QwikCheck™ Gold

HUMAN Service Manual

Version 1.00 I-Button

Catalog #F-A-00688-00

Rev: April 2011
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SECTION I: Introduction

The QWIKCHECK GOLD is a high performance analytical medical device that combines state-of-the-art technology in electro-optics and computer algorithms. The system performs a precise, 75-second semen analysis. The QWIKCHECK GOLD runs a self-test and auto-calibration on start-up and also runs external quality controls. The QWIKCHECK GOLD is an automated system and which allows flexibility to analyze all types of semen samples.

<table>
<thead>
<tr>
<th>Automated Test Results</th>
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</thead>
<tbody>
<tr>
<td>Technology</td>
</tr>
<tr>
<td>Automated System</td>
</tr>
<tr>
<td>Motility Channel</td>
</tr>
<tr>
<td>• Light disturbances</td>
</tr>
<tr>
<td>• The greater the</td>
</tr>
<tr>
<td>• The slower the</td>
</tr>
<tr>
<td>• The average analog</td>
</tr>
<tr>
<td>Concentration Channel</td>
</tr>
<tr>
<td>• Sperm concentration is measured in the cuvette section of the QWIKCHECK GOLD testing capillary.</td>
</tr>
<tr>
<td>• An infrared light wavelength specific to sperm cells is maximally absorbed by sperm cells and minimally absorbed by other seminal fluid components.</td>
</tr>
<tr>
<td>• In the final calculation of sperm concentration the QWIKCHECK GOLD algorithm makes an adjustment to account for the infrared light absorption of the seminal fluid components.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Automated Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automated System</td>
</tr>
<tr>
<td>Semen Parameters</td>
</tr>
<tr>
<td>Total Sperm Concentration (Count)</td>
</tr>
<tr>
<td>Motility</td>
</tr>
<tr>
<td>Progressive Motility (“a” and “b”)</td>
</tr>
<tr>
<td>Non-progressive Motility (“c”)</td>
</tr>
<tr>
<td>Immotility (“d”)</td>
</tr>
<tr>
<td>Normal Morphology</td>
</tr>
<tr>
<td>Motile Sperm Concentration</td>
</tr>
<tr>
<td>Progressively Motile Sperm Concentration</td>
</tr>
</tbody>
</table>
Step 1: The capillary is inserted into the measurement compartment.
Step 2: Sample concentration is evaluated in the "tall" 10 mm chamber of the capillary by measuring the amount of optical absorption of light as a beam traverses the seminal fluid.
Step 3: Motility is detected in the "thin" 0.3 mm section of the capillary by analyzing light modulations caused by sperm motion.
Step 4: This information is then digitized and routed to the microprocessor that applies algorithms to extract the required clinical semen parameters and performs internal self-testing and calibration.
SECTION II: System Specifications

Dimensions: 20cm Height x 29cm Width x 24cm Depth
Weight: 4.15 kg
AC power supply: 100 to 250 VAC, 50/60 Hz, 24W
Fuse rating: 1A 250V
Power stability requirements: Voltage fluctuations ± 5% nominal

Measurement Compartment

- Sources of radiant energy - two LEDs for motility and spectrophotometry channels
- Detector system - two photo detectors - Motility and Optical Density

Display

- Operational backlight LCD (16 lines x 40 characters)

Keypad

- Operational keys: ON/OFF, TEST, PRINT, SERVICE, DELETE, ENTER, four cursor buttons, ESC, ten numeric buttons (0-9)

Front Panel

- LCD operational display
- Measurement compartment
- Multi-button keypad
- I-Button

Rear Panel

- Power connector with fuse-holder (2 fuses: 250V, 1A)
- RS232 cable outlet

Specimen Testing Supplies

- Measurement capillary: Disposable, plastic, positive displacement testing capillary. Testing depth of capillary section: 300-micron; Cuvette section: 10 mm.

Operating System

- Control: Keypad
- Analysis Time: Normal Test – 75 seconds.
- Software: Resides on flash memory and drives all man-machine interface functions, runs algorithms for test measurements (according to WHO guidelines), and operates automated screen.
- Sample Testing Temperature: Calibrated for room temperature only 20-25° C / 68-77° F. Motility results will be impacted by 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.

Operational Temperature and Humidity

- System is operational at 15-38°C.
- NOTE: QWIKCHECK GOLD operates in a wide range of ambient temperatures however the system is calibrated to measure semen samples at room temperature: 20-25°C (68-77°F).
• **NOTE**: Variations in ambient temperature may impact the accuracy of test results because of the effect of temperature on human semen.

• System is fully operational at up to 80% humidity and 25°C.

### Maintenance Schedule

- Daily cleaning of measurement compartment (refer to User Guide - "Cleaning") or with each 10-15 tests and/or spillage. **USE ONLY the MANUFACTURER supplied cleaning kit, brush and solution to clean the QWIKCHECK GOLD or the system may be damaged and/or inoperable!**

### Manufacturer Recommendations

- Operate the QWIKCHECK GOLD 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 QWIKCHECK GOLD (HUMAN) is calibrated to test samples at room temperature: 20-25°C (68-77°F).

- Semen is considered a biologically hazardous material and is subject to individual laboratory protocols for handling such materials.

### Factory Default Settings

- **Chamber standard:** 2 (Neubauer)
- **Morphology:** WHO
- **Date format:** DD/MM/YY
- **Time/Date:** Manufacturer’s local time/date
- **Controls (all levels/types):** Exp date 01/01

### SECTION III: System Overview

**QWIKCHECK GOLD System**

**Front Panel**

- Operational Display
- Power Indicator
- I-Button
- Keypad

- Automated Measurement compartment
NOTE: The TEST button of the QWIKCHECK GOLD keypad is only active in the CALIBRATION mode.

Keypad Navigation

- Use NUMERIC keys to enter data; ARROW keys to move to the next field.
- Press ENTER to select menu options, confirm data entries and to move to the next screen or field.
- Use the ESC button to return to the previous screen or field.

Rear Panel

Rear Panel assembly screws
Ventilation slots
Power connector and main switch
Instrument label
RS232 COM port

Side Panel

Side Panel
- The side panel has an I-Button port (with clip in newer QWIKCHECK GOLD’s starting with Serial Number G0033)
- Refer to the Appendix Section for instructions on how to load I-button tests.

Assemblies

The Chassis Assembly
- The chassis assembly includes both the base and rear panel and contains the following sub-assemblies:
  - Main Board
  - Switch Power Supply
  - Surge Protector (starting with SN# G0023)
  - AC Power Inlet Assembly
  - Ventilation Fan
  - Communication Plug

The Cover Assembly
- The cover assembly includes the following:
  - Operational Display
  - Keypad
  - Power Indicator LED
  - Measurement Compartment
Schematic of the QWIKCHECK GOLD Motherboard

SECTION IV: System Components and Accessories

Testing Capillary

- Can be used in the measurement chamber of the QWIKCHECK GOLD.
- Disposable, designed to collect and test samples in a biologically safe manner.
- Motility is measured in the 0.3 mm (thin) "Capillary Section."
- Concentration is measured in the 10 mm (tall) "Cuvette Section."

Cleaning Kit

- NOTE: Only use the manufacturer's cleaning kit or the QWIKCHECK GOLD can be damaged.
- Daily cleaning is recommended or after testing 10-15 specimens.
- See the Appendix Section detailed instructions on how routine cleaning.
Accessory Kit

- Each kit contains:
  - Power Cables
  - Communication Cable
  - Instructional Guides

Electronic Self-Test and Auto-Calibration

A series of tests are automatically run on the QwikCheck GOLD to check the calibration and internal operating system. Tests are run when the QwikCheck GOLD is first turned-on and also prior to each semen analysis test.

Start-up:

- **Stabilization and auto calibration:** Checks system stability and reference ranges. The system sensors are analyzed for several minutes to insure that the values are within a very narrow acceptable range. Once the system is stable for 30 seconds it will pass stabilization and auto calibration. The system will fail if it is not stable for at least 30 seconds and a warning message will be displayed.

- **System noise:** The level of electronic noise in the system is measured to insure that noise thresholds are accurately defined to ensure effective measurement of electronic signals. The system will use this measurement prior to running a test and will automatically adjust the noise level thresholds to ensure accurate readings.

- **Self-test:** The system produces electronic signals that simulate motility and concentration in order to check the performance of the system and verify that the calibration settings are consistent with the factory specifications. The QwikCheck GOLD will report failures (see section on error and warning messages) and "freeze" the system if the system is not within the established ranges.

Prior to testing a sample:

- **Auto calibration verification:** Reference values are read again. The concentration and motility parameters are measured (without a testing capillary).

- **System noise:** Measures the electronic noise level of the system to insure that noise thresholds are accurately defined in the system to ensure effective measurement of electronic signals. The system will use this measurement prior to running a test and will automatically adjust the noise level thresholds to ensure accurate readings.

- **Electronic spikes:** Checks for any measurement points that are out of range electronically. More than three such points will fault the system and a warning message will be displayed.

The following procedure details how the user can document the system parameters to prepare for technical support if the system fails (see section of this user guide on Error Messages and Warning Messages).

Instructions for printing the QwikCheck GOLD Self Test parameters to prepare for technical support:

How to print a copy of the SELF TEST DATA:

- Remove the testing capillary from the system.
- When a FAILED SELF TEST message appears select: **MAIN MENU > SERVICE > PRINT SELF TEST DATA AND SETTINGS > SELF TEST DATA.**
- Press **ENTER** after highlighting **SELF TEST DATA** to print a copy of the data.

How to view the system parameters FROM QwikCheck GOLD:

- Go to: **MAIN MENU > SERVICE > SERVICE DATA.** All of the service screens can be viewed by pressing **ENTER.**
Refer to the table below. Enter numbers in the "QWIKCHECK GOLD Value" column that corresponds to #1 - #10 from the QWIKCHECK GOLD system parameters printout. Compare the values. If the value from the QWIKCHECK GOLD is within range mark the "Pass" column. If not, mark the "Fail" column.

<table>
<thead>
<tr>
<th>#</th>
<th>Parameter</th>
<th>Allowable Values</th>
<th>QWIKCHECK GOLD Value</th>
<th>Pass</th>
<th>Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Ref 1</td>
<td>150 – 350 mV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>LED Cur 1</td>
<td>5 – 25 mA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Amplitude</td>
<td>50 – 100 mV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Zero Level</td>
<td>500 - 525</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Ref 2</td>
<td>2500 – 3500 mV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>LED Cur 2</td>
<td>10 – 32 mA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>CONC. 1</td>
<td>0 – 1 M/ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>CONC. 2</td>
<td>50-150 M/ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>CONC. 3</td>
<td>300-600 M/ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Count (Internal Data, Item #12)</td>
<td>26 - 36</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION VI: Getting Started / Set-Up

Please refer to the relevant QWIKCHECK GOLD User Guide for start-up and set-up instructions (based upon the software version of the QWIKCHECK GOLD).

SECTION VII: Troubleshooting

Overview: The following sections describe how to troubleshoot and repair potential problems that may occur with the QWIKCHECK GOLD. These sections will discuss how to provide support for three types of issues:

- **Technical - Self test - Clinical**

**PLEASE NOTE:**

- Only a qualified MES distributor who has been trained to perform technical support is authorized to open the QWIKCHECK GOLD.
- If the QWIKCHECK GOLD is opened without authorization it may cause damage to the calibration AND will VOID THE WARRANTY.
- The electro-optical board should NEVER be touched when the QWIKCHECK GOLD is opened – it will cause damage to the QWIKCHECK GOLD calibration.

SECTION VIII: Technical Support/Part Replacement

1. **Opening the QWIKCHECK GOLD**
   - Turn off the main switch located on the rear panel and disconnect the from the electrical supply.
   - Using a Phillips screwdriver, unscrew all of the screws on The rear panel (four screws total).

2. **Closing the QWIKCHECK GOLD**
   - Grip each panel from the side and guide them back together making sure that all cables and connectors are free and not “pinched” between the panels.
   - Use a Phillips screwdriver to secure the panels using the four screws.
3. Keypad (Part # F-E-00436-00)

ISSUE: The Keypad is not working

- Open the QWIKCHECK GOLD
- Disconnect the keypad cable connector from location J11 on the main board
- Carefully peel off the damaged keypad from the front panel. Use a flat screwdriver for easier removal. Clean the surface with alcohol and let it dry for a few minutes.
- Pull the keypad cable through the slit in the front panel

- **Attach the new keypad:** Insert the new keypad cable into the slit in the front panel. **Please note:** DO NOT connect it at this time.
- Attach the keypad to its designated location on the front panel by gradually removing the paper while pressing it firmly into place from one side to the other. **Please note:** DO NOT bend the keypad during this process or electrical wires/ connectors will be damaged.
- Attach the keypad connector to the J11 location on the main board. **Please note:** The golden stripe on the cable connector should be facing the rear panel (the fan side).
- Close the QWIKCHECK GOLD using 4 screws on the rear panel of the QWIKCHECK GOLD.

4. Power Supply

ISSUE: The main switch is ON but the power indicator does not light up and the fan is not working.

- Check the fuse in the fuse box located on the rear panel of the QWIKCHECK GOLD.
- Replace the fuse if it is burned out.
- Reconnect the power supply and turn the unit back on.
- If the unit still does not work, check the input/output power inlet as instructed below.
How to check the input connector:

- Disconnect the input cable from the Power Supply Unit.
- Check the power supply to the input channels (ground, OV and 220V AC).
- If no power is evident, replace the power inlet (see paragraph 7).
- If power is being supplied to all channels, reconnect the input and check the output.

How to check the output connector:

- Disconnect the output cable from the motherboard.
- Check the power supply to the output channels (ground, 5V, 12V).
- If there is still no power supply in the output connector, contact support services.
- If the power is working but the problem continues, contact support services.

5. Power Supply Unit–PSU
   (Part #Fpe-E-00146-00 without harnesses)

- Open the QWIKCHECK GOLD.
- Disconnect the input connector of the power supply unit- location CN1.
- Disconnect the output connector of the power supply unit- location CN2.
- Using a #2 Philips screwdriver, unscrew the four screws that connect the PSU to the rear panel.
- Remove the old PSU.
- Secure a new PSU to the front panel using the same four screws.
- Re-connect the input and output cable connectors to the PSU.
- Close the QWIKCHECK GOLD. If the problem persists - Contact Technical Support.
6. Power Inlet (Part# AP-9081001)

**ISSUE:** There is no power supplied to the PSU from the inlet.

- Open the QWIKCHECK GOLD.
- Unscrew the power-inlet screws at the rear panel of the device.
- Disconnect the power supply connector from the power supply unit.
- Gently pull the plastic cover of the power inlet until the connectors are exposed.
- Disconnect the three connectors from the power inlet.
- Gently pull the power inlet out of the QWIKCHECK GOLD through the rear panel.
- Insert a new power inlet and re-connect the cables.
- Re-connect the internal cables, re-place the internal cover and re-connect the power supply cable to the power supply unit.

**Fan Assembly**

7. Fan Assembly (Part# P-H-00018 and # PE-EM-00410-00)

**ISSUE:** The master switch is ON, the power indicator is lit but the fan is not rotating.

- Open the QWIKCHECK GOLD.
- Check to see if all the connecting cables to the fan are in place.
- Using a Philips screwdriver, unscrew the four fan screws.
- Replace the fan assembly.
- Re-connect the cables and screw the new fan to the rear panel of the QWIKCHECK GOLD.
- Do not change the direction of the outlet air flow!

**Operation Monitor**

8. Operation Monitor – LCD Screen (Part# LCD-0009)

**ISSUE #1:** The QWIKCHECK GOLD is ON, both power indicators are functioning and the fan is working. But the LCD screen (Operation Monitor) is not illuminated although data is displayed on the screen.
NOTE: Turn off the power supply to the QWIKCHECK GOLD and disconnect the power supply cable from the back of the device before opening the QWIKCHECK GOLD.

WARNING: DO NOT TOUCH the illuminated area of the LCD Backlight – HIGH VOLTAGE is supplied there.

AFTER checking the LCD backlight, turn off the QWIKCHECK GOLD and disconnect it from the main.

ISSUE #2: Blank screen: There is no data displayed on the screen in spite of the fact that the QWIKCHECK GOLD is ON, both power indicators are functioning and the fan is working.

- Re-install QWIKCHECK GOLD software.
- If the problem persists, open the QwikCheck Gold and verify that the flat cable that connects the user screen to the main board is connected properly (see figures for the correct cable configuration).
- Replace the flat cable if it is damaged.
  (Part #KHD-908-000858 rev01).
- If the flat cable is connected properly and the problem persists, verify that the RS232 cable that connects the main board to the PC is connected properly and that the Connector located at J5 on the main board is secure. If the cable is damaged, replace it.
  The RS232 cable part # KHD-908-000851 Rev.02
- If the problem persists, replace the processor on the main board (see Appendix section for instructions).
If replacing the processor does not work:

- Re-start the QWIKCHECK GOLD and see if the LCD operational screen is still blank. If yes, replace the screen.
- Disconnect the operational display data and power cable - note the four screws.
- Replace the screen & reconnect the data and power cables.

9. Surge Protector Replacement (Part #V-A-00475-00)

**Issue: The QWIKCHECK GOLD does not turn-on**

An internal surge protector protects the QWIKCHECK GOLD from most damage caused by electrical surges or unstable electricity. To replace the surge protector:

- Turn off the power and then open the QWIKCHECK GOLD
- Turn the power on BRIEFLY just to check to see if the green light of the surge protector is on.
- Turn the system off and close the unit.
- If it is not on, replace the surge protector:

How to replace the Surge Protector:

- Turn off the QWIKCHECK GOLD and disconnect the power cable from the rear panel.
- Pull down and separate the two green sections of the surge protector.
- Using a 5.5mm socket screw driver, unscrew the 4 nuts connecting the Surge Protector to the rear panel.
- Replace the surge protector “body” (grey part) with a new one.
- Replace the four nuts.
- Close the QWIKCHECK GOLD.
Capillary Sensor

10. Capillary Sensor Troubleshooting and Replacement (KHD-908-000846 REV 02)

**Issue:** When the QWIKCHECK GOLD is turned on, it fails SELF TEST.

- Ensure there is no testing capillary in the measurement compartment.
- Remove the QWIKCHECK GOLD from all sources of electronic noise.
- Clean the measurement compartment as per the User Guide instructions.
- Reboot the QWIKCHECK GOLD without a testing capillary in the chamber:
  - 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.
- In case the self-test keeps failing after the reboot do the following:
  - Print a copy of the SELF-TEST parameters.
  - Check parameter #17. This parameter represents the noise level. In case the value is higher than 3- the noise level is too high. In this case replace the cables connecting the Optical Board to the LED Board.
- Check the values of Conc 1, Conc 2 and Conc. 3. If these values are ZERO- the capillary sensor might be damaged and needs to be replaced.

**How to replace the capillary sensor**

- Turn off the power and open the QWIKCHECK GOLD by unscrewing the screws from the rear panel using a #2 Philips screwdriver.
- Use a #2 Allen key to remove the two screws connecting the supporting rib to the front panel
- Use a #2 Allen key to remove the two screws connecting the optical assembly to the front panel of the QWIKCHECK GOLD.
- Carefully pull the optical assembly in order to release it from the front panel.
- Place the optical assembly on its side.
- Release the screw holding the capillary sensor using a #2 Philips screwdriver.
• Unwind the white plastic cable wrap that holds the capillary sensor and other cables

• Remove the damaged capillary sensor from the optical block and unplug the cable connector from its location on the main board- J13

• Install a new capillary sensor harness on the optical block and fasten it using the screw.

• Re-attach the cable to the cable bundle; fasten the cables using the white plastic cable wrap.

• Connect the cable connector to its designated location on the main Board- J13.

• Attach the optical assembly back to the front panel of the QWIKCHECK GOLD using the original 2 screws, verify that the supporting ribs were also re-connected using 2 screws.

• Close back the front and rear panels of the QWIKCHECK GOLD using a #2 Philips screwdriver.

11. Optical Board to LED Cable - Replacement (Part # KHD-908-000689 REV 01)

Issue: When the noise level of the QWIKCHECK GOLD (Parameter #17) is above 3, then the cables connecting the Optical Board to the LED Board need to be replaced.

• Turn off the power and open the QWIKCHECK GOLD by unscrewing the screws from the rear panel using a #2 Philips screwdriver.

• Using #2 Allen Key, remove the two screws connecting the supporting rib to the front panel and the two screws connecting the optical assembly to the front panel of the QWIKCHECK GOLD. (Shown in the pictures below).
• Remove the damaged cables from the Optical board by disconnecting the J5 and J6 connectors from the Optical Board.

• Carefully lay down the Optical assembly.

• Remove the damaged cables from the LED board: disconnect J1 and J2 connectors from their location on the LED board.

**Important Note:** Pay CLOSE attention to connect the cables in the CORRECT direction.

Connect a new pair of cables as follows:

• Connect the cables back to the J5 and J6 connectors on the Optical Board.

• Connect the cables back to the J1 and J2 connectors on the LED Board.

• Reattach the optical assembly to the front panel using the same 2 screws. Verify that the supporting ribs were also re-connected using 2 screws.

• Close the QWIKCHECK GOLD.
SECTION IX: Error Messages

1. Stabilization Failed:

- Ensure there is no testing capillary in the measurement compartment.
- Remove the QWIKCHECK GOLD from sources of electronic noise (cell phones, etc.).
- Clean measurement compartment thoroughly (refer to Appendix for instructions).
- Reboot the QWIKCHECK GOLD 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/Stabilization.
- Call technical support if failure recurs.

2. Self-test Failed:

- Ensure there is no testing capillary in the measurement compartment.
- Remove the QWIKCHECK GOLD from sources of electronic noise (cell phones, etc.).
- Clean measurement compartment thoroughly (refer to Appendix for instructions).
- Reboot the QWIKCHECK GOLD without a testing capillary in the chamber:
  - 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.
  - Call technical support if this message is displayed again. Prepare for technical support by printing a copy of the QWIKCHECK GOLD internal parameters.

3. Electronic Noise:

- Ensure there is no testing capillary in the measurement compartment.
- Remove QWIKCHECK GOLD from sources of electronic noise (cell phones, etc.).
- Clean measurement compartment thoroughly (refer to Appendix for instructions).
4. Concentration Out of Range

Normal Testing:

- A message will appear indicating that the tests results for SPERM CONC. and/or MSC are beyond the dynamic range established by the manufacturer for testing. This message will appear if the QWIKCHECK GOLD reads:
  - SPERM CONC. > 500 M/ml or
  - MSC > 450 M/ml
- Review sample handling technique (see Appendix "Filling the QWIKCHECK GOLD Capillary").
- Re-test the sample in a new QWIKCHECK GOLD capillary. If the message appears again, reboot the system.
- Call for technical assistance if problem persists.

Control Testing:

- A message will appear indicating that the CONTROL is out of the dynamic range for control testing (CONCENTRATION > 118 M/ml) due to:
  - Dehydrated control media
  - Bubbles in the testing capillary
  - Defective QWIKCHECK GOLD testing capillary
- Check control media expiration date.
- Run new control in a new QWIKCHECK GOLD testing capillary.
- Call for technical assistance if problem persists.
5. I-Button warning screen

- **I-BUTTON NOT PROPERLY ACTIVATED**
  - Remove the I-button
  - Press ESC and Retry (refer to Appendix 2 for specific instructions)

- **EMPTY I-BUTTON INSERTED**
  - Press ESC and Retry with a new I-Button

- **I-BUTTON WARNING**
  - This screen will be displayed when less than 10 tests remain in the QwikCheck Gold
  - Insert a new I-Button

6. COMMUNICATION ERROR

- A communication error may occur in one of the following cases:
  - Defective wire connection: The cable that connects the optical board to the main board is not well connected or was damaged
  - Hardware problem

7. COMMUNICATION ERROR

- CALL FOR TECHNICAL SUPPORT
Appendix: 1 SQA Cleaning Instructions

SQA and QwikCheck™ Cleaning Instructions

When to clean: DAILY or when...
- Self-test or any other failure occurs
- System becomes contaminated with semen

Cleaning kit contents:
- Blue “dot” cleaning capillaries
- Sponge drying capillaries
- Cleaning brush (wooden handled)
- Cleaning fluid

CLEANING: Step 1
1. TURN OFF the system and unplug it at the main electrical outlet.
2. Select a Blue dot cleaning capillary (Fig. 1)
   - Moisten with ONE drop of cleaning fluid
   - Shake off excess fluid
   - Insert into measurement compartment with fibrous material facing up, moving back and forth a few times
   - Repeat with fibrous material facing down
3. Select a sponge drying capillary (Fig. 2) and insert it in the same compartment in order to dry the chamber. (Fig. 3)

Only use the manufacturer’s cleaning kit and brushes to clean the system or damage will occur to the film and the system will not function

CLEANING: Step 2
If the system still does not pass self-test, the channel that measures concentration may need cleaning. Use the cleaning brush (Fig. 4)
1. Insert the brush (bristles-side down) fully into the upper portion of the lower chamber of the system in the same manner as a testing capillary (Fig. 5).
2. Pull the brush out of the chamber while sweeping or “dusting off” the lens (you will feel a step or shelf at the back and top of the chamber - this is the top of the lens) (Fig. 6)
3. Switch the system ON and observe self-test results. The system should now PASS the self-test; if not, repeat the cleaning procedure with the brush.

Cleaning the SQA Visualization Compartment
Open the visualization compartment door (upper slot) and swing the cover above the lens to the left. Wipe the lens with 70% isopropyl alcohol (not provided).
Instructions for RE-SEATING or REPLACING the SQA PROCESSOR

**Problem description:** In some cases, the LCD screen of the QWIKCHECK GOLD is blank (sometimes after trying to re-install the software). A very quick solution to the problem may be to just re-seat the processor with some downward pressure. If this doesn’t help, and compatible software was installed, the processor may be damaged and require replacement.

**Instructions:**

<table>
<thead>
<tr>
<th>Stage 1: Re-seating the processor to the correct position:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Turn off the QwikCheck GOLDL and disconnect the power supply cable.</td>
<td><img src="Image" alt="Fig. 1-2: Open the QWIKCHECK GOLD" /></td>
</tr>
<tr>
<td>2. Remove the 4 screws on the rear panel using a Philips screwdriver #2 (Fig.1) and open the QwikCheck GOLD(Fig.2)</td>
<td><img src="Image" alt="Fig. 1-2: Open the QWIKCHECK GOLD" /></td>
</tr>
<tr>
<td>3. Slightly press the center of the processor with an index finger to re-seat it into the correct position. (Fig. 3).</td>
<td><img src="Image" alt="Figure 3: Apply downward pressure to the processor" /></td>
</tr>
<tr>
<td>4. Close the QwikCheck GOLD and replace the 4 Phillips screws on the rear Panel (Fig.4)</td>
<td><img src="Image" alt="Fig. 4: Close the SQA" /></td>
</tr>
<tr>
<td>5. Connect the power cable of the QWIKCHECK GOLD.</td>
<td></td>
</tr>
<tr>
<td>6. Turn the QwikCheck GOLD on and run the SELF TEST.</td>
<td></td>
</tr>
<tr>
<td>7. If the QWIKCHECK GOLD passes, the repair process is complete.</td>
<td></td>
</tr>
<tr>
<td>8. If the QWIKCHECK GOLD does not turn-on or fails the self-test, go to stage 2.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 2: Replace the damaged processor:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Turn off the QwikCheck GOLD and disconnect the power supply cable.</td>
<td></td>
</tr>
<tr>
<td>2. Release the 4 screws on the rear panel using a Philips screw driver #2 and open the SQA.</td>
<td></td>
</tr>
<tr>
<td>3. Remove the damaged processor using tweezers as shown (see Fig.5).</td>
<td><img src="Image" alt="Fig. 5: Remove the damaged processor" /></td>
</tr>
</tbody>
</table>

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**SECTION X**

Appendix 2: Replacing the SQA PROCESSOR

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4. Replace the old processor with a new processor according to the following directions:
   - Align the “dot” which is marked on the processor with the “Arrow” mark in the processor cavity (see Fig. 6-7).

5. Slightly press the center of the processor with an index finger to re-seat it into the correct position (Fig. 8).

6. Close the unit and screwing in the 4 Phillips screws on the rear Panel (as shown in Fig. 4 above)

7. Connect the power cable, turn on the QwikCheck GOLD and verify that it passes the SELF-TEST.

Fig. 6-7: Align the processor in the cavity correctly

Figure 8: Re-seat the processor
Section X
Appendix

Appendix 3: Power Supply – Troubleshooting Flow Chart

Check the fuses
Page 12 (paragraph 4)

- Not OK → Replace the fuses
  Page 12 (paragraph 4)
  - OK → End of process
  - Not OK → Check the input cable of the main Power Supply Unit
    Page 13
- OK → Check the output cable of the main Power Supply Unit
  Page 13
  - OK → Contact MES support services
  - Not OK → Replace the power inlet
    Page 14 (paragraph 6)
  - Not OK → Replace the Main Power Supply Unit
    Page 13 (paragraph 5)