2 times** then go to Bowl 2.
- Bowl #2 Distilled Water: Completely fill each capillary with distilled water. Expel the solution into a hazardous waste container. **Repeat 2 times** then go to Bowl 3.
- Bowl #3 Isopropyl Alcohol: Completely fill each capillary with isopropyl alcohol and expel the solution into a hazardous waste container. **Repeat 2 times**.
- Remove the plunger from the syringe.

Step 5: Capillary Drying Options:

- Place the capillaries:
  - On a flat surface and dry overnight.
  - In a commercial desiccator - follow manufacturer instructions.
  - In an oven on low heat for a few hours.

Step 6: Final Preparation/Inspection:

- Replace the plunger into the syringe and inspect the capillary.
- Discard capillaries with debris, cracks or broken parts.
- Make a dot on the capillary with a water proof marker after each washing cycle to indicate the # washings.

Capillary re-assembly

- Confirm (using the jig) that the blue stopper is in the correct position.
- Check syringe by aspirating air in and out twice.

Washing 10 ml sample collection cups

Refer to Step 4 and Step 5 of the Capillary Washing Procedure above - follow the same process for washing in solution bowls #1; #2 and #3. Turn upside down on absorbent paper to dry overnight or place in a commercial warming oven for a few hours.

NOTE: The focus knob should not be forced to turn beyond the initial stopping point. Turn the knob gently and when resistance is felt it is at the maximum (or minimum) position. Forcing this knob beyond the stopping point will cause extensive damage to the SQA-Vb.

Appendix V: The Visualization System

The SQA-Vb Visualization System permits the user to analyze/view semen samples using either a standard slide or the SQA-Vb testing capillary. Additionally, the visualization system is a critical "link" to B-Sperm which allows the user to view samples on a PC monitor and capture and save video images. The visualization system:

- Accommodates both an SQA-Vb testing capillary and a standard slide.
- Control knobs located below the visualization screen can be used to set the focus, brightness and contrast.
- Operate the zoom, illumination and monitor on/off functions from the SQA-Vb keypad.
- Magnification can be changed within a range: x300 through x500 by pressing ZOOM IN or OUT.

Operating Instructions

Slide Preparation:

- Use 10 µl of semen (20 micron sample depth).
- Use only a standard slide with a 22mm x 22mm cover-slip.
- Load the prepared slide into the SQA-Vb slide adaptor and insert into the visualization compartment of the SQA-Vb.

Testing Capillary Preparation:

- Fill the SQA-Vb testing capillary following the instructions in the appendix section of this guide.
- Insert the capillary into the visualization compartment of the SQA-Vb.

Testing Process:

1. The video display will automatically illuminate when the SQA-Vb is turned on.
2. Use the monitor **ON/OFF** key on the keypad to independently operate the video display.
3. To ensure that the visualization system is working properly prior to use:
    a. Press the **HIGH ILLUMINATION** key multiple times to ensure a maximum level setting.
    b. Turn **BRIGHTNESS**, **CONTRAST** and **COLOR** buttons all the way counterclockwise.
    c. Turn FOCUS knob fully clockwise.
4. Use **ZOOM IN** for maximum magnification (x500) and **ZOOM OUT** for minimum magnification (x300).
5. Insert the semen sample into the visualization chamber.
6. Turn the **BRIGHTNESS** knob clockwise until the video screen just begins to lighten-up.
7. Turn the **FOCUS** knob counter-clockwise until the image is in focus.
8. Adjust **CONTRAST, COLOR, BRIGHTNESS, FOCUS** and object **ILLUMINATION** controls for optimal image quality.

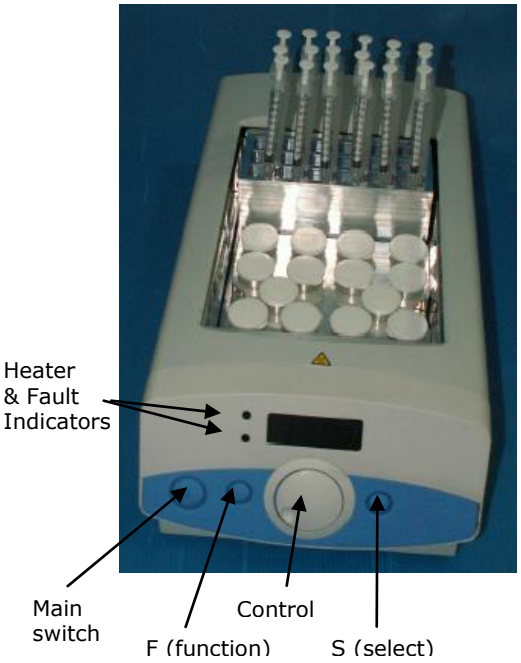
Appendix VI: Sample Heating Options (Block Heater and Stackable System)

For Use with A-Tech Sperm Quality Analyzers

BLOCK HEATER

Safety:

- Do not pre-fill the SQA testing capillaries with semen prior to heating.
- Do not touch the heating elements to check the temperature.
- If transported or stored in humid conditions, dry the unit before connecting it to power.
- Plug into a grounded electrical outlet that delivers the appropriate voltage indicated on the rear panel of the heater.
- If liquid is spilled inside the unit, disconnect the power supply, take out the metal heating blocks and wipe the spilled material with a damp cloth. Do not use chemical cleaning agents.
- Place the system on a level surface that is free from flammable materials, insuring that all ventilation slots on the base of the system are clear of obstructions.



Heater Operation:

- Place the metal heating racks for capillaries and sample containers into the heating system.
- Plug the electrical cord into the socket at the rear of the unit.
- Turn the unit on by pressing the Main Switch on the front panel - The display will illuminate showing the current temperature of the block.
- Press the 'S' button and adjust the temperature to 40°C using the Control knob. This will ensure a 37°C temperature for the testing capillary and semen samples.
- Press 'S' to confirm the temperature setting or press 'F' to exit without changing the value.
- The block heater will now begin to heat the racks.
- A light will indicate that the system is heating and will begin to flash when the set temperature is approached.
- The temperature setting will be stored in the memory.

Timer Operation:

- Press 'F' button and turn the Control knob until 'CLOC' is seen.
- Press 'S' button and turn the Control knob until 'On' is seen.
- Press 'S' button and turn the Control knob to select the required time (Example: 4 minutes (004) for Bull semen).
- Press 'S' button: The time and the Temperature will be displayed intermittently.
- A beep will sound and 'End' will be displayed when the time has expired; press 'S' to stop beeping.

Heating the SQA Testing Capillaries and Samples:

- Place **empty** testing capillaries in the heating rack (as shown in the picture above).
- Place **empty** 10-ml plastic containers in the appropriate heating rack.
- Wait 5-7 minutes for the heating unit to pre-heat the containers and testing capillaries.
- Distribute the diluent and add the semen sample into 10-ml container following User Guide instructions.
- Close the containers during pre-heating.
- Remove testing capillaries as needed for testing. Fill with semen per user guide instructions.

Note: If the processor detects an error in heating the fault indicator will illuminate, the buzzer will beep and the display will flash. To reset this fault, switch the unit off and on. If the fault re-occurs contact the service personnel at your local distributor.

Appendix VII: Glossary of Terms

	SQA-Vb Terms	Definition
	SN	Serial Number of the SQA-Vb
	DATE/TIME	The date and time the test was performed
Sample/Test Data	SAMPLE #	The number assigned to the semen sample
	BULL ID	The identifying number of the bull being tested
	BREED	Identification of the bull breed
Test Results	CONCENTRATION	Sperm Concentration expressed in millions/ml
	MOTILITY	% of Motile Sperm
	PROGRESSIVE MOT.	% of Progressively Motile Sperm
	NORMAL CELLS	% of Morphologically Normal Sperm

Appendix VIII: SQA-Vb System Specifications

Dimensions: 40 x 30 x 15 cm

Weight: 4 kg

AC power supply: 100 to 250 VAC, 50/60 Hz, 10 VA

Measurement Compartment

- **Sources of radiant energy** - two 880 nm LEDs for motility and spectrophotometry channels
- **Detector system** – 2 photo detectors - Motility and Optical Density

Visualization Compartment

- Green LED illumination system
- CCD, 350 TV lines
- Objective lens: Standard, x20
- Signal Output: PAL standard
- Zoom system for smooth magnification transition from x300 to x500
- Focus regulator

Display(s)

- Operational backlight LCD (16 lines x 40 characters)
- Video backlight LCD (8 x 10 cm)

Printer

- Built-in, Dot Matrix
- Non-thermostatic narrow paper with 20 characters per line (Citizen)
- Ribbon cassette (Citizen)

Keypad

- **Operational keys:** ON/OFF, TEST, PRINT, SERVICE, ARCHIVE, DELETE, ENTER, four cursor buttons, ESC, numeric buttons (0-9)
- **Video control keys**: ZOOM IN/OUT, ILLUMINATION HIGH/LOW, and MONITOR ON/OFF

Front Panel

- Built-in printer
- Visualization compartment
- LCD video display and controls
- Focus knob
- LCD operational display
- Measurement compartment
- Multi-button keypad

Rear/Side Panel

- Power connector with fuse-holder (fuse 250V, 1A)
- Video connector
- RS232 cable outlet
- I-Button port (side panel)

Specimen Testing Supplies

- **Measurement capillary:** Disposable, multi use plastic, positive displacement testing capillary (purchase from manufacturer).
- **Standard lab slide:** 76 X 25.6 mm with 22 x 22 mm cover-slip.
- **I-Button:** Required to run tests (purchase from manufacturer)

Archive Capacity

- 500 test records in each archive (Test and Controls)

Operating System

- **Control:** Keypad
- **Analysis Time:** Normal Test – 50 seconds
- **Software:** Resides on flash memory and drives all man-machine interface functions, runs algorithms for test measurements and operational screens. System can be upgraded from a PC CD-ROM.
- **Sample Testing Temperature:** Calibrated for room temperature only. Motility results will be impacted by over-heating the specimen.
- **Motility channel input signal:** Analog, up to 5V.
- **Spectrophotometer channel input signal:** Modulated (1 kHz) analog, up to 5V.

Quality Control

- **Internal:** Electronic Self-Test and Auto-Calibration.
- **External:** Latex beads control material (QwikCheck™ beads)

PC Compatibility

Minimum requirements for B-Sperm™ software

- **PC:** 1 GHz processor, Pentium 3
- **RAM:** 256 MB
- **AGP-video display card** with at least 16 MB of RAM memory
- **Video color**: At least 16 bit (65,535)
- **CD ROM drive**
- **40 GB free hard disk space** for image capturing/storage
- **Video resolution:** Minimum 640 x 480

Operating system compatibility

- **Windows** XP or VISTA or WIN7
- **Ports:** One serial; two USB ports
- **Monitor:** 15" color

Additional Software (supplied with system)

- **B-Sperm software:** Real time visualization interface between PC and SQA-Vb visualization system, data transfer, video/picture capture and archive.

Operational Temperature and Humidity

- System is operational at 15-38°C.
- *NOTE*: SQA-Vb operates in a wide range of ambient temperatures however the system is calibrated to measure semen samples pre-heated to 37°C / 98.6°F prior to testing (refer to the SQA-Vb User Guide Appendix I: Semen Sample Preparation).
- *NOTE*: Variations in ambient temperature may impact the accuracy of test results because of the effect of temperature on semen.
- System is fully operational at up to 80% humidity and 31°C.

Maintenance Schedule

- Cleaning daily or after every 25 tests (refer to the SQA-Vb User Guide Appendix IV: SQA-Vb Cleaning Instructions).

Manufacturer Recommendations

- Operate the SQA-Vb away from devices that may cause electronic noise (cell phones) or other devices causing vibrations such as centrifuges.
- Turn system **OFF** at the rear-panel when not in use for extended period of time.
- Variations in ambient temperature can affect semen samples. The SQA-Vb is calibrated to conduct tests at 37^0C / 98.6^0F.
- Semen is considered a biologically hazardous material and is subject to individual laboratory protocols for handling such materials.

Factory Default Settings

Date format: **DD/MM/YY**

Date/Time: Manufacturer's local date/time

Sample Type: **FRESH**

CONC STANDARD**: 1 (Neubauer)**

Operational Default Settings:

- Automatically Send to PC: **YES**
- Data Entry in B-Sperm: **YES**
- QwikClick Counter**: NO**

Appendix IX: Product Performance Data

Abbreviations:

CONC:	Sperm Concentration
MSC:	Motile Sperm Concentration
PMSC:	Progressively Motile Sperm Concentration
Mic.	Micron
Sec.	Second
M/ml	Million per milliliter

Performance Data Summary:
The performance of the SQA-Vb system for bull semen analysis is summarized in the text, tables and graphs below. Sperm concentration measurements are expressed as $x10^6$ sperm cells per milliliter (M/ml). Motility and Morphology values are expressed as a percent (%). Unless otherwise noted all testing was performed using fresh and frozen bull semen samples.

Calibration:
Each SQA-Vb device is biologically calibrated against two reference systems at Medical Electronic System's laboratory using bull semen.

Dynamic Range:

Sample Type	Test Mode	Conc. M/ml	Motility %	Morphology %	MSC M/ml	PMSC M/ml	Velocity, mic./sec.
Fresh	Fresh	0-2000	0-95	0-100	0-1900	0-1800	0-130
Frozen	Frozen	0-200	0-95	-	0-200	0-200	0-80

Precision and accuracy established against a known target (Latex beads)

Background: The precision and accuracy of the SQA-V was compared to a known target value using commercially available latex beads of two concentrations. Latex beads are run on the SQA-V in the same manner as semen samples.

Limitations of method:
Latex beads cannot:

- Measure sperm motility or morphology
- Correct for inaccurate chamber depths or technician errors

Method comparison:
A total of 320 latex bead samples were tested on ten SQA-V systems (32 samples per SQA-V). Precision of the SQA-V was estimated (Table 1). SQA-V concentration readings were compared to the established target values +/- the acceptable range for the latex beads (Fig. 1 & 2).

Accu-beads® published acceptable ranges (*Hemacytometer*):

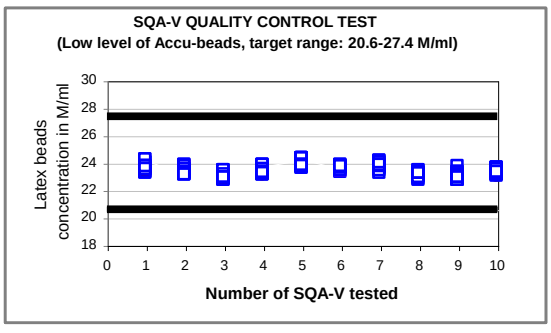
- Vial #1: 47 +/- 7.0 M/ml
- Vial #2: 24 +/- 3.4 M/ml

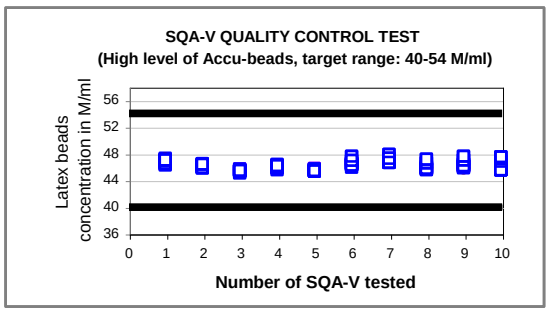
Table 1: Precision

SQA-V	Accu-beads®	CV %
Intra-device Variability	**High 47± 7.0 M/ml**	**≤ 0.01**
	Low 24 ± 3.4 M/ml	**≤ 0.01**
Inter-device Variability	**High 47± 7.0 M/ml**	**≤ 2.00**
	Low 24 ± 3.4 M/ml	**≤ 2.50**

Fig. 1- 2 Accuracy

Low/High Level Controls:





Conclusions:

The CONTROL mode software of the SQA-Vb (bull) device is exactly the same as the SQA-V (human) system. Both systems also have the same hardware platform. Therefore, the accuracy and precision results obtained on the CONTROL mode of the SQA-V will be the same as that of the CONTROL mode of the SQA-Vb.

Sensitivity, specificity, precision, accuracy and correlation to manual method established in the MES laboratory and field clinical trials using bull semen samples

FRESH SEMEN Performance Claims (Table 2-5)

Sensitivity

- Concentration: 90%
- Motility: 85%
- Morphology 80%

Specificity

- Concentration: 90%
- Motility: 80%
- Morphology 90%

Precision (CVs)

- Conc.: 3%
- Motility: 5%
- MSC: 7%
- Velocity: 10%

Accuracy (regression coefficients of "live/dead" trend line) Claims:

- Motility: 0.85
- MSC: 0.9
- PMSC: 0.9

Correlation to Manual Method Claims:

- Concentration: 0.9
- Motility: 0.8
- Morphology 0.7
- MSC: 0.9
- PMSC: 0.8
- Velocity: 0.75

FROZEN SEMEN Performance Claims (Table 3, 5)

Precision (CVs)

- MSC: 7%
- Velocity: 4%

Correlation to Manual Method

- MSC: 0.8
- PMSC: 0.7
- Velocity: 0.85

Table 2: Sensitivity/Specificity

SQA-Vb vs. Microscope	Sensitivity	Specificity
FRESH SEMEN		
Sperm Concentration M/ml	100.0%	98.4%
Motility, %	96.3%	85.0%
Morphology	85.7%	91.7%

Table 3: Precision
SQA-Vb intra-device Variability (CV, %)

Parameter	Sample Type	
	Fresh	Frozen
Sperm Concentration M/ml	2.4	-
Motility, %	4.1	-
Morphology %	5.0	-
MSC, M/ml	6.1	6.4
Velocity, microns/sec.	9.9	3.4

Table 4: Accuracy:
Regression coefficients from "live/dead" experiments

Parameter	SQA-Vb	Manual
Motility, %	0.9135	0.8325
MSC, M/ml	0.9348	0.7547
PMSC, M/ml	0.9340	-

Notes:

- Sensitivity and specificity claims are lower than actual values noted (Table 2).
- Precision CV claims are higher (lower precision) than actual values noted (Table 3).
- Accuracy regression coefficient claims are less than actual values noted (Table 4).
- Correlation to Manual Method claims are less than actual correlations noted (Table 5).

Method comparison:

SQA-Vb was compared to the microscope based on WHO '99 guidelines. The SQA-Vb automated readings of the sperm concentration, motility, MSC, PMSC and velocity were compared to microscopic results. A Makler chamber was used according to manufacturer's instructions for the manual sperm concentration measurements. A standard slide and B-Sperm software were used to assess manual motility, progressive motility and velocity measurements. Manual MSC and PMSC parameters were calculated from experimental results. The protocols were based on WHO '99 and MES guidelines. The alpha-site clinical trials were conducted at the Sion farm. A total of 104 fresh and 138 frozen semen samples were analyzed.

Analytical Specificity:

- To achieve analytical specificity a specific wave length of light which is maximally absorbed by sperm cells and minimally absorbed by other cells and seminal plasma is used.
- Low noise and high electronic resolution hardware components and compensation circuits ensure that analytical specificity is optimized.

Limitations of method:

Samples were assessed in duplicate on the automated SQA-Vb system and manually using a microscope. Statistical counting errors and intra-operator variability (subjectivity) may have affected the results of the study.

Accuracy assessment: "live/dead" sperm plots.

The SQA-Vb accuracy was assessed by "live/dead" bull sperm experiments. Fresh bull semen was distributed into two aliquots. The first aliquot was intact ("live") and the second one was treated with the liquid nitrogen ("dead"). Then different "live-to-dead" proportions were created providing a constant Sperm Concentration but varying MSC, PMSC and Motility. The samples were tested using the SQA-Vb device and under the microscope and the results plotted. The linear trend lines were established for motility, MSC and PMSC variables vs. "Live/Dead" sperm ratio.

Table 5: Correlation to manual method

Parameters	Correlation coefficients	
	Fresh semen	Frozen semen
Sperm Concentration, M/ml	**0.93**	**-**
Motility, %	**0.81**	**-**
Morphology %	**0.71**	**-**
MSC, M/ml	**0.94**	**0.84**
PMSC, M/ml	**0.86**	**0.74**
Velocity, mic./sec.	**0.81**	**0.91**

Fig. 3: Method comparison: Regression plot of SQA-Vb Sperm Concentration in fresh bull semen vs. manual results

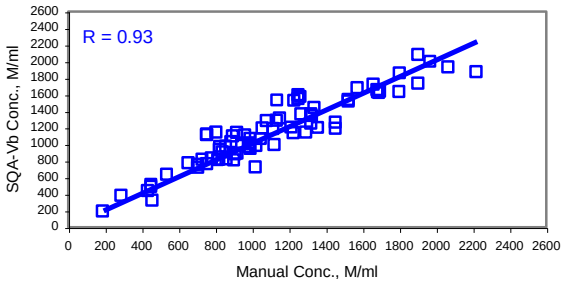


Fig. 4: Method comparison: Regression plot of SQA-Vb Motility in fresh bull semen vs. manual results

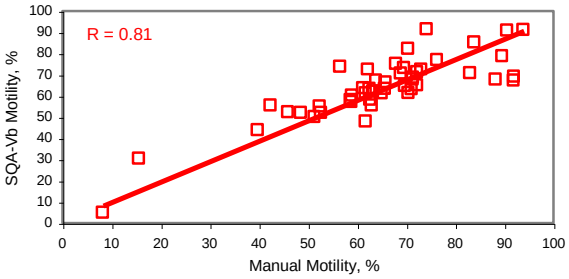
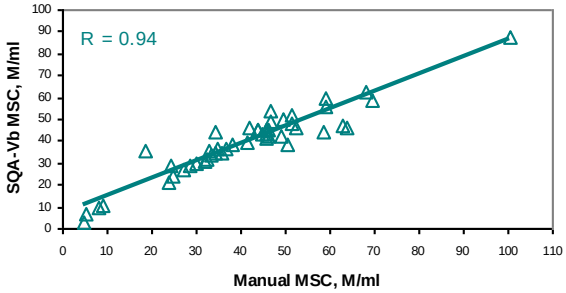


Fig. 5: Method comparison: Regression plot of SQA-Vb MSC in fresh bull semen vs. manual results



Performance parameters:

- Sensitivity and specificity were calculated using ROC analysis formulas. The cutoffs normally used for the sperm concentration and motility of the fresh semen samples were used for calculation of sensitivity and specificity. As for the frozen samples there are no cutoffs, sensitivity and specificity were not calculated for this type of samples (Table 2).
- Precision of the SQA-Vb device was estimated by calculation of the intra-device coefficients of variation (CV) of the duplicate measurements (Table 3). CV is calculated according to the formula:
    - CV = SD / MEAN x 100
- The accuracy of the SQA-Vb device was characterized by regression coefficients of the trendline obtained in the “live/dead” experiment (Table 4).
- Correlation to manual method was established by calculation of correlation coefficients (Table 5, Fig. 3-5).

Conclusions:

- High levels of sensitivity, specificity and correlation of the SQA-Vb device results to the manual method were found. Therefore the instrument can be used in the field for the semen quality assessment, dose preparation and in the frozen semen QC.
- SQA-Vb provides the precise and accurate results with low coefficients of variation (<6%) and high regression coefficients of the “live/dead” trend lines (>0.95).

Appendix X: SQA-Vb Service Menu

Press **Service** button of the SQA-Vb system to open **SERVICE MENU** and access one of 5 functions:

SERVICE DATA: Select this option to view three service screens:

- **Service Data screen (Communication screen)**: Establishes communication between the SQA-Vb and the PC (B-Sperm) in order to:
  - Set-up the CONTROLS default settings
  - Report SQA-Vb service information for technical troubleshooting
- **Self-Test Data screen (1):** Provides system information after Self-Test (Self-Test Data) and after regular testing (Internal Data).
- **Self-Test Data screen (2):** This screen displays internal parameters and tests remaining.

SERVICE PERSONNEL:

- For technical services personnel only and requires a password to access.

PRINT SELF-TEST DATA:

Select to print the SQA-Vb **Self-Test Data.**

DATE SETTING: Select this option to set the date:

DATE SETTING

LOCAL TIME:	08:15:45	HH:MM:SS 24 h
DATE FORMAT:		MM/DD/YY D/MM/YY
DATE SETTING:		04/01/07

- **LOCAL TIME:** enter local time
- **DATE FORMAT:** Select the format **DD/MM/YY or MM/DD/YY** using the right/left arrows on the keyboard. Press **ENTER** to confirm.
- **DATE SETTING:** enter current date.

ADD TESTS TO COUNTER: I-button tests

- Select **SERVICE MENU >ADD TESTS TO COUNTER** and press **ENTER**
- The SQA-Vb screen will instruct the user to:

TO ADD MORE TESTS

HOLD NEW I-BUTTON AGAINST PORT

AND PRESS ENTER

- Make sure the I-Button touches the internal surface and edges of the port. Press the I-button firmly in the port, moving it left and right to make sure it also touches the edges of the port.
- The **# TESTS ADDED** and the cumulative **# TESTS NOW REMAINING** will be displayed on the screen of the SQA-Vb.
- The screen will warn the user if an **EMPTY I-BUTTON** (was) **INSERTED**

NOTE: If the I-Button is not properly inserted a message: **I-BUTTON NOT PROPERLY ACTIVATED** will be displayed. Remove the button, press ESC and try again.

Appendix XI: Troubleshooting SQA-Vb Warning Screens

Stabilization Failed:

STABILIZATION FAILED
TURN OFF MAIN SWITCH ON REAR PANEL
REACTIVATE UNIT

IF PROBLEM PERSISTS,
CALL FOR TECHNICAL SUPPORT

- Ensure there is no testing capillary in the measurement compartment.
- Remove the SQA-Vb from sources of electronic noise (centrifuge, cell phones, etc.).
- Clean measurement compartment (refer to Appendix).
- Reboot the SQA-Vb without a testing capillary in the chamber:
  - Turn system **OFF** then back **ON** at the main switch on the rear panel.
  - Press the front panel **ON/OFF** key to begin Auto-Calibration/Self-Test
  - Call for technical support if failure recurs.

Failed Self-Test:

FAILED SELF-TEST
TURN OFF MAIN SWITCH ON REAR PANEL
CLEAN OPTICAL CHAMBER
REACTIVATE UNIT

IF PROBLEM PERSISTS,

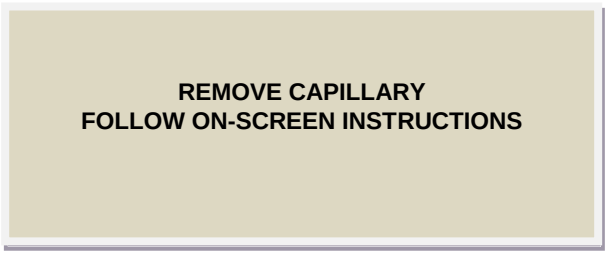
- Ensure there is no testing capillary in the measurement compartment.
- Remove the SQA-Vb from sources of electronic noise (centrifuge, etc.).
- Clean measurement compartment (refer to Appendix).
- Reboot the SQA-Vb without a testing capillary in the chamber:
  - From the rear panel switch, turn the system **OFF** then back **ON.**
  - Press the front panel **ON/OFF** key to begin Auto-Calibration, Stabilization and Self-Test.
- Call for technical support if this message is displayed again. Prepare for technical support by printing a copy of the SQA-Vb Self-Test/Service Data:
  - Press **SERVICE** key. The **SERVICE MENU** will be displayed.
  - Select **PRINT SERVICE DATA** option.
  - Press **ENTER** to print a copy of the self-test/service data.

Electronic Noise:

ELECTRONIC NOISE
TURN OFF MAIN SWITCH ON REAR PANEL
REACTIVATE UNIT

IF PROBLEM PERSISTS,
CALL FOR TECHNICAL SUPPORT

- Ensure there is no testing capillary in the measurement compartment.
- Remove SQA-Vb from sources of electronic noise (centrifuge, etc.).
- Clean measurement compartment (refer to Appendix).
  - After cleaning, activate **MAIN MENU > TEST NEW SAMPLE** and re-run the test.
- If this message is displayed again, reboot the SQA-Vb:

	○ Turn the system **OFF** then back **ON** at the main switch on the rear panel. ○ Press the front panel **ON/OFF** key to begin Auto-Calibration and Stabilization. ○ Re-run the test. ○ Call technical support if this message is displayed again. Prepare for technical support by printing a copy of the Self-Test/Service parameters: ○ Press **SERVICE** key. The **SERVICE MENU** will be displayed. ○ Select **PRINT SERVICE DATA** option. ○ Press **ENTER** and the service parameters will be printed.
	Remove Capillary:  • If the testing capillary has been left in the measurement chamber after testing a sample the message above will be displayed. • Remove the testing capillary before running a new test.