VerifyNow® SYSTEM

# User Manual

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# VerifyNow System User Manual

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# About this Manual

This user manual is the place to begin if you are not familiar with the VerifyNow Instrument. It includes information on the Aspirin, P2Y12, and IIb/IIIa assays. For help with use of this instrument, please contact your laboratory supervisor or your Accumetrics customer support representative.

# Intended Use

The VerifyNow System is intended for use with human whole blood and VerifyNow Assay Devices. The VerifyNow System should be operated by health care professionals trained on use of the system and in accordance with institution policies and procedures. An Accumetrics representative will assist your institution in the installation of the system and training of operators.

## Document Conventions

Several notations will be used consistently throughout this manual that require your attention.

**NOTE**: A note is supplementary information or a recommendation for optimizing performance.

**CAUTION:** A caution indicates a potential hazard that could cause minor personal injury, and/or damage to equipment.

**WARNING:** A warning indicates a potential hazard that could cause serious personal injury, and/or damage to equipment.

**WARNING:** This symbol indicates a potential biological hazard.

# 1 Introduction

Before you begin to use the VerifyNow System, it is appropriate to review the purpose of the test.

## 1.1 Platelet Function Testing

In general, platelet function testing measures the activity of platelets. Therapies that inhibit platelet function have been used extensively to prevent the clinical complications of atherothrombosis. Three classes of potent anti-platelet agents, including acetylsalicylic acid (aspirin), P2Y12 inhibitors (e.g. thienopyridines), and glycoprotein (GP) IIb/IIIa inhibitors, have been developed.

One method detects platelet activity by measuring *in vitro* platelet aggregation in a blood sample exposed to specific agonists. This includes inhibition of platelet activity in response to anti-platelet therapies. The VerifyNow system is a whole blood, point-of-care assay, which measures platelet-induced aggregation as an increase in light transmittance. It consists of a turbidimetric-based optical detection instrument, single-use assay devices, and associated quality controls (Figure 1-1).

**Figure 1-1 VerifyNow System**


There are three types of VerifyNow assays: Aspirin, P2Y12, and IIb/IIIa (specifically for monitoring of abciximab or eptifibatide). Each assay device contains a lyophilized preparation of human fibrinogen coated beads and a platelet agonist. The platelet agonist varies by assay type. Each assay is based upon the ability of GP IIb/IIIa receptors on activated platelets to bind to fibrinogen-coated beads. When the activated platelets are exposed to the fibrinogen-coated beads, agglutination occurs in proportion to the number of available platelet receptors. The instrument is designed to measure this agglutination as an increase in light transmittance. The following sections describe the mechanism of action for the three assays. Refer to Chapter 2, *Overview of System Components* for more information on the instrument and consumables.

It should be noted that GP IIb/IIIa inhibitors such as abciximab (ReoPro®), eptifibatide (Integrilin®) and tirofiban (Aggrastat®) interfere with the VerifyNow® Aspirin and P2Y12 assays. Patients who have been treated with Glycoprotein IIb/IIIa inhibitor drugs should not be tested with the VerifyNow® Aspirin or P2Y12 assays until platelet function has recovered. This time period is approximately 14 days after discontinuation of drug administration for abciximab (ReoPro®) and up to 48 hours for eptifibatide (Integrilin®) and tirofiban (Aggrastat®). The platelet function recovery time varies among individuals and is longer for patients with renal dysfunction. Results obtained from patients tested prior to platelet function recovery may be inconsistent and unreliable.

The following sections describe the mechanism of action for the three assays. Refer to Chapter 2, *Overview of System Components* for more information on the instrument and consumables.

### 1.1.1 Aspirin Assay

Acetylsalicylic acid (aspirin) has a significant antiplatelet effect by blocking the production of thromboxane A2. A potent platelet agonist, thromboxane A2 is released by activated platelets and acts to cause vasoconstriction and amplify platelet recruitment by binding to thromboxane receptors on the surface of circulating platelets. In an activated platelet, arachidonic acid is converted by cyclo-oxygenase (COX-1) to prostaglandin $G_2$ ($PGG_2$) and $PGH_2$ and then to thromboxane A2. Aspirin affects platelet function by irreversibly inhibiting the cyclo-oxygenase (COX) activity of prostaglandin (PG) H-synthase, which in turn blocks the metabolism of arachidonic acid to thromboxane A2 (TXA2). The primary pharmacological effect of aspirin on platelets is to decrease the activation of the GP IIb/IIIa receptor and activation of other platelets.

VerifyNow Aspirin assay is a qualitative test to aid in the detection of platelet dysfunction due to aspirin ingestion in whole blood for the point-of-care or laboratory setting. The assay incorporates the agonist arachidonic acid to activate platelets, and it measures platelet function based upon the ability of activated platelets to bind to fibrinogen. Fibrinogen-coated microparticles aggregate in whole blood in proportion to the number of activated platelet GP IIb/IIIa receptors. If aspirin has produced the expected antiplatelet effect, such aggregation will be reduced. The VerifyNow Aspirin assay reports the extent of platelet aggregation as aspirin reaction units (ARUs). Given an ARU range of 350-700, ARU values less than 550 are consistent with aspirin-induced inhibition of platelet function, whereas values greater than or equal to 550 ARUs are not consistent with aspirin-induced inhibition.

**NOTE**: The Aspirin assay is not for use in patients with underlying congenital platelet abnormalities, patients with non-aspirin induced acquired platelet abnormalities or in patients receiving non-aspirin anti-platelet agents. Refer to the VerifyNow Aspirin package insert for information to be considered for patients receiving NSAIDS. The Aspirin assay may be used in patients treated with selective COX-2 inhibitors, e.g. celecoxib (Celebrex®).

### 1.1.2 P2Y12 Assay

P2Y12 inhibitors (e.g. thienopyridines) are a class of therapy that has significant antiplatelet effect by inhibiting adenosine diphosphate (ADP)-mediated platelet activation. Platelet activation by ADP plays a key role in the development of arterial thrombosis. When secreted by activated platelets from storage granules, the ADP activates additional platelets in circulation through two G protein-coupled P2 receptors, P2Y1 and P2Y12. P2Y12 inhibitors irreversibly inhibit ADP binding to the P2Y12 receptor on the platelet surface. By blocking this receptor, these agents interfere with additional platelet activation, degranulation, and - by inhibiting the modification of the glycoprotein IIb/IIIa receptor— aggregation.

The VerifyNow P2Y12 assay is a whole blood assay used in the laboratory or point of care setting to measure P2Y12 receptor blockade. The assay incorporates the agonist ADP to activate platelets. The VerifyNow P2Y12 assay also uses PGE1 to increase intraplatelet

cAMP and reduce the contribution of the P2Y1 receptor on activation. This makes the assay more specific for the effects of ADP on the P2Y12 receptor. It measures platelet function based upon the ability of activated platelets to bind to fibrinogen. Fibrinogen-coated microparticles aggregate in whole blood in proportion to the number of activated platelet GP IIb/IIIa receptors; and if the P2Y12 inhibitor has produced the expected antiplatelet effect, such aggregation will be reduced. The VerifyNow P2Y12 assay reports the extent of platelet aggregation in P2Y12 reaction units (PRU) and percent inhibition. PRU reports the amount of ADP-mediated aggregation specific to the platelet P2Y12 receptor, and is calculated as a function of the rate and extent of platelet aggregation in the ADP channel. Percent inhibition (%) is the percent change from baseline aggregation, and is calculated from the PRU result and a base result. The base result is an independent measurement based on the rate and extent of platelet aggregation from the thrombin receptors, specifically the PAR-1 and PAR-4 receptors. To activate platelets, the base channel incorporates the thrombin receptors' activating peptide, (iso-TRAP) and PAR-4 activating peptide (PAR-4 AP) for the PAR-1 and PAR-4 channels respectively. High percent inhibition values are reported if the drug has produced the expected antiplatelet effect.

**NOTE**: Refer to the VerifyNow P2Y12 package insert for information to be considered for patients receiving anti-platelet agents.

### 1.1.3 IIb/IIIa Assay

The final common pathway to platelet aggregation involves binding of fibrinogen to the glycoprotein (GP) receptor complex IIb/IIIa. The GP IIb/IIIa inhibitors block platelet aggregation by preventing fibrinogen and other adhesion molecules (vWF) from binding to the IIb/IIIa integrin on platelets. This in turn, interferes with the transformation of the glycoprotein IIb/IIIa receptor complex, platelet activation, and eventual formation of a stable platelet aggregate at the site of vascular wall injury.

The VerifyNow IIb/IIIa assay is a semi-quantitative, whole blood platelet function assay used to measure GP IIb/IIIa receptor blockade in patients treated with abciximab or eptifibatide. The assay incorporates the agonist thrombin receptor activating peptide (iso-TRAP) to activate platelets, and it measures platelet function based upon the ability of activated platelets to bind to fibrinogen. A synthetic peptide, iso-TRAP, serves as a surrogate for thrombin and activates the platelet through the PAR-1 receptor. Fibrinogen-coated beads aggregate in whole blood in proportion to the number of unblocked platelet GP IIb/IIIa receptors. If IIb/IIIa inhibitors have produced the expected antiplatelet effect, such aggregation will be reduced. The VerifyNow IIb/IIIa assay reports the extent of platelet aggregation in platelet aggregation units (PAUs). Typically, a baseline sample can be drawn prior to GP IIb/IIIa inhibitor administration, and the PAU result can be used as a baseline reading for determining percent inhibition (when compared to a PAU result for a sample drawn shortly after administering the agent). High percent inhibition values are reported if the agent has produced the expected antiplatelet effect.

**NOTE**: The IIb/IIIa assay can detect platelet inhibition by tirofiban (Aggrastat®), another intravenous GP IIb/IIIa inhibitor; therefore VerifyNow IIb/IIIa assay results for these patients should be interpreted with care. A sample taken prior to

abciximab or eptifibitide administration cannot be used to establish a “baseline” or uninhibited result if a GP IIb/IIIa inhibitor was administered within the past 10 days.

## 1.2 Test Procedure

The VerifyNow system has been developed to provide a simple, accurate and reliable means to measure platelet aggregation. This section provides an overview of the test procedure.

Whole blood is collected from an indwelling catheter or from a peripheral site into a vacuum collection tube. The tube is gently inverted five times and stored at room temperature until use (up to 4 hrs, depending on the assay type). Refer to Chapter 6, *Patient Testing* for more information on sample collection.

At the start of the test, the assay device is inserted into the instrument, and the sample collection tube is gently inverted again several times and placed on the assay device, requiring no cap removal, specimen preparation, or pipetting step. The instrument automatically draws the sample from the vacuum collection tube into the assay device, and proceeds with the analysis of the sample. The used device and tube are removed and discarded. There is no blood handling required by the user. Results are reported within 2-5 minutes, depending on the assay.

Refer to Chapter 5, *Quality Controls* and Chapter 6, *Patient Testing* for more information on operating the instrument.

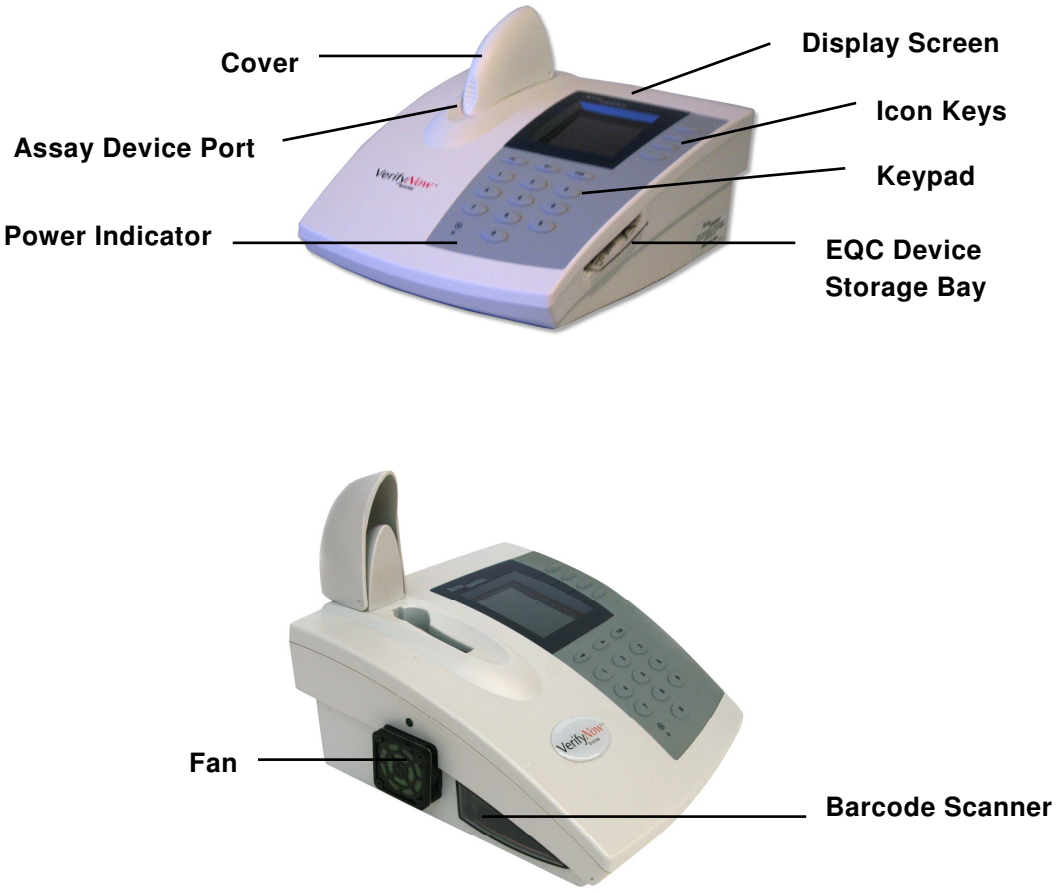
# 2 Overview of System Components

The VerifyNow System consists of an instrument, disposable assay devices, sample collection tubes, and quality control materials. This section provides a brief overview of each component of the system, beginning with the instrument.

## 2.1 Instrument

The VerifyNow instrument provides the platform for an automated assay. It receives an assay device and sample collection tube inserted into the assay device port. Then, it automatically draws the blood sample into the assay device and proceeds with the analysis of the sample. An operator specifies an automated activity and retrieves test results using the display screen, keypad, and icon keys (Figure 2-1).

**Figure 2-1 Instrument**



### 2.1.1 Assay Device Port and Cover

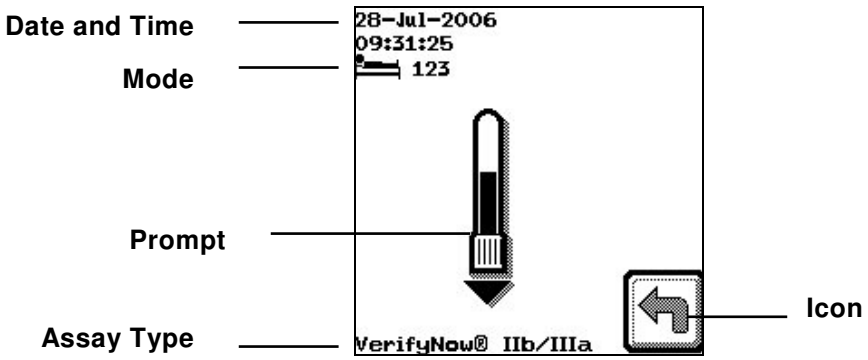
The assay device port holds a VerifyNow assay device during the test. When seated in the port, the assay device is aligned with optical detection components to measure the agglutination of the sample using light transmittance through wells in the assay device. When closed, the assay device port cover blocks ambient light in the room from interfering with the test.

The assay device port is also equipped with a spot code scanner that scans information on the assay device to determine which assay is being performed and the assay device lot number.

### 2.1.2 Display Screen

All messages and instructions for the operator display on the screen. The display screen provides information about each step in the test, the assay type, mode, as well as the current date and time. Figure 2-2 highlights the common features of the software screens.

**Figure 2-2 Display Screen**




| Feature | Description |
|---|---|
| Icons | Icons are used to navigate through the steps in a test. Icons display along the right side of the display screen and correspond to an adjacent icon key. Selecting an icon key displays another screen or directs the instrument to perform an action. Refer to the Appendix for a description of each icon. |
| Prompt | Most automated activities involve several steps and associated screens. Instructions on what to do at the next step are provided in the center of the display screen. In Figure 2-2, the image prompts the operator to insert the sample collection tube. |

| Feature | Description |
|---|---|
| Mode | The software supports two different modes, depending on whether the instrument is performing a quality test (QC mode) or processing a patient sample (assay mode). In Figure 2-2, a patient bed indicates an assay mode. |
| Assay Type | Displays the quality control or sample test being performed (Aspirin, P2Y12, or IIb/IIIa). |
| Date and Time | Displays the current date and time. |

**NOTE**: The instrument goes into “stand-by” mode when not in use for more than five minutes. In stand-by mode, the screen will be blank and the green LED indicator on the keypad will be illuminated. Pressing any key will return the instrument to the VerifyNow instrument Main Menu. See section 9.4 to adjust this setting.

### 2.1.3 Icon Keys

The four icon keys directly to the right of the display screen correspond to the different icons displaying on the screen. Selecting an icon key displays another screen or directs the instrument to perform an action.

### 2.1.4 Keypad

The keypad contains 13 labeled keys located directly below the display screen. The “0” through “9” keys are used to enter operator and patient identification numbers, change the time and the date, and make selections from menu options. They can also be used to perform numeric entries. The right (→) and left (←) arrow keys move the cursor as needed and work as toggle switches within certain screens. The Tab key is used to move the cursor from field to field within certain screens.

### 2.1.5 Power Switch and Indicator

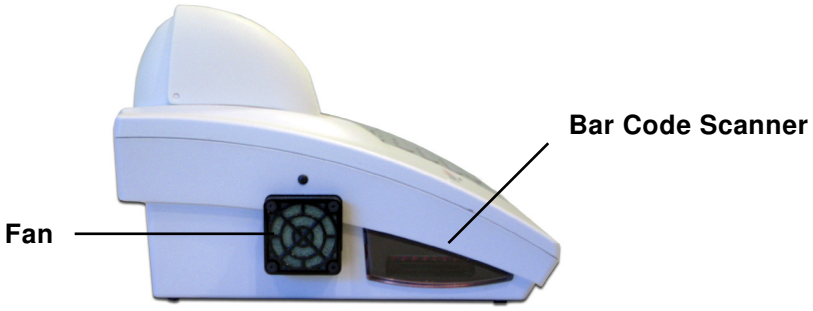
The power switch is located on the back of the instrument (“I” designates on, “O” designates off). When the instrument is initially powered on, a series of internal diagnostics occurs, which takes approximately 30 seconds. When power is on, a green LED indicator on the lower left corner of the keypad remains illuminated.

**Figure 2-3 Power Switch**


### 2.1.6 Bar Code Scanner

The bar code scanner is located on the left side of the instrument (Figure 2-4). When activated, it illuminates a bar code light so that the bar code on the white assay pouch can be presented by the user to be scanned, decodes the bar code, and transmits the information to the instrument software. The instrument software identifies the assay device expiration date and lot information. See section 6.4, Procedure number 10 for additional information.

**Figure 2-4 Bar Code Scanner and Fan**




### 2.1.7 Fan

The instrument is equipped with an exterior fan vent next to the bar code scanner to cool the internal electronic components. Avoid placing equipment adjacent to the fan that obstructs airflow. Periodic cleaning of the fan filter may be performed to avoid overheating of the instrument. See section 9.3 for fan filter replacement instructions.

### 2.1.8 Printer (Accessory)

The printer is an optional accessory to the instrument. The printer enables an operator to print assay results, QC results, and instrument usage statistics. See section 8.8 for instructions on enabling the printer.

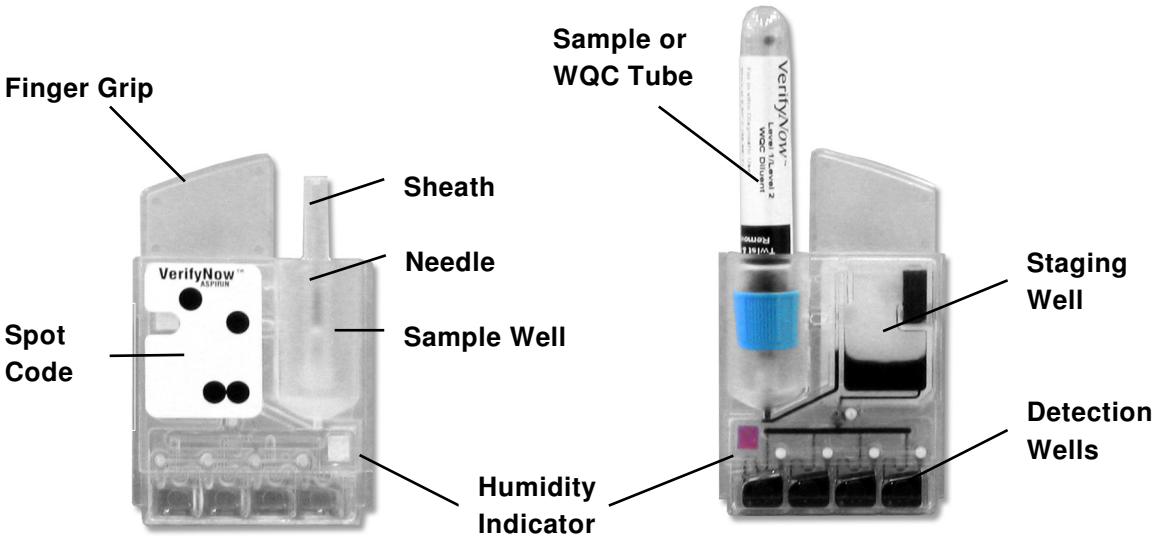
## 2.2 Assay Device

The VerifyNow System uses disposable assay devices to conduct the test. There are three types of assay devices relating to the appropriate platelet function test: Aspirin, P2Y12, and GP IIb/IIIa inhibitors (specifically for monitoring abciximab or

eptifibatide). Assay devices are individually sealed in foil pouches and may be used until the expiration date printed on each kit box and on the foil pouch.

Each single-use assay device consists of a sample well, staging well, and four detection wells (Figure 2-5). The instrument automatically draws whole blood into the assay device from a sample collection tube in the sample well. It then heats the blood to 37°C for a period of time specific to each assay, and proceeds with the analysis of the blood in the detection wells.

**Figure 2-5 Assay Device**




The detection wells of an assay device contain a lyophilized preparation of human fibrinogen-coated beads and platelet agonist. Fibrinogen-coated beads bind to available platelet receptors in the blood sample. When the activated platelets are exposed to the fibrinogen-coated beads, agglutination occurs in proportion to the number of available platelet receptors. The instrument measures this agglutination as an increase in light transmittance through the detection wells.

### 2.2.1 Humidity Indicator

Each assay device contains a humidity indicator and is labeled with a unique spot code. If the assay device has degraded due to prolonged exposure to room air, a color change of the humidity indicator will be observed. If the humidity indicator is pink on both sides, the assay device should be discarded.

### 2.2.2 Spot Code

Each assay device is labeled with a spot code. Upon insertion of the assay device into the assay device port, the instrument automatically scans the spot code and determines which assay is being performed, whether the particular lot has been used previously, and if the lot expiration date has been reached.

Assay devices are calibrated at the factory. No additional calibration is required by the user. Information about calibration and the device expiration date is contained in the bar code on the pouch of each assay device. The bar code must be scanned whenever a new lot of assay devices is to be used.

**NOTE**: Handle assay devices as biohazardous material. Dispose of them in an appropriate manner.

## 2.3 Sample Collection Tubes

The VerifyNow System uses whole blood collected in a partial-fill vacuum tube. During the test, the tube is inserted onto the needle in the sample well of the assay device - requiring no cap removal, specimen preparation, or pipetting step. There are several types of sample collection tubes recommended for use with the system (Table 2-1).

**Table 2-1 Sample Collection Tubes**

| Collection Tube | Description | Assay |
|---|---|---|
| Greiner Bio-One Vacuette tube (Greiner #454321) | Partial fill, 2 mL, 3.2% sodium citrate. Blue top | Aspirin, P2Y12, IIb/IIIa (only for use with ReoPro – abciximab) |
| Greiner Bio-One Vacuette tube (Greiner #454082) | Partial fill, 3 mL lithium heparin. Green top | IIb/IIIa - for use with Integrilin (eptifibatide) or ReoPro (abciximab) |
| Greiner Bio-One Vacuette tube (Greiner #454237) | Partial fill, 2 mL lithium heparin. Green top | IIb/IIIa - for use with Integrilin (eptifibatide) or ReoPro (abciximab) |

**NOTE**: The use of sample collection tubes other than those listed may adversely affect assay results.

## 2.4 Quality Control

Accumetrics rigorously tests each VerifyNow System to ensure it meets performance standards. In addition, the system supports several types of quality controls to verify continued performance during use.

### 2.4.1 EQC Device and Storage Slot

The Electronic Quality Control (EQC) is the primary quality control mechanism for the VerifyNow instrument. It consists of a re-usable device that is inserted by the operator into the assay port and is used to perform a comprehensive testing routine that confirms instrument performance.

**Figure 2-6 EQC Device**

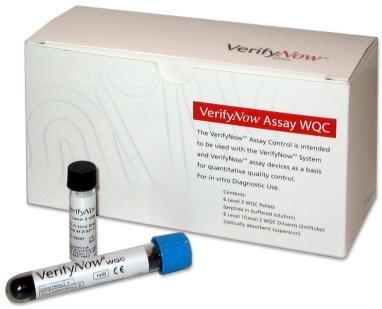

When not in use, the EQC device is kept in a storage bay on the right side of the instrument.

**NOTE**: If the EQC device is lost or damaged, the instrument will be inoperable.

### 2.4.2 Assay Wet Quality Controls (WQC)

Assay Wet Quality Controls consist of an optically absorbent solution and a pellet (Figure 2-7). When used in lieu of a patient sample during a test, it verifies continued performance. Controls are formulated at clinically relevant levels, and are individually packaged in tubes (Level 1 and 2) and vials (Level 2). They may be used until the expiration date printed on each kit box and on the container label when stored at the temperature indicated on the box.

**Figure 2-7 Wet Quality Controls**




Refer to Chapter 5, *Quality Controls* for more information on quality control tests and detailed descriptions of the procedures.

# 3 Precautions

This section provides an overview of safe operating procedures and identifies potential hazards when operating the VerifyNow instrument.

## 3.1 Safe Operating Procedures

The VerifyNow System is for *in vitro* diagnostic use only. Read the contents of this user manual completely. The VerifyNow instrument and its components should only be used as directed in this user manual. In particular, observe the following guidelines when collecting and handling samples and operating the instrument:

### 3.1.1 Sample Collection and Handling

All patient samples should be handled as if capable of transmitting disease. Always follow Universal Precautions[1] to minimize the risk of exposure to biohazardous blood products.

**WARNING:** Samples should be treated as biohazardous material and handled according to your institution's policies.

### 3.1.2 Instrument Operation

Operating the instrument involves the use of reagents and blood samples. The assay device reagents are manufactured with a material purified from human plasma that was found negative for all communicable diseases tested, including HIV-1, HIV-2, Hepatitis B surface antigen ($Hb_sAg$) and HCV.

**WARNING:** Handle assay devices and sample tubes as biohazardous material and dispose of in an appropriate manner.

Observe the following guidelines to ensure the safe operation of the VerifyNow instrument, and to limit operator exposure:

- Always follow Universal Precautions and your organization's safety protocols when working around the VerifyNow instrument to minimize the risk of exposure to biohazardous blood products.
- Do not insert fingers or anything other than an assay device, cleaning device or EQC device into the assay device port of the VerifyNow instrument.
- The assay device sample well contains a sharp needle. Do not insert fingers or anything other than a sample tube into the sample well.
- The VerifyNow instrument operates with the assay device under pressure once a test has begun. Do not remove the assay device or tube from the instrument until the test has completed.

- Do not remove sample tubes from used assay devices. Discard used assay devices and attached sample tubes as a single unit.

# 4 Reagent Storage and Handling

This section describes special considerations for receiving, storing and handling of VerifyNow reagents and devices.

## 4.1 Storage and Stability

Store assay devices (in their unopened pouches) and quality control materials until use at temperatures described in Table 4-1. Do not freeze.

**Table 4-1 Recommended Storage Conditions**

| Assay | Storage Temperature |
|---|---|
| VerifyNow Aspirin assay device | 2-25ºC (36-77ºF) |
| VerifyNow P2Y12 assay device | 2-25ºC (36-77ºF) |
| VerifyNow IIb/IIIa assay device | 2-8ºC – extended storage<br>18-25ºC (64-77ºF) - may be stored for up to 8 weeks, but not beyond the expiration date. When removed from refrigeration, write the discard date on the pouches and/or kit box |
| VerifyNow Assay WQC pellets and diluents | 15-30ºC (59-86ºF) |

Assay devices and quality control materials are suitable for use until the expiration date printed on the label. Do not use assay devices or WQC materials beyond the expiration date. Refer to assay kit boxes and pouch for designated expiration date and recommended storage conditions.

# 5 Quality Controls

Accumetrics has designed the VerifyNow System with a comprehensive set of quality control measures that provide control of the complete analytical process as defined in the CLIA regulation. This includes control of the following factors:

- Test system performance (both instrument and reagents)
- Environmental conditions
- Variations in operator performance

The extensive quality control features of the VerifyNow system are outlined in the Appendix. Accumetrics' recommendations for frequency of external control (Electronic Quality Control, Wet Quality Control levels 1 and 2) testing are stated in the individual assays' package inserts and are summarized in Table 5-1.

Electronic Quality Control (EQC) is a procedure during which the software will verify instrument optics performance, reagent mixing, and instrument pneumatics. Assay Wet Quality Control (WQC) follows the same procedure as an actual patient test, except that optically absorbent solution is used in lieu of blood. It verifies continued performance by checking that actual results are within a standard range.

**Table 5-1 Quality Control (QC) Tests**

| Quality Control | When do I use it | What it does |
|---|---|---|
| Electronic (EQC) | Recommended to run once a day to confirm the integrity of the instrument.<br>Run after resetting the date and time. | Verifies that instrument components are functioning properly – including optics, reagent mixing, and pneumatics. It also confirms correct calibration parameters and simulates assay testing at two levels of results to check correct data acquisition and calculations. |
| Level 1 WQC | Run during troubleshooting to resolve unexpected events.<br>Use as part of your institution's quality control program. | Verifies instrument performance by checking that actual results are within a lower range of values. |

| | | |
|---|---|---|
| Level 2 WQC | Run before the first use of each new lot (or shipment) of assay device kits.<br>Run during troubleshooting to resolve unexpected events. Refer to Chapter 10, *Troubleshooting*.<br>Run when the assay device kit temperature indicator shows exposure to elevated temperatures. Refer to Chapter 4, *Reagent Storage and Handling*.<br>Run every 30 days (only for IIb/IIIa assay).<br>Use as part of your institution's quality control program | Verifies instrument performance by checking that actual results are within a higher range of values. |

The following sections provide a detailed description of the procedures.

## 5.1 Electronic Quality Control

Electronic Quality Control (EQC) is the primary quality control mechanism for the VerifyNow Instrument. It consists of a re-usable device that is inserted by the operator into the assay port and is used to perform a comprehensive testing routine that confirms performance of key instrument components.

This procedure involves a reusable EQC device and takes up to two minutes. If a fault is detected in any of its systems, the instrument cannot perform patient testing until the fault is corrected.

Use the following procedure to perform an EQC:

**NOTE**: Pressing the Back  key will stop the EQC test at any point and return to the main menu.

1. Power on the instrument using the power switch on the back panel ("I" designates on). The instrument will power on and perform a self-testing routine lasting approximately 30 seconds. After the self-testing is complete, the start screen will display. Press the Next  key to advance to the main menu (**Error! Reference source not found.**). The instrument should be allowed to warm-up for at least 15 minutes prior to use.

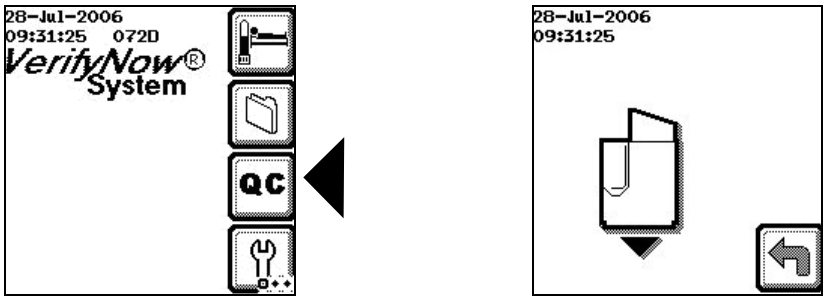
**Figure 5-1 Main Menu**


A flashing message will display while the instrument is warming up. During this time the icon keys are inactive and you will be unable to start an assay. Go to the next step when the warm-up message no longer displays.

2. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

3. Press the QC key. Wait for the image of the device to display (Figure 5-2).

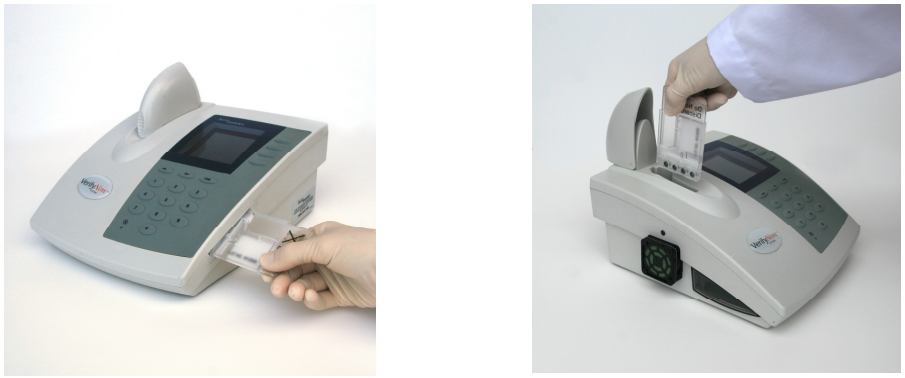
**Figure 5-2 Start EQC**




4. Remove the EQC device from the storage bay on the right side of the instrument. Open the cover and using the finger grip, insert the EQC device into the assay device port until it clicks (Figure 5-3). The instrument will produce two audible beeps. Close the cover to the assay port.

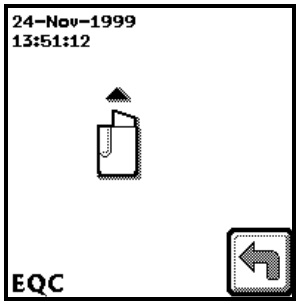
**NOTE**: Do not open the cover until the test has completed.

**Figure 5-3 Insert Device**



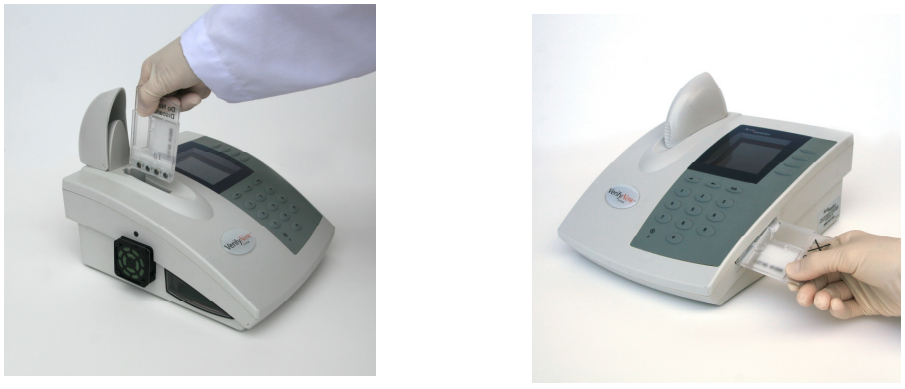
5. The instrument will automatically proceed with the EQC test. A countdown screen will display while electronic quality control is in progress. When the electronic quality control is complete, the instrument will beep and prompt the user to completely remove the EQC device from the assay port (Figure 5-4).

**Figure 5-4 Prompt**




6. Open the cover. Remove the EQC device and return it to the storage bay (Figure 5-5). Close the cover.

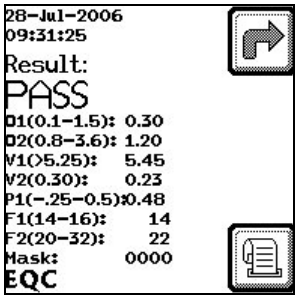
**Figure 5-5 Remove Device**

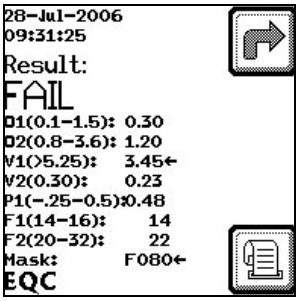


7. After the EQC device is completely removed from the port, a calculation screen will display briefly prior to displaying the final result. Wait for the electronic quality control results to display.

8. If the instrument is operating within its specifications, PASS will display at the conclusion of the testing (Figure 5-6). In addition, numeric values will be reported for the diagnostics, along with the acceptable range for each parameter. When the EQC is complete, press the Next key to return to the main menu.

**Figure 5-6 EQC Result**




If there is a problem detected during the EQC process and the instrument is not operating within its specifications, a FAIL message will display. The failed parameter(s) will be indicated by an arrow (←) to the right of the measured value(s). Press the Next key and perform the corrective action described. When the corrective action is completed, repeat the EQC. If diagnostic failure displays a second time, record the name of the parameter(s) indicated by an arrow (←) (e.g. V1, V2, O1) and contact Customer Support. Refer to Chapter 10, *Troubleshooting* for more information.

**NOTE**: Results can be printed using the printer accessory. Press the key to print results if this accessory is included with your system.

## 5.2 Wet Quality Control

The VerifyNow instrument also supports two levels of wet quality controls. Wet Quality Control (WQC) is intended to be used with a diluent and an assay device as a basis for quantitative quality control. Specifically, the WQC measures two levels of turbidimetric signal that verify the dynamic range of the instrument. One of these signals is at the level that would be observed in a patient with a minimal amount of platelet aggregation (negative control), and the other represents a patient who demonstrates a significant amount of aggregation (positive control).

**NOTE**: VerifyNow Assay WQC also may be used as a tool for activities other than routine quality control requirements. These activities include: proficiency testing, laboratory personnel competency evaluation, establishment and verification of system performance specifications and analytical system quality assessment.

### 5.2.1 Level 1 WQC

WQC Level 1 is formulated at a clinically relevant level and is representative of a sample with platelet inhibition. During Level 1 WQC, diluent is used to verify

continued performance by checking that actual results are within a standard range. It takes approximately 3 to 5 minutes to complete using the following procedure:

**NOTE**: Pressing the Back key will stop the quality control test at any point and return to the main menu.

## Materials

You will need the following materials:

- 1 Assay device
- 1 WQC diluent tube

**NOTE**: Do not use assay devices or WQC materials beyond the expiration date.

## Procedure

1. Locate one assay device and one WQC diluent tube.

2. Power on the instrument using the power switch on the back panel ("I" designates on). The instrument will power on and perform a self-testing routine lasting approximately 30 seconds. After the self-testing is complete, the Start screen will display. Press the Next key to advance to the main menu (Figure 5-7). The instrument should be allowed to warm-up for at least 15 minutes prior to use.

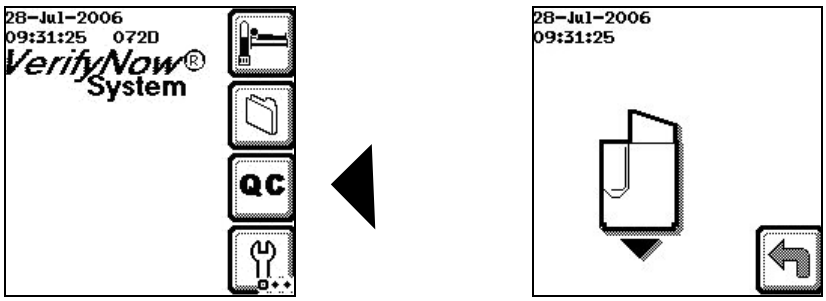
**Figure 5-7 Main Menu**


A flashing message will display while the instrument is warming up. During this time the icon keys are inactive and you will be unable to start an assay. Go to the next step when the warm-up message no longer displays.

3. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

4. Press the QC key. Wait for the image of the device to display (Figure 5-8).

**Figure 5-8 Start WQC Level 1**




5. Open the foil pouch and remove the assay device just before use. Hold it by the finger grip.

**NOTE**: Each assay device has a finger grip. Avoid handling other surfaces of the assay device.

6. Inspect the humidity indicator. The humidity indicator (small square) should be pink on one side and white on the other. If it is pink on both sides, discard and use a new assay device (

7. **NOTE:** Do not try to re-attach any assay device needles that may inadvertently removed. If this occurs, discard the device and use a new one

8. Figure 5-9

8. ).

9. Remove the needle's protective sheath by pulling directly up on the sheath (

10. **NOTE:** Do not try to re-attach any assay device needles that may inadvertently removed. If this occurs, discard the device and use a new one

11. Figure 5-9

11. ). Do not twist the sheath, as this may remove the needle.

**NOTE**: Do not try to re-attach any assay device needles that may inadvertently removed. If this occurs, discard the device and use a new one

**Figure 5-9 Inspect Humidity Indicator and Prepare Needle**

12. Open the cover. Using the finger grip, insert the assay device into the assay device port until it clicks (Figure 5-10).

**Figure 5-10 Insert Device**


13. If the assay device is the first from a new lot, the instrument will display a bar code screen as soon as the assay device is inserted into the port and the device spot code is read. (Figure 5-11). Position the barcode of the assay device pouch in front of the bar code scanner on the left side of the instrument so that the bar code on the bottom edge of the pouch lines up with the scanner window. Move the pouch both towards and away from the red barcode light. An audible beep will be heard when the instrument reads the information. Press the Retry key if you are unable to scan the bar code the first time.

**Figure 5-11 Scan Bar Code**

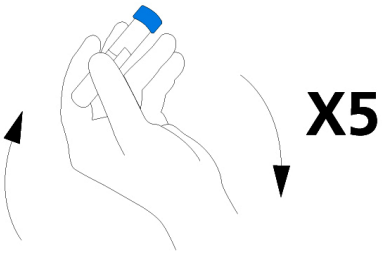


After the bar code has been scanned once, the instrument will accept all remaining assay devices from that lot without displaying the bar code screen.

**NOTE**: If you are experiencing difficulty with the bar code scanner scanning the label, try adjusting the angle of the scan by raising the corner of the instrument.

14. ***Gently*** invert the diluent tube five times to mix the reagents immediately before use (Figure 5-12).

**Figure 5-12 Invert Tube**

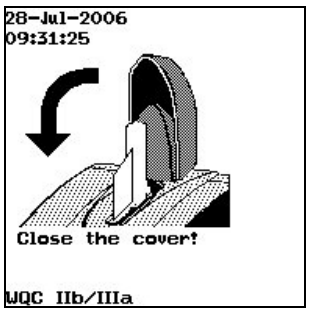



15. **Wait for the image of the tube to display**, then insert the WQC sample into the sample well of the assay device with the rubber stopper facing downward, so that the needle fully pierces the stopper. The instrument will produce two audible beeps when the tube has been fully inserted (Figure 5-13).

**Figure 5-13 Insert Tube**


16. Close the cover to the assay device port (Figure 5-14).

**Figure 5-14 Close the Cover**



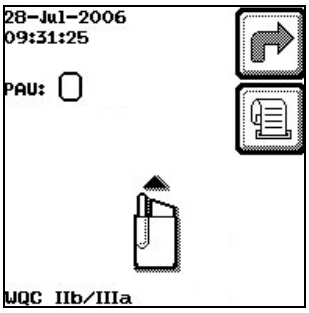

17. The instrument automatically draws the sample from the vacuum collection tube into the assay device, heats the sample, and proceeds with the analysis of the sample. During this time the screen will flash the assay device icon, indicating that the sample is processing. Do not open the cover until the assay has completed and a result displays. A calculator will display when the assay is near completion (Figure 5-15).

**Figure 5-15 Assay Progress**


**CAUTION:** The sample is pressurized during parts of the assay. Never remove the sample tube or assay device during the assay. To abort a test, press the Back key. Wait for the prompt before removing the assay device and tube.

18. When the results display, record the results or print the results, if your instrument has an attached printer (Figure 5-16).

**Figure 5-16 WQC Level 1 Result**

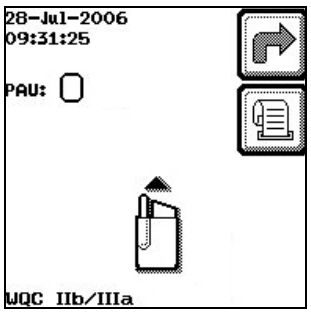



19. Open the cover. Remove the assay device and tube together in one piece by grasping the assay device finger grip and pulling straight up (Figure 5-17). Never separate the tube from the assay device. Close the cover. Discard the assay device and tube in a biohazard waste in accordance with institutional guidelines.

**Figure 5-17 Remove Device**

20. At the conclusion of the test, the resulting value will be displayed on the screen. Look up the expected values printed on the assay device pouch for Control 1 (Figure 5-18).

**Figure 5-18 Interpreting WQC Level 1 Results**





**Control Level 1 Range**

21. Compare the WQC result to the Control Level 1 range, and verify the result falls within the expected range. If the result falls within the expected range, the

instrument has passed WQC Level 1. If the control material does not produce a result within the expected range, perform an EQC test to ensure that the instrument is working properly. If the EQC is OK, prepare a new WQC Level 1 sample and repeat the WQC procedure with a new assay device. If the EQC is not OK, follow the instructions in Chapter 10, *Troubleshooting*. If the WQC result fails on the second attempt, contact Accumetrics Customer Support.

22. Press the Next key to return to the main menu.

### 5.2.2 Level 2 WQC

WQC Level 2 is formulated at a clinically relevant level, and is representative of a sample with minimal platelet inhibition. During Level 2 WQC, a pink pellet is added to the diluent to verify continued performance, by checking that actual results are within a standard range. It takes approximately 3 to 5 minutes to complete using the following procedure:

**Materials**

You will need the following materials:

- 1 Assay device
- 1 WQC diluent tube
- 1 WQC pellet

**NOTE**: Do not use assay devices or WQC materials beyond the expiration date.

**Procedure**

1. Locate one assay device, one WQC pellet tube and one WQC diluent tube.

2. Power on the instrument using the power switch on the back panel ("I" designates on). The instrument will power on and perform a self-testing routine lasting approximately 30 seconds. After the self-testing is complete, the Start screen will display. Press the Next key to advance to the main menu (Figure 5-19). The instrument should be allowed to warm-up for at least 15 minutes prior to use.

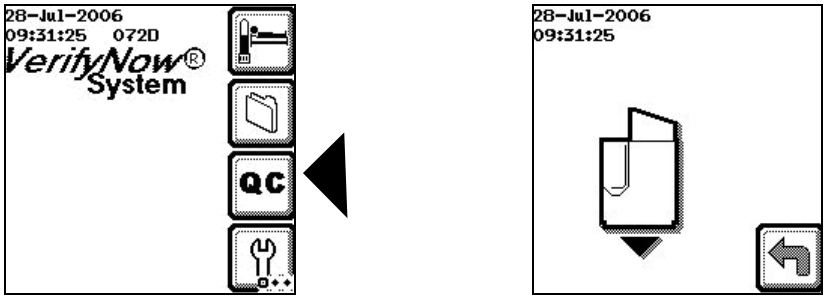
**Figure 5-19 Main Menu**

A flashing message will display while the instrument is warming up. During this time the icon keys are inactive and you will be unable to start an assay. Go to the next step after the warm-up message no longer displays.

3. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

4. Press the QC key. Wait for the image of the device to display (Figure 5-20).

**Figure 5-20 Start WQC Level 2**



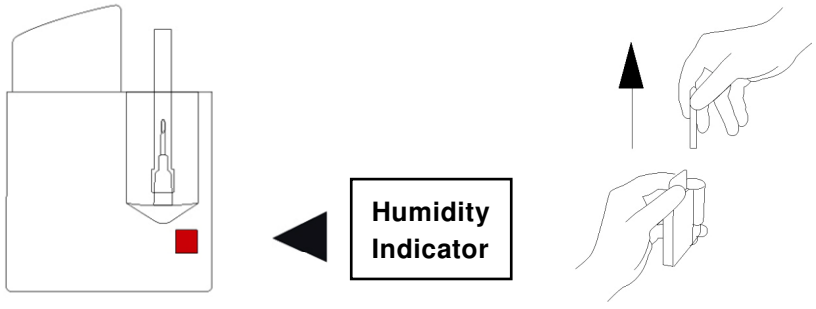

5. Open the foil pouch and remove the assay device just before use. Hold it by the finger grip.

**NOTE**: Each assay device has a finger grip. Avoid handling other surfaces of the assay device.

6. Inspect the humidity indicator. The humidity indicator (small square) should be pink on one side and white on the other. If it is pink on both sides, discard and use a new assay device (Figure 5-21).

7. Remove the needle's protective sheath by pulling directly up on the sheath. Do not twist the sheath, as this may remove the needle (Figure 5-21).

**Figure 5-21 Inspect Humidity Indicator and Prepare Needle**



8. Open the cover. Using the finger grip, insert the assay device into the assay device port until it clicks (Figure 5-22).

**Figure 5-22 Insert Device**

9. If the assay device is the first from a new lot, the instrument will display a bar code screen as soon as the assay device is inserted into the port and the device spot code is read. (Figure 5-11). Position the barcode of the assay device pouch in front of the bar code scanner on the left side of the instrument so that the bar code on the bottom edge of the pouch lines up with the scanner window. Move the pouch both towards and away from the red barcode light. An audible beep will be heard when the instrument reads the information. Press the Retry key if you are unable to scan the bar code the first time.

**Figure 5-23 Scan Bar Code**

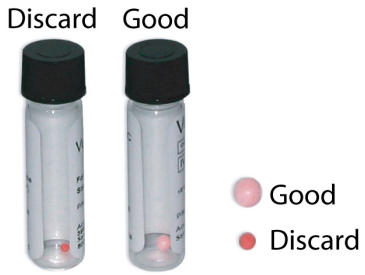


After the bar code has been scanned once, the instrument will accept all remaining assay devices from that lot without displaying the bar code screen.

**NOTE**: If you are experiencing difficulty with the bar code scanner scanning the label, try adjusting the angle of the scan by raising the corner of the instrument.

10. Inspect the pellet. It should appear pink. If the pellet appears smaller, red or is stuck to the vial, discard and use a new pellet (Figure 5-24).

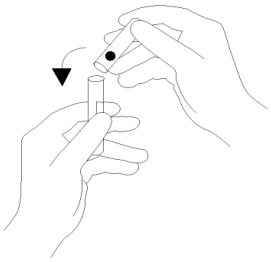
**Figure 5-24 Inspect Pellet**



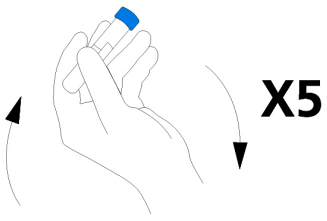

11. Immediately before use, open the vial containing the pellet. Remove the cap from the diluent tube by twisting and pulling the cap simultaneously.

12. Hold the diluent tube vertically. Then, invert the tube containing the pellet so that the pellet falls into the diluent tube (Figure 5-25). Ensure the pellet does not stick to the side of the diluent tube, as it will not reconstitute properly. If you are unsure, discard the tube and retry using another WQC diluent tube and pellet.

**Figure 5-25 Add Pellet**



**Replace the cap on the diluent tube by pressing and turning simultaneously. Immediately after replacing the cap, gently invert the tube five times to mix the reagents (Figure 5-26). Control material should be used within 15 minutes of reconstitution.Figure 5-26 Invert Sample**



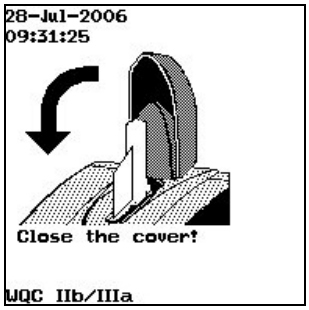
If the reconstituted control is not used immediately, gently invert the tube five times to mix the reagents again just before use (Figure 5-26).

13. Wait for the Insert Tube image to display, then insert the WQC sample into the sample well of the assay device with the rubber stopper facing downward so that the needle pierces the stopper (Figure 5-27). The instrument will produce two audible beeps when the tube has been fully inserted.

**Figure 5-27 Insert Tube**


14. Close the cover to the assay port (Figure 5-28).

**Figure 5-28 Close Cover**




15. The instrument automatically draws the WQC sample from the vacuum collection tube into the assay device, heats the sample, and proceeds with the analysis of the sample. During this time the screen will flash an icon of the assay device indicating that the sample is processing. Do not open the cover until the assay has completed and a result displays. A calculator will display when the assay is near completion (Figure 5-29).

**Figure 5-29 Assay Progress**


**CAUTION:** The sample is pressurized during the assay. Do not remove the sample tube or assay device during the assay. To abort, press the Back key. Wait for the prompt before removing the assay device along with the tube.

16. When the results display, record the results or print the results, if your instrument has an attached printer (Figure 5-30).

**Figure 5-30 WQC Level 2 Result**


17. Open the cover. Remove the assay device and tube together in one piece by grasping the assay device finger grip and pulling straight up (Figure 5-31). Do not separate the tube from the assay device. Close the cover. Discard the assay device and tube in a biohazard waste in accordance with institutional guidelines.

**Figure 5-31 Remove Device**

18. At the conclusion of the test, the resulting value will be displayed on the screen. Look up the expected values printed on the assay device pouch for Control Level 2 (Figure 5-32).

**Figure 5-32 Interpreting WQC Level 2 Result**



**Control Level 2 Range**

19. Compare the WQC result to the Control Level 2 range, and verify the result falls within the expected range. If the result falls within the expected range, the instrument has passed WQC Level 2. If the WQC result does not fall within the stated range, perform an EQC test to ensure that the instrument is working properly. If the EQC is OK, prepare a new WQC sample and repeat the WQC procedure with a new assay device. If the EQC is not OK, follow the instructions in Chapter 10, *Troubleshooting*. If the WQC result fails on the second attempt, contact Accumetrics' Customer Support.

20. Press the Next key to return to the main menu.

# 6 Patient Testing

The VerifyNow System has been developed to provide a simple, accurate and reliable means to measure platelet function from a patient's blood sample. This section provides instructions on performing the test procedure. The test procedure includes patient preparation, sample collection, sample handling, preparing the instrument for use and running a test.

## 6.1 Patient Preparation

Laboratory testing was performed to determine the effects of several classes of drugs on VerifyNow Aspirin, P2Y12, and IIb/IIIa results. In addition, laboratory and clinical testing were performed to assess the effect of the levels of several blood constituents. **Refer to the respective assay package insert for information to be considered for patients who are to be tested with the VerifyNow assay.**

## 6.2 Sample Collection

Samples can be collected from an indwelling catheter or using direct venipuncture.

**NOTE**: For an Aspirin or IIb/IIIa platelet function test, whole blood may be collected from peripheral venous or arterial sites.

### 6.2.1 Peripheral Samples

Perform the following procedure for sample collection directly into vacuum collection tubes:

**Materials**

You will need the following materials:

- Discard tube – may be a tube with no additive, sodium citrate, blood culture, or heparin tube (IIb/IIIa assay only). The tube cannot contain EDTA (purple top).
- Aspirin or P2Y12 assay sample tube - 2mL Greiner Bio-One Vacuette® partial-fill blood collection tube with 3.2% sodium citrate - blue top (Greiner #454321)
- IIb/IIIa assay sample tube: use one of the following tubes, depending on the type of GP IIb/IIIa inhibitor administered.
  - Greiner Bio-One Vacuette partial-fill blood collection tube- lithium heparin (3 mL fill volume) - green top (Greiner #454082) **–for use with Integrilin® (eptifibatide) or ReoPro® (abciximab)**
  - Greiner Bio-One Vacuette partial-fill blood collection tube (2 mL fill volume) containing lithium heparin (Greiner #454237) **–for use with Integrilin® (eptifibatide) or ReoPro® (abciximab)**

- Greiner Bio-One Vacuette partial-fill blood collection tube (2 mL fill volume) containing 3.2% sodium citrate (Greiner #454321) **– only for use with ReoPro (abciximab)**

- 1 Label with patient ID (optional)

## Blood Draw Procedure

Collection of blood sample should be performed with care to avoid hemolysis or contamination by tissue factors.

1. Locate a discard tube and the appropriate sample tube.

2. Obtain samples from an extremity free of peripheral venous infusions according to your institution's phlebotomy procedures. The median antecubital and cephalic veins are most commonly used.

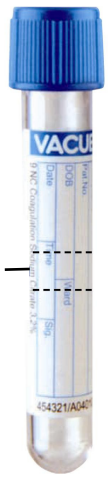
3. If drawing for a CBC at the same time, fill the CBC tube **last** to avoid contamination by EDTA.

4. Prepare the phlebotomy collection system using a 21 gauge or larger needle. Butterfly (21 gauge or larger) is OK to use.

5. Collect a discard sample of at least 2mL in a tube containing sodium citrate, blood culture medium, no additive, or heparin (IIb/IIIa assay only).

6. Fill the second tube (sample tube) to the black line. For the Greiner Vacuette partial-fill tube (2 mL fill volume), 3.2% sodium citrate (#454321), the fill line is at approximately ½ of the tube height (Figure 6-1). Do not under fill.

**Figure 6-1 Sample Tube**




**NOTE**: Always ensure collection tubes are filled to the indicated fill volume.

**NOTE**: At altitudes greater than 2500 feet above sea level, blood collection tubes may not fill to the specified volume, which results in an incorrect ratio of blood to anticoagulant. Users at these elevations should use tubes designed for high altitudes or refer to their facility's blood collection protocols for instructions to properly fill blood collection tubes.

7. Gently invert the tube at least 5 times to ensure complete mixing of the contents. **Samples with evidence of clotting should not be used.**

**NOTE**: Re-draw sample if there is evidence of hemolysis in any other tube that was collected at the same time.

8. Discard the first tube in a biohazard waste container. Keep the second tube for testing. Label the second tube with the patient ID, date, and time it was drawn. Dispose of blood collection supplies according to your institution's policy.

### 6.2.2 Indwelling Catheter

Perform the following procedure for sample collection from an indwelling catheter:

**NOTE**: For an Aspirin or IIb/IIIa platelet function test, whole blood may be collected from venous or arterial sites.

**Materials**

You will need the following materials:

- Aspirin or P2Y12 assay sample tube - 2mL Greiner Bio-One Vacuette partial-fill blood collection tube with 3.2% sodium citrate - blue top (Greiner #454321)
- IIb/IIIa assay sample tube: use EITHER of the following tubes, depending on the type of GP IIb/IIIa inhibitor administered.
  - Greiner Bio-One Vacuette partial-fill blood collection tube- lithium heparin (3 mL fill volume) - green top (Greiner #454082) **–for use with Integrilin (eptifibatide) or ReoPro (abciximab)**
  - Greiner Bio-One Vacuette partial-fill blood collection tube- lithium heparin (2 mL fill volume) – green top (Greiner #454237) **–for use with Integrilin® (eptifibatide) or ReoPro® (abciximab)**
  - Greiner Bio-One Vacuette partial-fill blood collection tube- 3.2% sodium citrate (2 mL fill volume) – blue top (Greiner #454321) **– only for use with ReoPro (abciximab)**
- 1 Label with patient ID (optional)

**Blood Draw Procedure**

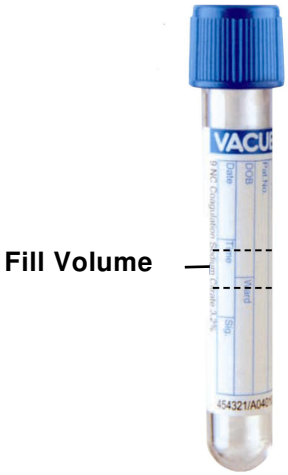
Collection of blood sample should be performed with care to avoid hemolysis or contamination by tissue factors.

1. Discard the first 5 mL from an indwelling catheter to clear the line. Ensure the catheter is free of clots.

2. If drawing for a CBC at the same time, fill the CBC tube last to avoid contamination by EDTA.

3. When using a syringe, immediately transfer blood to the sample tube. Fill to the black line (Figure 6-2). Do not under fill. If using a needle for sample transfer, the needle must be 21 gauge or larger (18 gauge preferred).

**Figure 6-2 Sample Tube**




**NOTE**: Always ensure collection tubes are filled to the indicated fill volume.

**NOTE**: At altitudes greater than 2500 feet above sea level, blood collection tubes may not fill to the specified volume, which results in an incorrect ratio of blood to anticoagulant. Users at these elevations should use tubes designed for high altitudes or refer to their facility's blood collection protocols for instructions to properly fill blood collection tubes.

4. Gently invert the tube at least 5 times to ensure complete mixing of the contents. **Samples with evidence of clotting should not be used.**

**NOTE**: Re-draw sample if there is evidence of hemolysis in any other centrifuge tube that was collected at the same time.

5. Label the tube with the patient ID, date, and time it was drawn. Dispose of blood collection supplies according to your institution's policy.

## 6.3 Sample Handling

Fresh whole blood samples in the appropriate Greiner partial-fill collection tubes are required for use with the VerifyNow instrument. Keep samples at room temperature. Do not centrifuge, separate, freeze or refrigerate sample. Table 6-1 provides the amount of time blood must incubate at room temperature after collection and before assay. Blood samples older than indicated must be discarded and a new sample drawn.

**Table 6-1 Assay Times**

| Assay | Wait Time | Assay Window |
|---|---|---|
| Aspirin | 30 min | 30 min to 4 hrs |
| P2Y12 | 10 min | 10 min to 4 hrs |
| IIb/IIIa | None | Within 15 minutes |

Samples should be handled according to your institution's policies and procedures pertaining to biohazardous materials.

## 6.4 Performing an Assay

### Materials

You will need the following materials:

- 1 Assay device
- 1 Sample tube

**NOTE**: Assay device should remain sealed in the foil pouch until ready for use to prevent damage by humidity.

**NOTE**: Do not use assay devices or WQC materials beyond the expiration date.

### Procedure

1. Locate one assay device and the sample tube. If assay device is refrigerated, allow it to reach room temperature (18-25ºC or 64 -77ºF) prior to use. Do not remove the assay device from the foil pouch during this step.

2. Power on the instrument using the power switch on the back panel ("I" designates on). The instrument will power on and perform a self-testing routine lasting approximately 30 seconds. After the self-testing is complete, the Start screen will display. Press the Next key to advance to the Main Menu (Figure 6-3). The instrument should be allowed to warm-up for at least 15 minutes prior to use.

   **Figure 6-3 Main Menu**

   A flashing message will display while the instrument is initially warming up. During this time the icon keys are inactive and you will be unable to start an assay. You will not be able to go to the next step until after the warm up message no longer displays.

3. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

4. If sufficient time has elapsed, the instrument will prompt you to perform an EQC (Figure 6-4). Refer to Chapter 5, *Quality Controls* for more information.

**Figure 6-4 EQC Required**

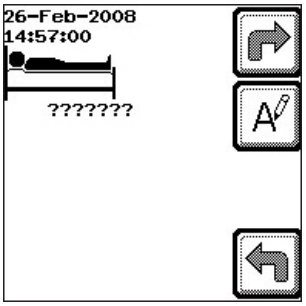

After a PASS has been achieved on EQC the instrument will be ready to perform an assay.

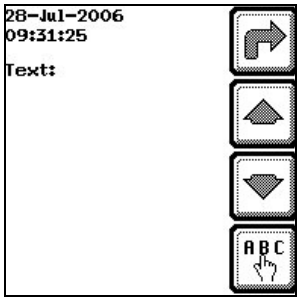
5. When the initial screen displays, press the Assay key. If the patient ID is required, the patient ID prompt will display. If not, the instrument will prompt you to insert the assay device (go to step 3).

   A series of question marks will signify the required length of the patient ID established by your institution. Use the numerical pad to input a numerical patient ID and then press the Next key (

   Figure 6-5).

**Figure 6-5 Patient ID**




**NOTE**: A question mark is not a valid input. All question marks must be replaced by valid patient ID numbers in order to proceed with performing the assay.

To enter a letter for patient ID, press the Text key.

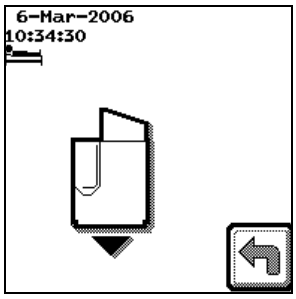
- Use the up and down arrows to scroll through the text option screens. At the desired screen, press the (←) or (→) to move to the desired character.

- Press the Text key to select the character. It will then show up at the Text: ___ prompt.
- Advance to the next character by pressing the (←) or (→) and repeat steps to select additional characters.
- After the Patient ID is entered, press the Next key.

The earlier patient ID screen will display. Press the Next key again to continue. The screen will prompt to insert the assay device (Figure 6-6).

**NOTE**: If you make a mistake while entering a text character, press the Next key to return to the Patient ID Entry Screen. Use the (→) key to move the cursor to the end of the Patient ID entered, then press the (←) key to erase character(s) until the mistaken character is deleted. Press the Text key to go back to the Text Entry Screen and select the correct character using the directions from above.

**Figure 6-6 Insert Device**




6. Open the foil pouch and remove the assay device just before use. Hold the assay device by the finger grip.

**NOTE**: Each assay device has a finger grip. Avoid handling other surfaces of the assay device.

7. Inspect the humidity indicator. The humidity indicator (small square) should be pink on one side and white on the other. If there is any evidence of a pink color on both sides, discard and use a new assay device (Figure 6-7).

8. Remove the needle's protective sheath by pulling directly up on the sheath. Do not twist the sheath, as this may remove the needle (Figure 6-7).

**Figure 6-7 Inspect Humidity Indicator and Prepare Needle**

9. Open the cover. Using the finger grip, insert the assay device into the assay device port until it clicks (Figure 6-8).

**Figure 6-8 Insert Device**

10. If the assay device is the first from a new lot, the instrument will display a bar code screen as soon as the assay device is inserted into the port and the spot code is read. (Figure 6-9). Place the assay device pouch in front of the bar code scanner on the left side of the instrument so that the bar code on the bottom edge of the pouch lines up with the scanner window. Move the pouch both towards and away from the instrument. An audible beep will be heard when the instrument reads the information. Press the Retry key if you are unable to scan the bar code the first time.

**Figure 6-9 Scan Bar Code**

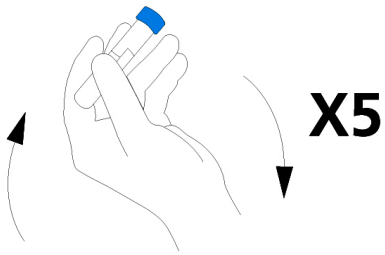


After the bar code has been scanned once, the instrument will accept all remaining assay devices from that lot without displaying the bar code screen.

**NOTE**: If you are experiencing difficulty scanning the bar code, try adjusting the angle of the scan by raising the corner of the instrument.

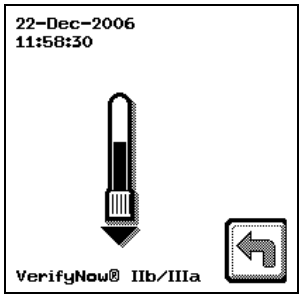
11. Gently invert the sample tube five times to mix the reagents immediately before use (Figure 6-10).

**Figure 6-10 Invert Tube**



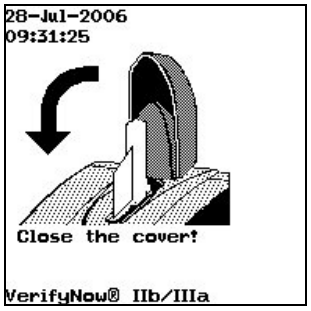

12. Wait for the Insert Tube icon to display, then insert the sample into the sample well of the assay device with the rubber stopper facing downward so that the needle pierces the stopper (Figure 6-11). The instrument will produce two audible beeps when the tube has been fully inserted.

**Figure 6-11 Insert Tube**




13. Close the cover to the assay port (Figure 6-12).

**Figure 6-12 Close Cover**




14. The instrument automatically draws the sample from the vacuum collection tube into the assay device. It then heats the blood to 37°C for a period of time specific to each assay, and proceeds with the analysis. During this time the screen will flash indicating that the sample is processing. Do not open the assay port cover until the assay is complete. A calculator will display when the assay is near completion (Figure 6-13).

**Figure 6-13 Assay Progress**


**CAUTION:** The sample is pressurized during parts of the assay. Do not remove the sample tube or assay device during the assay. To abort, press the Back key. Wait for the prompt before removing the assay device along with the tube.

15. It typically takes 3 to 5 minutes for the assay to complete. When the results display, record or print the results, if your instrument has an attached printer.

16. Open the cover. Remove the assay device and tube together in one piece by grasping the assay device finger grip and pulling straight up (Figure 6-14). Do not separate the tube from the assay device. Close the cover. Discard the assay device and tube in a biohazard waste in accordance with institutional guidelines.

**Figure 6-14 Remove Device**

17. Press the Next key to return to the main menu.

## 6.5 Interpreting Assay Results

Refer to the following sections for information specific to each assay.

### 6.5.1 Aspirin Assay Results

The sample result (Figure 6-15) for the Aspirin assay is interpreted based on the rate of platelet aggregation measured and is reported in Aspirin Reaction Units (ARU).

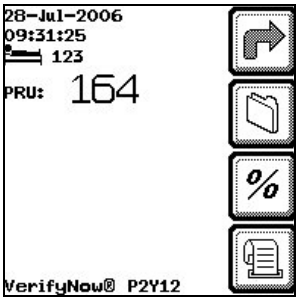
**Figure 6-15 Aspirin Assay Results**


Interpretation of results is based on the following assigned cutoffs: Results ≥ 550 ARU implies platelet dysfunction consistent with aspirin has not been detected. Results < 550 ARU implies platelet dysfunction consistent with aspirin has been detected. Results should be interpreted in conjunction with other laboratory and clinical data available to the clinician. The result may be printed by pressing the Print key, if your instrument has an attached printer. Press the Next key to return to the Main Menu. Press the Retrieve key to retrieve past assay results. Refer to Chapter 5, *Quality Controls* for more information on retrieving results.

### 6.5.2 P2Y12 Assay Results

The P2Y12 assay reports patient results in P2Y12 Reaction Units and Percent Inhibition (Figure 6-16). P2Y12 Reaction Units (PRU) report the amount of P2Y12 receptor mediated aggregation specific to the platelet and are calculated as a function of the rate and extent of platelet aggregation in the ADP channel. Press the % key to display the percent inhibition.

**Figure 6-16 P2Y12 Results**




Percent Inhibition (%) is the percent change from baseline aggregation and is calculated from the PRU result and the Base result. The Base result is an independent measurement based on the rate and extent of platelet aggregation from thrombin receptors, specifically the PAR-1 and PAR-4 receptors. The Base result serves as an estimate of a patient's baseline platelet function independent of P2Y12 receptor inhibition. The Base result is normalized to report units that are equivalent to baseline PRU. Percent inhibition is calculated using the following formula:

$$\% \text{ Inhibition} = \frac{(\text{Base} - \text{PRU}) \times 100}{\text{Base}}$$

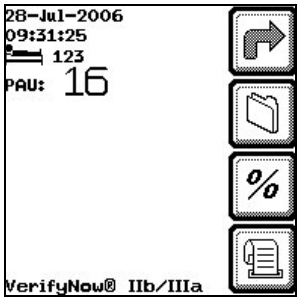
This feature can be used without first obtaining a baseline sample prior to P2Y12 drug administration. In the example shown here**,** if the baseline result was 328 PRU and the post-drug result was 164 PRU, this would calculate to 50% inhibition.

The result may be printed by pressing the Print key, if your instrument has an attached printer. Press the Next key to return to the Main Menu. Press the Retrieve key to retrieve past assay results. Refer to Chapter 7, *Retrieving Test Results* for more information on stored results.

### 6.5.3 IIb/IIIa Assay Results

The IIb/IIIa assay reports patient results in Platelet Aggregation Units (PAU) with an option to calculate Percent Inhibition (Figure 6-17). Platelet Aggregation Units (PAU) are calculated as a function of the rate and extent of aggregation.

**Figure 6-17 IIb/IIIa Assay Results**




When a blood sample is drawn prior to administering the GP IIb/IIIa inhibitor, it can serve as a baseline reading for determining percent inhibition in samples drawn shortly after injecting the GP IIb/IIIa inhibitor (10 minutes). Percent inhibition is calculated using the following formula:

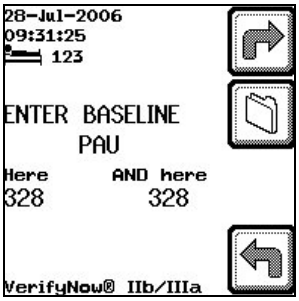
$$\% \text{ Inhibition} = \frac{(\text{pre-drug PAU} - \text{post-drug PAU}) \times 100}{\text{pre-drug PAU}}$$

Use the following procedure to calculate percent inhibition.

**NOTE**: A sample taken prior to abciximab or eptifibitide administration cannot be used to establish a “baseline” or uninhibited result if a GP IIb/IIIa inhibitor has been administered within the past 10 days.

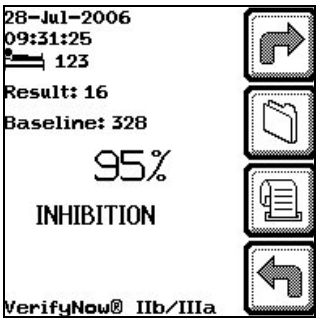
1. Press the Percent key.

**Figure 6-18 Enter PAU**




2. Obtain the patient’s baseline (pre-drug) PAU result. Enter the baseline PAU result in the space indicated “Here”, press the Tab key, and re-enter the baseline PAU result in the space indicated “AND here” (Figure 6-18). Press the Next key to display the percent inhibition. In the example (Figure 6-19), if the baseline result was 328 PAU and the post-drug result was 16 PAU, this would calculate to 95% inhibition.

**Figure 6-19 Percent Inhibition**




3. The result may be printed by pressing the Print key, if your instrument has an attached printer.

4. Press the Next key to return to the Results screen (Figure 6-17). Press the Retrieve key to retrieve past assay results. Refer to Chapter 7, *Retrieving Test Results* for more information on retrieving results.

## 6.6 Shutting down the Instrument

Prior to shutting down the instrument, ensure that all operations involving the VerifyNow instrument are complete. Power off the instrument using the power switch on the back panel (“O” designates off).

# 7 Retrieving Test Results and Performance Data

The instrument stores information on patient test results, quality control tests, troubleshooting events, and usage statistics. This section covers the activities to retrieve stored information and display it on the screen, print it, or export it to a network (where network connectivity is enabled). Table 7-1 lists and describes the six activities available to an operator.

**Table 7-1 Retrieving Test Results and Performance Data**

| Activity | Description |
|---|---|
|  Retrieve patient results | This feature enables you to retrieve the last 150 patient results from earlier tests. Refer to Section 7.1. |
|  View WQC results (Level 1 & 2) | Use this feature to view earlier WQC results. This feature enables you to retrieve the last 100 WQC results. Refer to Section 7.2. |
|  View EQC diagnostic results | Use this feature when troubleshooting instrument performance. This feature enables you to retrieve the last 100 EQC results. Refer to Section 7.2. |
|  View usage log | This feature enables you to view the quantity and type of assays performed on the instrument. Refer to Section 7.3. |
|  View alarms and errors log | Use this feature when troubleshooting instrument performance. This feature enables you to retrieve information on recent alarms and errors. Refer to Section 7.4. |
|  Transfer data across a network | This optional accessory enables you to transfer information across a network. This includes all assay, WQC and EQC results as well as messages, alerts, alarms, and errors logged. Refer to Section 7.5. |

## 7.1 Retrieving Patient Test Results

The instrument stores the last 150 patient results in its memory. You can retrieve and print information about the patient result, assay type, assay date and time, and operator identification (when configured).

Patient information can be retrieved by date and time or by patient identification, depending on the instrument setting. Refer to Section 7.1.2 if the instrument is configured to use patient identification; otherwise, refer to 7.1.1 for the appropriate procedure.

### 7.1.1 Patient Information Stored by Date/Time

From the main menu, enter  Operator ID and  Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance

to the Password prompt to enter the password number. Press the Retrieve Results key. See Section 7.1.3 for a description of the assay results log.

### 7.1.2 Patient Information Stored by Patient ID

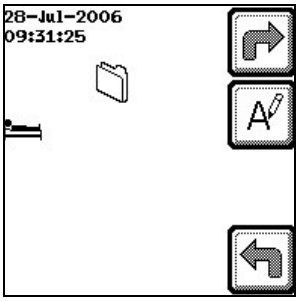
If the instrument is configured to use patient identification, then the instrument retrieves all assay results for a particular patient.

1. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

2. Press the Retrieve Results key.

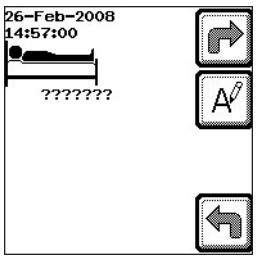
3. When the following screen displays (Figure 7-1), enter the numerical Patient Identification and press the Next key.

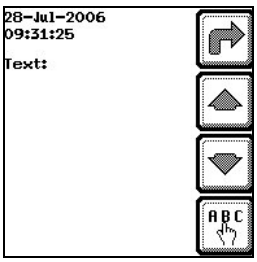
**Figure 7-1 Patient Identification**




To enter an alphanumeric patient ID, press the Text key (Figure 7-2).

**Figure 7-2 Alphanumeric Patient ID**




- Use the and arrows to scroll through the text option screens.
- At the desired screen, press the (←) or (→) to move to the desired character.
- Press the Text key to select the character. It will then show up at the Text: ___ prompt.

- Advance to the next character by pressing the (←) or (→) and repeat steps to select additional characters.

After the Patient ID is entered, press the Next key.

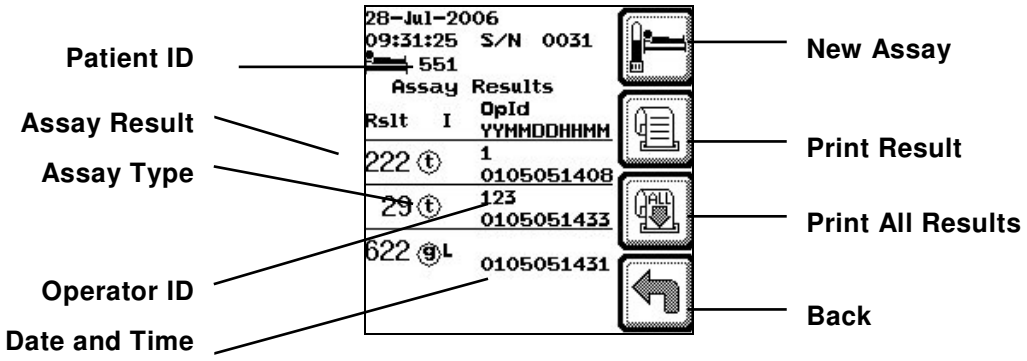
**NOTE**: If you make a mistake while entering a text character, press the Next key to return to the Patient ID Entry Screen. Use the (→) key to move the cursor to the end of the Patient ID entered, then press the (←) key to erase character(s) until the mistaken character is deleted. Press (TEXT) to go back to the Text Entry Screen and select the correct character using the directions from above.

See Section 7.1.3 for a description of the assay results log.

### 7.1.3 Assay Results Log

The screen displays a scrollable log of the last 150 patient results arranged chronologically. If the instrument is configured to use patient identification, then the instrument will retrieve all assay results for a particular patient. The cursor is positioned on the most recent assay result. Navigate up and down the list using the (← , →) keys.

**Figure 7-3 Assay Results Log**




| Feature | Description |
|---|---|
| Patient ID | Displays the patient identification and filters the stored results so that only results for the selected patient are displayed. This feature is available when patient identification is activated. |
| Assay Result | Displays the numerical result. |
| Assay Type | Displays a symbol indicating the type of assay performed. |
| | (t) IIb/IIIa assay (PAU result) |
| | (a) Aspirin assay (ARU result) |

| Feature | Description | |
|---|---|---|
| |  | P2Y12 assay (PRU result) |
| |  | P2Y12 assay (Base result) |
| | % | P2Y12 assay (Percent Inhibition result) |
| Operator ID | Displays the operator ID of the user who performed the test (when configured). | |
| Date and Time Stamp | Displays the date and time by year, month, day, hour (24 hr clock), and minute using the following notation, “YYMMDDHHMM.” | |

To calculate percent inhibition for IIb/IIIa assays from the listed results, locate a matching set of pre-drug PAU and post-drug PAU values for a patient using the date and time stamp. Calculate the % inhibition using the following formula:

$$\% \text{ Inhibition} = \frac{(\text{pre-drug PAU} - \text{post-drug PAU}) \times 100}{\text{pre-drug PAU}}$$

In addition to viewing earlier results, icons keys enable results to be printed (optional) or another assay started.

| Icon | | Description |
|---|---|---|
|  | New Assay | Select this icon to perform another assay on the same patient (when Patient ID is enabled). The instrument will display the Patient ID screen with the Patient ID completed. |
|  | Print Result | Scroll to the selected record, and select this icon to print the selected assay results. |
|  | Print All Results | Scroll backwards through results using the ← key, and select this icon to print all assay results in the log that are positioned forward of the cursor, or all of the assay results for a particular patient (when Patient ID function is activated). |
|  | Back | Select this icon to return to the Main Menu. |

## 7.2 Retrieving Quality Control

The instrument stores the last 100 EQC and WQC results in its memory. You can retrieve and print information about the earlier EQC parameters, WQC results, assay type, date and time, and operator identification (when configured). Use the following procedure to view the quality control results.

1. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

2. Press the Maintenance key.

3. Press the Next key three times. Refer to the Appendix for information on navigating within the Maintenance section.

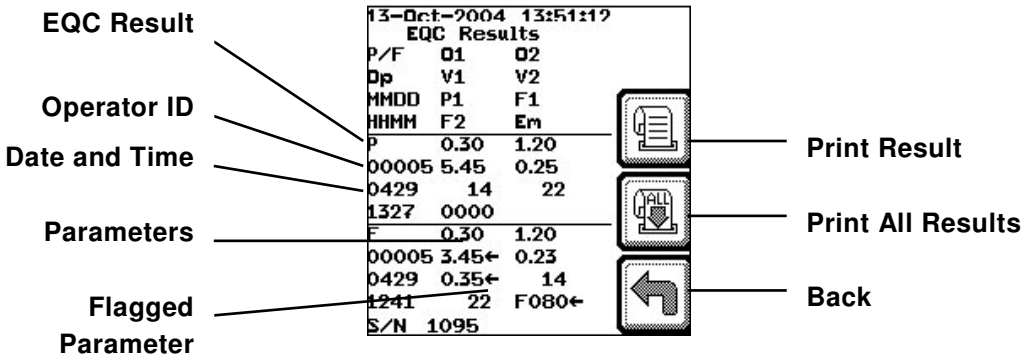
4. Press the EQC key or the WQC key to retrieve the appropriate results.

See Section 7.2.1 for a description of the EQC results log or Section 7.2.2 for a description of the WQC results log.

### 7.2.1 Electronic Quality Control Results Log

The cursor is positioned on the most recent assay result (Figure 7-4). Navigate within an individual EQC test result using the (← , →) keys.

**Figure 7-4 EQC Results Log**




| Feature | Description |
|---|---|
| EQC Result | Displays the result as either a Pass (P) or Fail (F). A Pass result indicates the instrument was operating within its specification limits. If there was an earlier problem detected during the EQC process, then a FAIL result would display. |
| Operator ID | Displays the operator identification for the user who performed the test (when configured). |
| Date and Time Stamp | Displays the date and time by month, day, hour (24 hr clock format), and minute using the following notation, “MMDD HHMM.” |
| Parameter | Displays the result for the following measured parameters: |

| Feature | Description |
|---|---|
| | O1: High optical signal level<br>O2: Low optical signal level<br>V1: Maximum vacuum level<br>V2: Maximum leak rate<br>P1: Maximum pressure level<br>F1: Mixer frequency flag count<br>F2: Mixer frequency transitions high-to-low<br>Mask: Identifies failing component element |
| Flagged Parameter | The failed parameter(s) will be indicated by an arrow (←) to the right of the measured value(s). Refer to the Appendix for a description of parameters. |

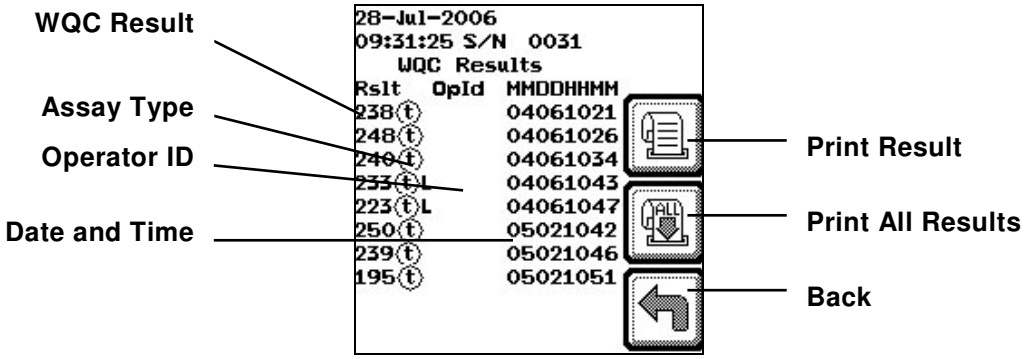
In addition to viewing earlier results, icons keys enable results to be printed (optional).

| Icon | | Description |
|---|---|---|
|  | Print Result | Scroll to the selected record, and select this icon to print the selected EQC results. |
|  | Print All Results | Scroll backwards through the results using the ← key, and select this icon to print all EQC results in the log that are forward of the cursor position. |
|  | Back | Select this icon to return to the previous screen. |

### 7.2.2 Wet Quality Control Results Log

The cursor is positioned on the most recent assay result (Figure 7-5). Navigate up and down an individual list using the (← , →) keys.

**Figure 7-5 WQC Results Log**




| Feature | Description |
|---|---|
| WQC Result | Displays the numerical result for each WQC test performed. |
| Assay Type | Displays a symbol indicating the type of WQC test performed. |
| | IIb/IIIa assay (PAU result) |
| | Aspirin assay (ARU result) |
| | P2Y12 assay (PRU result) |
| | P2Y12 assay (Base result) |
| Operator ID | Displays the operator who performed the test (when configured). |
| Date and Time Stamp | Displays the date and time by month, day, hour (24 hr clock format), and minute using the following notation, “MMDDHHMM.” |

In addition to viewing earlier results, icons keys enable results to be printed (optional).

| Icon | | Description |
|---|---|---|
| | Print Result | Scroll to the selected record, and select this icon to print the selected WQC results. |
| | Print All Results | Scroll backwards through the results using the ← key, and select this icon to print all WQC results in the log that are forward of the cursor position. |
| | Back | Select this icon to return to the previous screen. |

## 7.3 View Instrument Usage Log

The instrument usage log shows how many assays of each type have been run, as well as the running total of errors and alarms that have occurred during use. Use the following procedure to view the Instrument Usage Log (Figure 7-6).

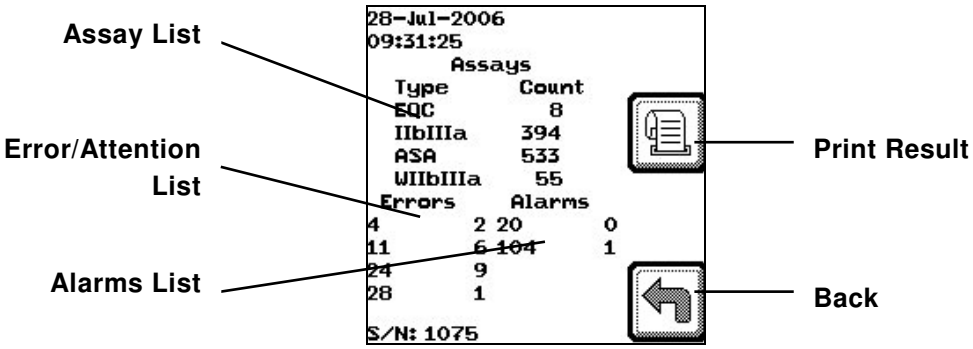
1. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.
2. Press the Maintenance key.
3. Press the Next key four times. Refer to the Appendix for information on navigating within the Maintenance section.
4. Press the Statistics key to retrieve the appropriate usage information.

See Section 7.3.1 for a description of the instrument usage log.

### 7.3.1 Instrument Usage Log

Navigate within an individual list using the (← , →) keys or between lists (Assays, Errors, Alarms) using the Tab key.

**Figure 7-6 Instrument Usage Log**




| Feature | Description |
|---|---|
| Assay List | Lists the quantity of tests (count) for each assay type or QC. In the assay list, a W preceding an assay type (e.g. WIIb/IIIa) indicates a WQC assay run using a specific (IIb/IIIa) assay device. |
| Error/Attention List | Lists the quantity of errors or alerts (attentions) logged during operation arranged chronologically by event number (e.g. errors, alerts). The left column of the list provides the error/attention |

| Feature | Description |
|---|---|
| | number and the right column provides a count of the number of incidents. |
| Alarms List | Lists the quantity of alarms logged during operation. The left column of the list provides the alarm number and the right column provides a count of the number of incidents. |

In addition to viewing earlier results, icons keys enable results to be printed (optional) or another assay started.

| Icon | | Description |
|---|---|---|
|  | Print Result | Scroll to the selected record, and select this icon to print the selected results from the lists. |
|  | Print All Results | Scroll backwards through the results using the ← key, and select this icon to print all results in the log that are forward of the cursor position. |
|  | Back | Select this icon to return to the previous screen. |

## 7.4 View Event Log

The instrument stores the last 50 error/attention events and the last 11 alarms in its memory. The instrument Event log displays the errors and alarms that have occurred during use. They are arranged chronologically. Use the following procedure to view the Event log (Figure 7-7):

1. From the main menu, enter  Operator ID and  Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

2. Press the Maintenance  key.

3. Press the Next  key two times. Refer to the Appendix for information on navigating within the Maintenance section.

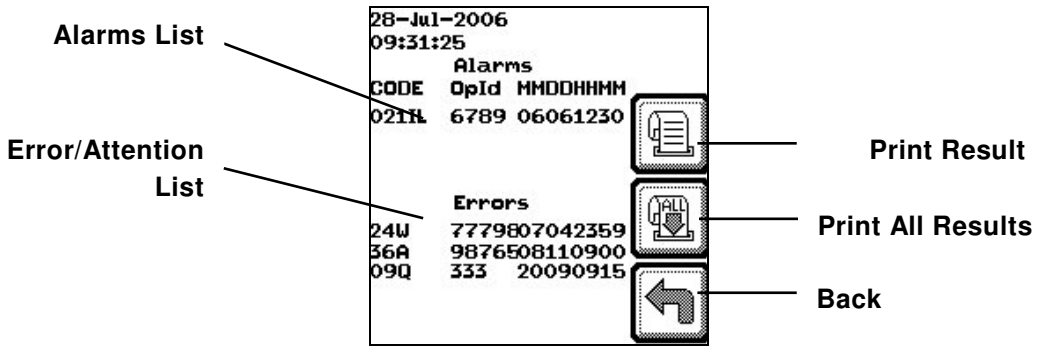
4. Press the Event Log  key to retrieve the appropriate usage information.

See Section 7.4.1 for a description of the event log.

### 7.4.1 Alarm and Error/Attention Log

The cursor is positioned on the most recent event (e.g. errors, alarms, alerts). Navigate up and down an individual list using the (← , →) keys or between lists (Alarms, Errors) using the Tab key.

**Figure 7-7 Alarm and Error/Attention Log**




| Feature | Description |
|---|---|
| Alarms List | Lists the most recent of alarms logged during operation. This includes the alarm code, operator identification (if enabled), and the date and time stamp in month, day, hour (24 hr clock format), and minute, in “MMDDHHMM” format. |
| Error/Attention List | Lists the most recent errors or alerts (attentions) logged during operation. This includes the error/alert code, operator identification (if enabled), and the date and time stamp in month, day, hour (24 hr clock format), and minute, in “MMDDHHMM” format. |

In addition to viewing earlier results, icons keys enable results to be printed (optional) or another assay started.

| Icon | | Description |
|---|---|---|
|  | Print Result | Scroll to the selected record, using the ← and → keys, and select this icon to print the selected results from the lists. |
|  | Print All Results | Scroll backwards through the results using the ← key, and select this icon to print all results in the selected log that are forward of the cursor position. |
|  | Back | Select this icon to return to the Main Menu. |

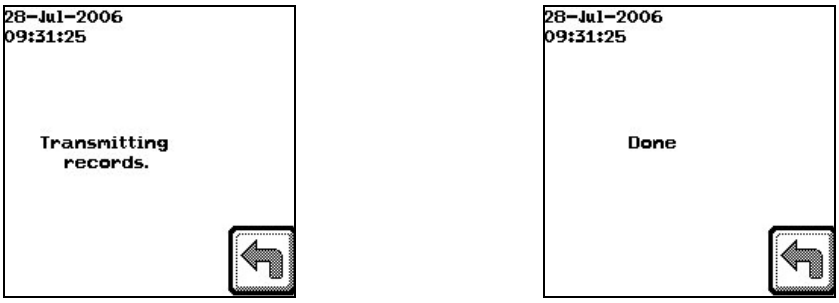
## 7.5 Transfer Network Data

The VerifyNow network integration package is an optional accessory to the instrument. This software package enables an operator to transfer a data file from the instrument to a computer connected to the network. The data file contains all assay results, WQC and EQC results, and error reports stored in the instrument's memory. Contact Accumetrics Customer Support for ordering information.

If your instrument is configured to support network integration, use the following procedure to transfer instrument data to a network computer:

1. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.
2. Press the Maintenance key.
3. Press the Next key four times.
4. Press the Network key to initiate the data transfer.
5. The instrument will display the status of the transfer and indicate when the transfer has completed (Figure 7-8).

**Figure 7-8 Network Data Transfer**




6. A message displays when the data transfer has completed successfully. Press the Back key six times to return to Main Menu.

# 8 Instrument Settings

This section describes the instrument configuration and procedures to change a setting. Refer to Table 8-1 for information:

**Table 8-1 Instrument Settings**

| Setting | | Description |
|---|---|---|
|  | Adjust contrast | This setting adjusts the contrast level for viewing the display. Refer to Section 8.1. |
|  | Adjust display backlight | This setting toggles the backlight level for viewing the display. Refer to Section 8.2. |
|  | Set date and time | The date and time is initially configured during installation. However, this setting will need to be adjusted during a leap year and twice annually for Daylight Savings Time. Refer to Section 8.3. |
|  | Set time out length | This setting specifies the length of time the instrument waits before the display automatically changes. Refer to Section 8.4. |
|  | Enable patient ID | The instrument supports patient identification (ID) for each patient sample. Refer to Section 8.5. |
|  | Set operator ID and password | The instrument supports controlled user access using operator identification and passwords. Refer to Section 8.6. |
|  | Set EQC frequency | Electronic Quality Control (EQC) is the primary quality control mechanism for the instrument. This setting specifies the frequency at which the instrument will require an EQC test to be performed. Refer to Section 8.7. |
|  | Enable printer | The VerifyNow printer is an optional accessory. To enable the printer, the software must be configured to support it. Refer to Section 8.8. |
|  | Enable network | The VerifyNow network integration package is an optional accessory. To enable the VerifyNow instrument to transfer data, the network feature must be switched on and the baud rate for data transfer set. Refer to Section 9.9. |

## 8.1 Adjust Contrast

The contrast can be adjusted to improve visibility of the screen - depending on the ambient lighting in the room where the VerifyNow instrument is located.

1. From the main menu, enter  Operator ID and  Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

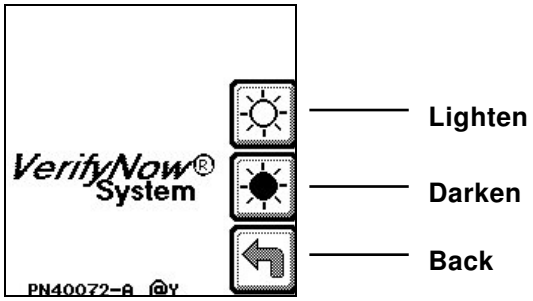
2. Press the Maintenance  key.

3. Press the Next key. Refer to the Appendix for information on navigating within the Maintenance section.

4. Press the Adjust Contrast key.

5. Press the Lighten key or the Darken key to adjust the screen to the desired contrast (Figure 8-1). Find a setting that has better visibility with the room's lighting.

**Figure 8-1 Adjust Contrast**




6. Press the Back key twice to return to the Main Menu.

## 8.2 Adjust Backlight

The backlight can be toggled on or off to improve visibility of the screen - depending on the ambient lighting in the room where the VerifyNow Instrument is located.

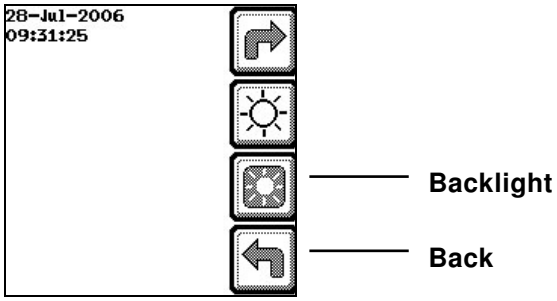
1. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

2. Press the Maintenance key.

3. Press the Next key. Refer to the Appendix for information on navigating within the Maintenance section.

4. Press the Adjust Backlight key, to toggle the backlight on or off (Figure 8-2). Find a setting that has better visibility with the room's lighting.

**Figure 8-2 Adjust Backlight**




5. Press the Back key once to return to the Main Menu.

## 8.3 Set the Date and Time

The date and time is initially configured during installation. However, this setting will need to be adjusted during a leap year and twice annually for Daylight Savings Time. Use the following procedure to adjust the setting:

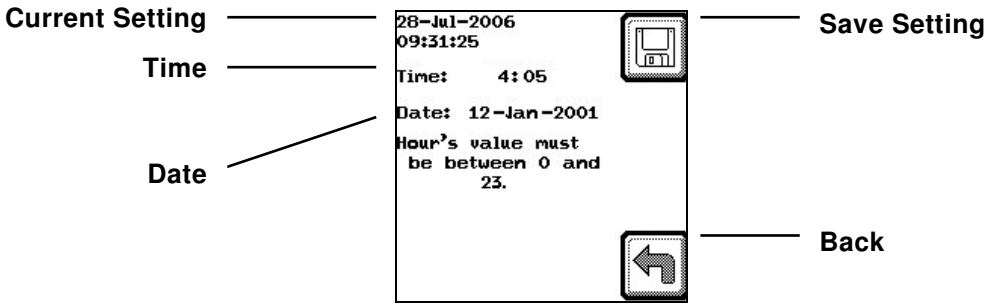
1. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

2. Press the Maintenance key.

3. Press the Next key two times. Refer to the Appendix for information on navigating within the Maintenance section.

4. Press the Date/Time key to display the setting (Figure 8-3).

**Figure 8-3 Date and Time Setting**




5. Record the new time stamp according to a 24-hour clock format. Press the Tab key to move between the settings. For example, 1:30 pm is equivalent to 13:30 in

the instrument time setting. The hour value should be between 0 and 23. The minute value should be between 0 and 59.

6. Record the new date stamp. Press the Tab key to move between the settings. The year value consists of four characters and must be 1999 or later. Use either arrow key (←,→) to scroll through the months when setting the date. The day value should be greater than 0, but not greater than the number of days in the given month.

7. Press the Save key to keep the new setting and return to the Maintenance menu. Press the Back key three times to return to the Main Menu without saving the changes.

**NOTE**: In the event a setting value is not within an expected range, an error message will display after the Save key is pressed. Return to the setting and correct the mistake, then press the Save key again.

8. Whenever an adjustment is made to the date or time setting, the instrument will require an EQC be performed.

## 8.4 Set Time Out

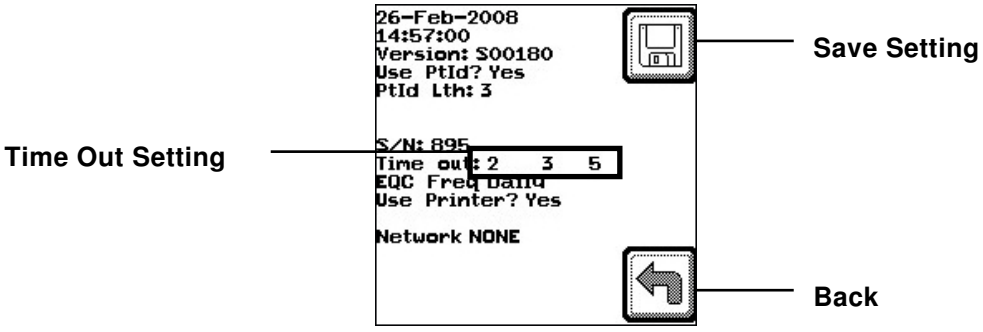
The VerifyNow Instrument has been designed with features that restrict instrument access after a specified time period. If the instrument is idle for a longer period, the display screen will go blank. When an operator presses a key, the instrument automatically returns to the Main Menu and requires user login, if applicable. This time period can vary based on the operation being performed and can be adjusted by the user. It does not affect the display of assay results, QC results, or calculations. Use the following procedure to adjust the setting:

1. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

2. Press the Maintenance key.

3. Press the Parameter key to display the time out setting (Figure 8-4). Refer to the Appendix for information on navigating within the Maintenance section.

**Figure 8-4 Time Out Setting**




4. Press the Tab key 3 times to advance the cursor to the Time Out setting. The instrument supports three different time out settings, depending on the operation being performed. These settings correspond to the following three different fields (Table 8-2).

**Table 8-2 Time Out Settings**

| Field | Activities Affected | Default Time Setting |
|---|---|---|
| 1 | Affects all input operations associated with an assay or QC. | 2 minutes |
| 2 | Affects the time that a user's password will remain on the screen (when configured). | 3 minutes |
| 3 | When idle, affects when the screen saver "stand-by" feature is engaged. When engaged, the "stand-by" feature returns to the main menu and dims the display. | 5 minutes |

5. Record the new timeout settings for the three fields – between 0 and 255 minutes. Assigning a timeout value to 0 means the affected screens will not time out. Press the Tab key to move between the settings.

**NOTE**: Unless the third field is set to 0, the second field needs to be less than or equal to the third field.

6. Press the Save key to keep the new setting and return to the Maintenance menu. Press the Back key twice to return to the Main Menu without saving the changes.

## 8.5 Enable Patient ID

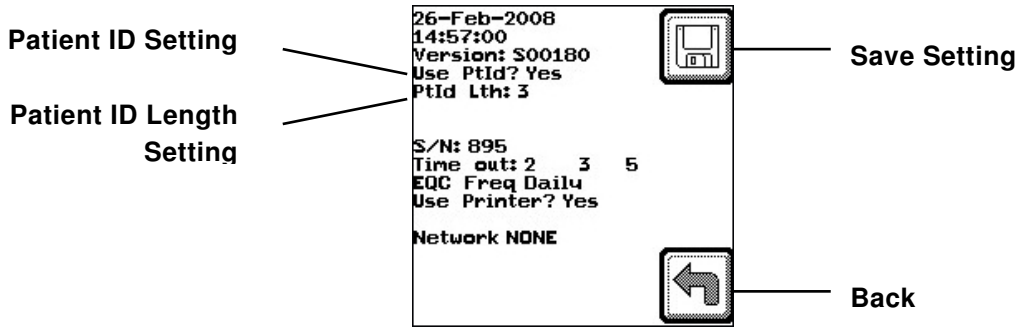
The VerifyNow Instrument supports patient result traceability. This includes a feature that assigns a patient identification (ID) to each patient sample. The instrument's default setting does not assign patient ID; however, use the following procedure to adjust the setting:

1. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

2. Press the Maintenance key.

3. Press the Parameter key to display the settings (Figure 8-5). Refer to the Appendix for information on navigating within the Maintenance section.

**Figure 8-5 Patient Identification Setting**




4. At the Use Pt ID prompt, press either the (←) or (→) key to change the setting between Yes and No.

5. If Patient ID is enabled, press the Tab key to move to “Pt ID Lth:” prompt. The patient identification length can be any combination of letters and/or numbers up to 11 characters. Enter the number of characters in the institution’s patient identification. For example, if a sample patient identification is “325679”, the number “6” should be entered to designate a Patient ID length of six characters.

**NOTE**: After the patient identification length is defined in the system, only a Patient ID with the correct number of characters will be accepted in order to start an assay. At the start of the assay, a series of “?” will represent the established patient ID length. For example, if the ID length is set to 6 characters and the patient ID is five characters, then a leading zero (0) must be entered. A “?” is not a valid input and all “?” must be replaced by alpha-numeric characters. If a different number of digits is entered the will display. The assay cannot proceed until the correct number of digits is entered.

6. Press the Save key to keep the new setting and return to the Maintenance menu. Press the Back key twice to return to the Main Menu without saving the changes.

## 8.6 Set Operator ID and Password

The VerifyNow Instrument has been designed with features that restrict instrument access. If this feature is enabled, a user identification number and a matching password must be entered before an operator can use the instrument. In addition, it is also possible to assign different authority levels to each user, depending upon the instrument functions delegated to each user (e.g. running patient samples, QC procedures or changing instrument settings).

The instrument's default setting does not provide for operator identification; however, use the following procedure to adjust the setting or add/remove users based on your institution's policy:

1. From the main menu, enter  Operator ID and  Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

2. Press the Maintenance  key. Refer to the Appendix for information on navigating within the Maintenance section.

3. Press the Password  key to display the Operator Authority Log. See Section 8.6.1 for a description of features of the Operator Log.

4. **To enable or disable operator identification/passwords**, press either the (←) or (→) key to change the setting between Yes and No.

5. **To add a user**, press the Tab key to advance to "Oper" prompt.

    - Record an Operator ID by entering up to 5 numbers using the keypad. If an error is made during entry, use the (→) key to move the cursor to the mistake, then press the (←) key to erase the mistake. Up to 100 users may be entered.
    - Next, press the Tab key to advance the cursor to the password setting (Pswd). Enter a password (up to 5 characters) using the keypad.
    - Next, press the Tab key to advance the cursor to the authority setting. Use either (←,→) to scroll through the list of authority levels. If you do not wish to establish authority levels for all users then choose the blank option when scrolling through the authority level lists.
    - Once all information is entered for an operator, press the Add Item  key to add the operator to the list.

**NOTE**: At least one operator must have P,M,R,Q,A authority to access the Operator Authority Log. Record operator names, operator IDs, and password information and store the information with the instrument files.

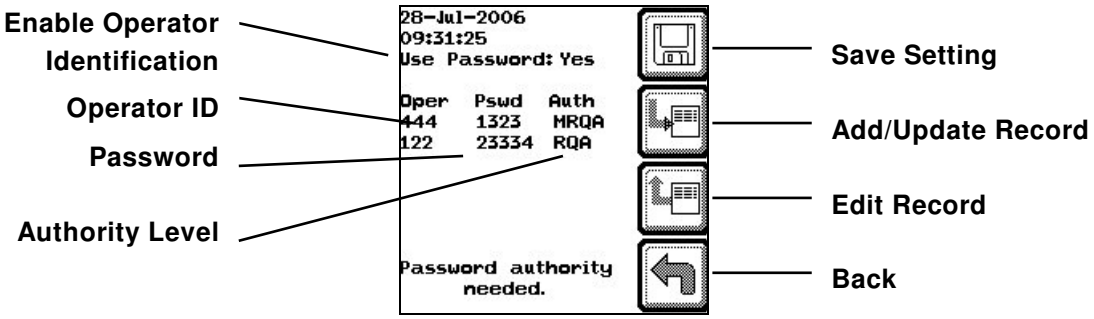
**NOTE**: Routine users (at least one person per shift) should be assigned an authority level of Q,A or greater.

6. **To edit a user record**, press the Tab key until the cursor moves into the list of operators.
   - Press the (←,→) keys to scroll up or down the list.
   - Once you have highlighted the operator information to be edited, press the Edit Record key to bring the information to the top of the list.
   - Next, use the (←,→) keys to edit the information.
   - When editing is complete, press the Update Record key to add the information to the operator list.
7. **To delete a user record**, select the operator as above for editing, then press the Delete key. This will remove all information on the user.
8. Press the Save key to keep the new setting and return to the Maintenance menu. Press the Back key twice to return to the Main Menu without saving the changes.

### 8.6.1 Operator Authority Log

The cursor is initially positioned on the Use Password field. Navigate up and down an individual list using the (← , →) keys or between lists by using the Tab key.

**Figure 8-6 Operator Authority Log**




| Feature | Description |
|---|---|
| Enable Operator Identification | Displays whether operator identification is enabled. A “Yes” indicates that operator ID and password is required to log in. A “No” indicates this feature is not active. |

| Feature | Description |
|---|---|
| Operator ID | Displays the list of numerical operator IDs currently assigned (when configured). |
| Password | Displays the numerical password assigned to each user. |
| Authority Level | Displays one of six authority levels assigned to each user.<br>**Blank** — If no authorization level is selected, the password feature will not activate<br>**A** — This level allows the user to perform patient **Assays** and print results.<br>**Q,A** — In addition to all features available under A, this level allows the user to perform electronic and wet **Quality** control tests.<br>**R,Q,A** — In addition to all features available under Q,A, this level allows the user to **Retrieve** earlier patient results.<br>**M,R,Q,A** — In addition to all features available under R,Q,A, this level allows the user to change instrument settings/**Maintenance**.<br>**P,M,R,Q,A** — In addition to all features available under M,R,Q,A, this level allows the user to add other users and change authority levels and **Passwords**. |

| Icon | | Description |
|---|---|---|
|  | Save | Select this icon to save any changes made to the Operator Authority Log and return to the prior screen. |
|  | Add/Update Record | Select this icon to add an operator's log-in, password, and authority information to the list. |
|  | Edit Record | When adding or changing operator information, select this icon to add information to the operator list. |
|  | Delete Record | Select this icon to remove the highlighted (where the cursor is positioned) user information. |
|  | Back | Select this icon to return to the Main Menu without saving the changes. |

## 8.7 Set EQC Frequency

Electronic Quality Control (EQC) is the primary quality control mechanism for the VerifyNow Instrument. This setting specifies the frequency at which the instrument will require an EQC test to be performed.

**NOTE**: When the established interval has elapsed, the user is locked out from

running a patient test until the EQC test has been successfully completed.

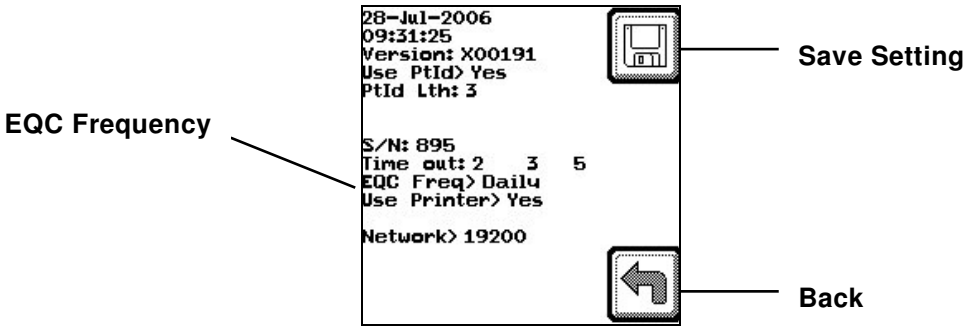
The instrument's default setting is daily. Use the following procedure to adjust the setting based on your institution's preference:

1. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

2. Press the Maintenance key.

3. Press the Parameter key. Refer to the Appendix for information on navigating within the Maintenance section.

**Figure 8-7 EQC Frequency**




4. Press the Tab key 6 times to advance the cursor to the EQC Frequency setting. At the EQC Freq prompt, press either the (←) or (→) key to change the setting to 6 hours, 8 hours, 12 hours, daily, weekly, or monthly.

5. Press the Save key to keep the new setting and return to the Maintenance menu. Press the Back key twice to return to the Main Menu without saving the changes.

## 8.8 Enable Printer

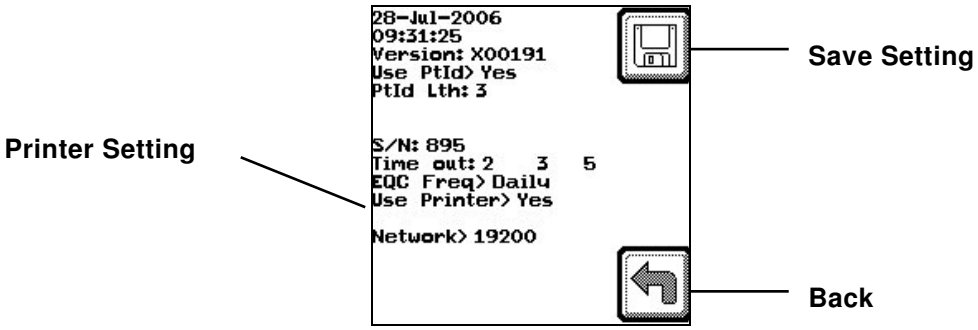
The VerifyNow printer is an optional accessory to the instrument. The printer enables an operator to print assay results, QC results, and instrument usage statistics. To enable the VerifyNow instrument to output this information to the printer, the printer feature must be set to "Yes." Use the following procedure to configure the instrument to support the printer accessory:

1. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

2. Press the Maintenance key.

3. Press the Parameter key. Refer to the Appendix for information on navigating within the Maintenance section.

**Figure 8-8 Printer Setting**




4. Press the Tab key 7 times to advance the cursor to the Printer setting. At the Use Printer prompt, press either the (←) or (→) key to toggle the setting between Yes and No.

5. Press the Save key to keep the setting and return to the Maintenance menu. Press the Back key twice to return to the Main Menu without saving the changes.

## 8.9 Enable Network

The VerifyNow network integration package is an optional accessory. This software package enables an operator to transfer a data file from the instrument to a computer connected to the network. The data file contains all assay results, WQC and EQC results, and error reports stored in the instrument's memory. Contact Customer Support for more information.

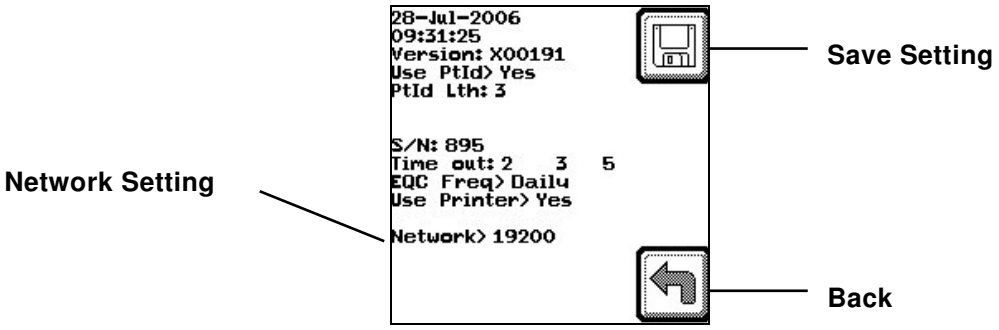
To enable the VerifyNow instrument to transfer data, the network feature must be switched on and the baud rate for data transfer set. Use the following procedure to configured the instrument to support network integration:

1. From the main menu, enter Operator ID and Password, if required. Use the keypad to enter the Operator ID number at the prompt. Press the Tab key to advance to the Password prompt to enter the password number.

2. Press the Maintenance key.

3. Press the Parameter key to display the network setting (Figure 8-9). Refer to the Appendix for information on navigating within the Maintenance section.

**Figure 8-9 Network Setting**




4. Press the Tab key 9 times to advance the cursor to the Network setting. At the Network prompt, press either the (←) or (→) key to change the setting between NONE and a specific baud rate. If configuring a network, change the setting to the rate that matches the capabilities of the network being used.

5. Press the Save key to keep the new setting and return to the Maintenance menu. Press the Back key twice to return to the Main Menu without saving the changes.

6. In order to activate the saved baud rate, turn the VerifyNow instrument off and then on again.

**NOTE**: Unless a Network connection has been established, the network setting should always be set to NONE.

# 9 Cleaning and Maintenance

The VerifyNow Instrument does not require frequent maintenance by the user. However, it is important to perform light cleaning and simple maintenance on a routine basis in order to maintain the reliability of the VerifyNow instrument. Table 9-1**Error! Reference source not found.** lists a recommended cleaning schedule.

**Table 9-1 Recommended Instrument Cleaning Schedule**

| **Inspection / Maintenance** | **Bi-weekly** (every other week) | **Monthly** | **Annually** |
|---|---|---|---|
| Use the cleaning device (see Section 9.1) | X | | |
| Clean exterior surfaces (see Section 9.2) | | X | |
| Replace the fan filter (see Section 9.3) | | | X |

The recommended cleaning schedule should be used as a general guideline. Consider adjusting the schedule based on the environmental conditions in the room.

## 9.1 Use the Cleaning Device

Depending on the room conditions, small amounts of dust and debris may build up on the pneumatic port connection of the instrument. A single use, disposable cleaning device is provided to remove this debris. It consists of a clear plastic component with an adhesive strip. Use the cleaning device to remove debris from a pneumatic port connection inside the assay device port according to the following procedure:

**CAUTION:** Excessive use of cleaning devices can damage the instrument. Cleaning more often than once a week is not recommended, unless prompted at the display screen.

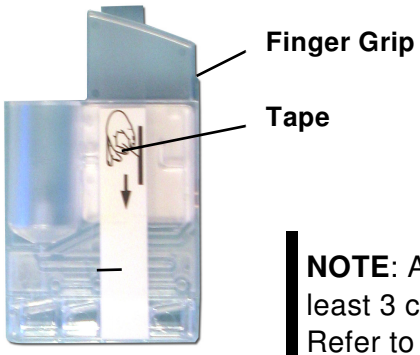
**Materials**

- Cleaning device (Accumetrics Catalog No. 85062, 10/pack)

**Procedure**

1. Locate the cleaning device pack. Cleaning devices come individually packed in a clear plastic bag with a brightly colored label (Figure 9-1).

**Figure 9-1 Cleaning Device**

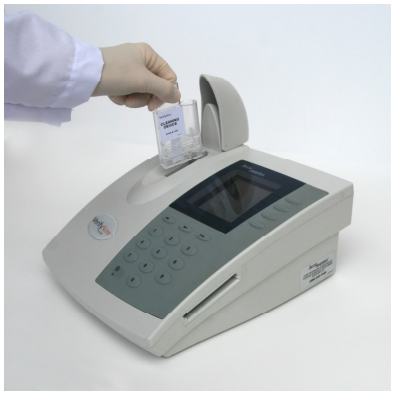



**NOTE**: Accumetrics recommends you have at least 3 cleaning devices on hand for routine use. Refer to the Appendix for ordering information.

2. Grasp the cleaning device using the finger grip and **remove the clear plastic tape**. Discard the tape.

3. Open the cover and insert the cleaning device into the assay device port until it clicks (Figure 9-2). The adhesive strip removes dust and debris on the internal pneumatic port cleaning strip.

**Figure 9-2 Insert Cleaning Device**



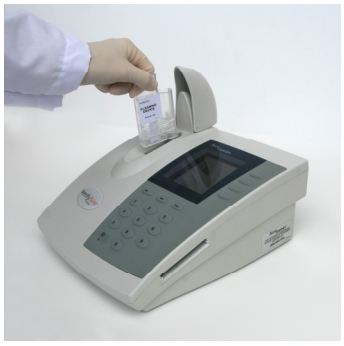
**NOTE**: The instrument does not need to be in any particular mode to use the cleaning device.

4. Leave the cleaning device in the assay port for five seconds, but never longer than ten seconds.

**CAUTION: Leaving the cleaning device in the assay port for an extended period of time can damage the instrument from adhesive adhering to the internal pneumatic port.**

5. Remove the cleaning device completely from the assay device port (Figure 9-3). Discard the device. The cleaning device is for single use only.

**Figure 9-3 Remove Cleaning Device**



6. Repeat using another cleaning device if, upon inspection, there is visible dust and debris.

## 9.2 Clean Exterior Surfaces

Occasionally, a liquid may spill near the instrument or small amounts of dust may build up on the exterior of the instrument. Periodic cleaning of the exterior surface may be performed to remove accumulation on the instrument.

**Materials**

- Lint-free cloth (clean room wipes)
- Non-abrasive cleaner (such as Cidex®, pHisoHex®, 7X®, Super Edisonite®, 10% household bleach solution in water, dish washing detergent, or isopropyl alcohol)

**Procedure**

Use a recommended cleaning solution on the exterior surfaces according to the following procedure:

1. Solutions may be applied by moistening a soft, lint-free cloth, and/or a cotton swab. Do not to allow liquids to flow freely or be sprayed on the instrument.

2. After cleaning with one of the solutions listed above, a cloth moistened with fresh water should be used to dilute and remove all of the residual cleaning solution from the instrument's surfaces.

3. Wipe the EQC device with a damp cloth moistened with isopropyl alcohol.

**CAUTION:** Do not spray or pour cleaning fluids near the assay device port or other openings. Introduction of fluids into the interior can damage the VerifyNow instrument.

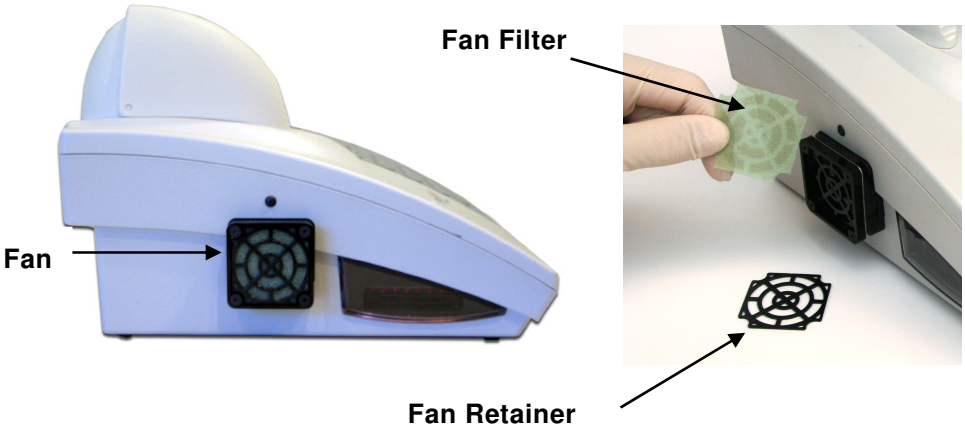
**CAUTION:** Do not steam-sterilize or autoclave the instrument. Do not immerse the instrument in any solution. Do not clean the instrument with acetone or any other plastic solvent or abrasive cleaner.

**CAUTION:** Prolonged exposure to alcohol or other strong cleansers can result in damage or discoloration to the instrument's case materials. Always use a soft cloth when cleaning the display screen and bar code window. Abrasive cleaners, pads, or cloths will permanently damage the surface of the plastic windows.

**CAUTION:** Be careful not to spill any liquids on the instrument, printer (accessory), or power supply while cleaning the exterior surfaces.

## 9.3 Replace the Fan Filter

The instrument is equipped with an exterior fan vent to cool the internal electronic components. Depending on the room conditions, small amounts of dust and debris may accumulate over time within the fan filter and obstruct airflow. Periodic cleaning of the fan filter may be performed to avoid overheating of the instrument.




**Materials**

- Replacement fan filter (Accumetrics Catalog No. 37056)
- Replacement fan filter retainer (Accumetrics Catalog No. 37050)

**Procedure**

Use the following procedure to remove and clean the fan filter:

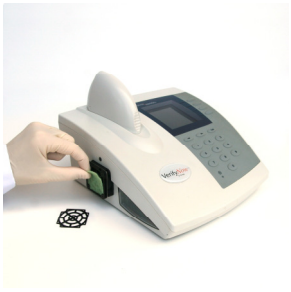
1. Power off the instrument ("O" designates off).

2. The fan filter is held in place by a press fit retainer. Using your fingernail or a small tool (e.g. paperclip), gently pull from the center of the filter retainer (Figure 9-4).

**NOTE**: There are no screws to be removed.

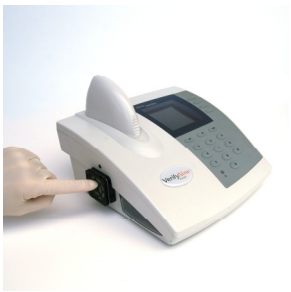
**Figure 9-4 Remove Fan Filter**

3. Remove the fan filter and inspect it for dust accumulation.



4. If necessary, replace it with a new filter.

5. Gently replace the fan filter and plastic filter retainer. Do not position the instrument so that airflow to the fan is obstructed.



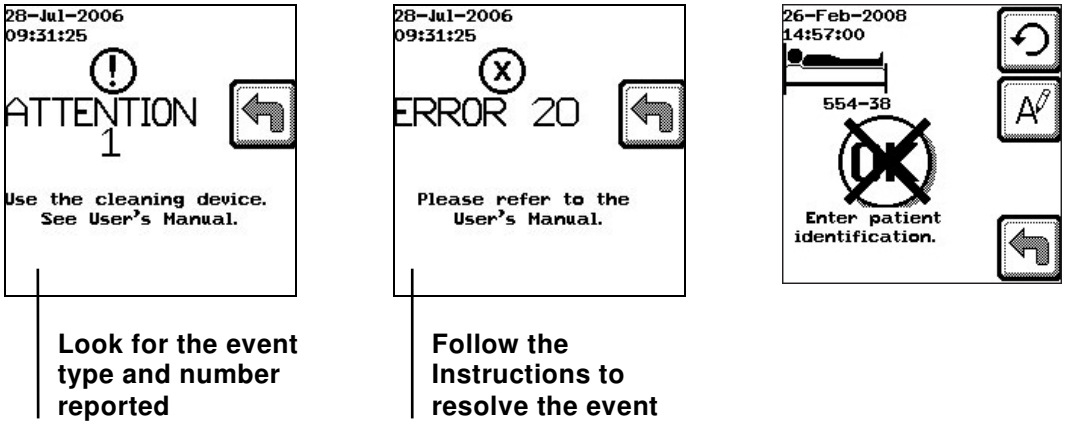
6. Power on the instrument (“I” designates on).

# 10 Troubleshooting

Occasionally, an unanticipated event occurs which interrupts the operation of the VerifyNow instrument. The VerifyNow System is equipped to detect events due to system malfunction, adverse environmental conditions, and variations in operator technique. This section covers the resolution of minor events that may be experienced during use of the VerifyNow instrument. In most situations, the recommended recovery consists of removing the affected assay device, looking up the displayed code in the following section, and re-performing the assay after correcting the issue. In the event of a major malfunction, please notify Accumetrics Customer Support.

The instrument reports five different types of events. These include messages, alerts, errors, alarms, and electronic diagnostics. Figure 10-1 **Error! Reference source not found.**provides an example of an error message and an alert (attention) message.

**Figure 10-1 Example Alert (Attention) and Error Messages**




Refer to Table 10-1 for instructions on what to do if you experience one of the five events.

**Table 10-1 What To Do When an Unexpected Event Occurs**

| Event and Description - What it means | | Resolution – What to do |
|---|---|---|
| | **Message**- A message displays when information needs to be entered or an activity performed before proceeding to the next step. | Refer to Table 10-2 for solutions. |
| ⓘ | **Attention-** Along with this symbol, a message displays with the word "Attention" followed by a number. These events may be simple issues that can be easily addressed by the customer. | Refer to Table 10-3 for solutions organized by number. |
| ⓧ | **Error-** Along with this symbol, a message displays with the word "Error" followed by a number. Typically these events occur when the instrument detects an abnormal condition, and often can be corrected by the customer. | Refer to Table 10-3 for solutions organized by number. |

**Table 10-1 What To Do When an Unexpected Event Occurs**

| | | |
|---|---|---|
|  | **Alarm-** Alarms also produce a constant audible tone. Along with this symbol, a message displays with the word “Alarm” followed by a number. Alarms are likely system problems and, in general, are not serviceable by the customer. | If one of these alarms should occur, note the code number displayed, power off the VerifyNow instrument and call Customer Support. |
|  | **Electronics Diagnostics-** During an EQC, the system monitors the electronic and mechanical components, and reports a diagnostic failure if a value is out-of-range. | The failed parameter(s) will be indicated by an arrow (←) to the right of the measured value(s). Refer to Table 10-5 for solutions organized by parameter. |

**CAUTION:** Seek technical assistance if you are uncertain how to respond to a malfunction or if you are unable to correct the malfunction. If possible, please have the numerical code that was displayed on the screen available when contacting Customer Support.

**WARNING:** The VerifyNow Instrument is not intended to be serviced by the user. Instruments in need of repair are required to be returned to the manufacturer. If there are problems related to the VerifyNow System, contact Accumetrics Customer Support.

## 10.1 Messages

Table 10-2 lists alert messages and provides a brief description of the issue and instructions for resolving it.

**Table 10-2 Troubleshooting Messages**

| Issue Description | Resolution |
|---|---|
| **Message – Operator ID error**<br>The Operator ID number entered does not match those of registered users. | This typically occurs when the wrong operator number has been entered.<br>Press the Next key to return to the previous screen and re-enter your operator identification number. |
| **Message – Password error**<br>The password number entered does not match the Operator ID. | This typically occurs when the wrong password has been entered.<br>Press the Next key to return to the previous screen and re-enter the password associated with your operator identification number. |

| Issue Description | Resolution |
|---|---|
| **Message – Enter Patient identification**<br>  <br>An incorrect number of characters for Patient ID have been entered during an assay. | This typically occurs when the patient ID number entered does not match the specified number of characters for the patient ID.<br>1) Check the Patient ID displayed on the screen to see if it is the correct length.<br>2) Re-enter the correct Patient ID using the correct Patient ID length. To verify correct Patient ID length see section 8.5 |
| **Message – Retrieve patient identification**<br>  <br>A Patient ID has been entered where there is no matching record. | This typically occurs when retrieving patient test results and an incorrect patient ID number is entered. It does not match the patient ID of the patient tests stored in memory.<br>1) Check the Patient ID displayed on the screen to see if it is the correct length.<br>2) Re-enter the correct Patient ID using the correct Patient ID length. To verify correct Patient ID length, see section 8.5 |
| **Message – Remove assay device**<br>A used assay device inadvertently remains in the assay port. | Remove the device and tube together before proceeding. The instrument will produce two audible beeps. |
| **Message – Perform EQC**<br>The time between EQC checks exceeds the set interval specified in the instrument settings. | The instrument prompts an operator to perform a simple electronic quality control (EQC) check at periodic intervals.<br>1) Perform an EQC test (see Section 5.1).<br>2) If the EQC is OK, proceed with the patient test. |
| **Message – Non-matching baseline values** (IIb/IIIa assay only)<br>The two baseline entries do not match. | A message displays while entering the baseline PAU result if the two entries do not match.<br>1) Use the Tab key to move to the field that was entered incorrectly, and re-enter the correct baseline.<br>2) Press the Next key to calculate percent inhibition. |
| **Message – Low baseline value** (IIb/IIIa assay only)<br>The baseline result entered is a lower PAU value than the post-drug result. | A flashing ⚠ and "≤" symbol will display when a suspicious baseline has been entered.<br>1) Verify that the baseline result entered was correct.<br>2) If correct, press the Next key to calculate % inhibition as above. If incorrect, re-enter the correct baseline as above and press the Next key to calculate % inhibition. |
| **Message – Reference range baseline values** (IIb/IIIa assay only)<br>A baseline result is entered that is not within the expected range. | A reference range has been established for baseline patient samples (before GP IIb/IIIa inhibitor administration) using the VerifyNow System. Refer to VerifyNow IIb/IIIa package insert. This message appears if the entered baseline is outside the reference range.<br>1) Verify that the baseline result entered was correct.<br>2) If correct, press the Next key to calculate % inhibition as above. If incorrect, re-enter the correct baseline as above and press the Next key to calculate % inhibition. |

## 10.2 Attention, Error and Alarm Messages

Table 10-3 lists alerts (attention) and errors messages and provides a brief description of the issue and instructions for resolving it.

**Table 10-3 Troubleshooting Attention and Error Messages**

| No. | Issue Description | Resolution |
|---|---|---|
| 1 | **Attention - Bubbles in sample**<br>One or more of the assay detectors received too high a light signal. | This event can be caused by an air bubble in the sample, a very low hematocrit sample, or incomplete reconstitution of the reagent.<br>1) Keep the assay device for troubleshooting, and verify there were no bubbles in the detection wells. Also verify that the correct sample tube has been used. If there are bubbles present, use a cleaning device (See Section **Error! Reference source not found.**). If there are no bubbles present, the blood sample may have a low hematocrit. See assay package insert for details.<br>2) Perform an EQC test (see Section 5.1). If the EQC is OK, run WQC Level 1 (see Section 5.2.1).<br>3) If the EQC is not OK or the problem persists, call Customer Support and have the assay device handy.<br>**NOTE: Make sure to gently invert the sample as specified in Section 6.4 to avoid bubbles.** |
| 3 | **Attention - Assay device lot expired**<br>An expired assay device has been inserted into the instrument. | 1) Check the expiration date on the packaging of the assay device as well as the current date and time on the instrument.<br>2) If the assay device has expired, remove it and discard.<br>3) If the instrument's date and time is incorrect, change the setting (see Section 8.3). |
| 4 | **Error – Assay device spot code**<br>The instrument does not recognize the spot code on the assay device. | This error may occur if the instrument is located under bright light or if the spot code on the assay device does not match the bar code scanned from the assay device pouch (lot information).<br>**Place the instrument away from direct sunlight, bright light, or other radiant heat sources (refer to installation guidelines)**.<br>1) If the error occurs when running an assay, check to see if the spot code label is marred or crooked. If so, use another assay device.<br>2) If this error occurs while attempting to run an EQC, turn the instrument on and off. Next, perform another EQC (see Section 5.1).<br>3) Scan the bar code from another pouch from the same lot (do not open the pouch).<br>4) If the problem continues, call Customer Support. |
| 5 | **Error - Invalid bar code**<br>The scanned bar code label is not the proper length or type | 1) Press the Back  key, and scan a bar code from another pouch from the same lot (do not open the pouch).<br>2) If this does not work, perform an EQC test to ensure the instrument is working properly (see Section 5.1). If EQC is OK, try the assay again.<br>3) If the EQC is not OK or the problem continues, call Customer Support. |

| No. | Issue Description | Resolution |
|---|---|---|
| 6 | **Attention – Printer not responding**<br>There is a problem with the printer that prevents printing. | The printer is not responding. The printer may be turned off or the printer not properly attached to the instrument.<br>1) Check to make sure the printer is turned on. If not, turn the printer on and press the Repeat key to start printing.<br>2) Ensure that the printer and instrument are correctly connected and that the printer cable is seated correctly at the back of the instrument.<br>3) If the problem continues, call Customer Support. |
| 7 | **Attention – Printer out of paper**<br>There is a problem with the printer roll that prevents printing. | The printer may be out of paper or there may be a paper jam.<br>1) Make sure the printer is loaded with paper. If not, insert paper into the printer and press the Repeat key to start printing.<br>2) Check that paper moves properly through the printer. Press Repeat key to start printing.<br>3) If the problem continues, call Customer Support. |
| 8 | **Attention – Printer not ready**<br>There is a problem with the printer that prevents printing. | The printer is not responding. The printer may be turned off or the printer not properly attached to the instrument.<br>1) Turn the printer on and off. Then press the Repeat key to start printing.<br>2) Ensure that the printer and instrument are correctly connected and that the printer cable is seated correctly at the back of the instrument.<br>3) If the problem continues, call Customer Support. |
| 10 | **Attention - Detection wells fill**<br>The sample did not fill the detection wells in time, which is required for consistent activation of platelets. | Typical causes of this event include a low or high fill volume in the sample tube, wrong sample tube use, or not inserting the sample tube firmly against needle hub.<br>1) Keep the assay device, and verify there was adequate volume of blood and the correct sample tube was used. Refer to Section 6.2, Patient Sample Collection for more information.<br>2) Use the cleaning device (see Section 9.1).<br>3) Perform an EQC test (see Section 5.1)<br>4) If the EQC is OK, run a Wet QC Level 1 (see Section 5.2.1) and verify the result falls within expected range.<br>5) If the EQC is not OK, call Customer Support and have the assay device handy. |

| No. | Issue Description | Resolution |
|---|---|---|
| 11 | **Attention - Air leak**<br>The sample left the staging well prematurely during the warming cycle. | Typical causes of this event include a dirty port connection, use of an incompatible sample tube, and not inserting the sample tube firmly against needle hub.<br>1) Keep the assay device for troubleshooting, and verify the detection wells filled with blood and the correct Greiner tube was used. Refer to Section 6.2, Patient Sample Collection for more information.<br>2) Use the cleaning device (see Section **Error! Reference source not found.**).<br>3) Perform an EQC test (see Section 5.1)<br>4) If the EQC is OK, run a Wet QC Level 1 (see Section 5.2.1) and verify the result falls within expected range.<br>5) If the EQC is not OK, call Customer Support and have the assay device handy. |
| 12 | **Attention - Tube or assay device removed**<br>The sample tube or assay device was removed during the assay. | Either the sample tube/assay device was removed by the operator before the test was completed OR a non-compatible tube was used.<br>1) Inspect the tube, and verify that the correct Greiner tube was used. Refer to Section 6.2, Patient Sample Collection for more information.<br>2) Discard the sample and the assay device. Do not reuse. Re-draw a blood sample.<br>3) Wait for the prompt before removing the assay device during the next assay (see Section 6.4).<br>**NOTE: Once an assay has started, do not remove the assay device or the sample tube until prompted, or until after aborting the assay.** |
| 13 | **Error - Measurement Timeout**<br>An error occurred during the measurement portion of an assay or WQC. | 1) Power the instrument off. Wait 10 seconds, and then power it on.<br>2) Perform an EQC test (see Section 5.1)<br>3) If the EQC is OK, run a Wet QC Level 2 (see Section 5.2.2) and verify the result falls within expected range. If so, proceed with the assay.<br>4) If the EQC is not OK or the WQC produces an error, call Customer Support. |
| 14 | **Attention - Scheduled EQC**<br>An EQC test needs to be run and current operator does not have authority to do so. | Typically, this event occurs when a routine user has not been given the authority to perform a diagnostic EQC test.<br>1) Have an operator with QC authority return to the Main Menu screen and Login.<br>2) Perform an EQC test (see Section 5.1).<br>3) If the EQC is OK, verify the authority level of the original user (see Section 8.6), and update, if necessary.<br>4) If the EQC is not OK or the problem continues, call Customer Support. |

| No. | Issue Description | Resolution |
|---|---|---|
| **15** | **Attention - Failed EQC**<br>An assay was attempted although an EQC was required before the assay could start. | This event occurs when an assay was attempted following a failed EQC, or if the date or time was changed since the last EQC was run and an assay was attempted. Typically, this event occurs when the current user has not been given the authority to perform a diagnostic EQC test, and the user tried to run an assay when an EQC was required.<br>**NOTE: An EQC must pass before an assay can be performed.**<br>1) Have an operator with QC authority return to the Main Menu screen and Login.<br>2) Perform an EQC test (see Section 5.1).<br>3) If the EQC is OK, verify the authority level of the original user (see Section 8.6.1), and update, if necessary. If the EQC is not OK or the problem continues, call Customer Support. |
| **16** | **Error - Mixer frequency**<br>**OR**<br>**EQC F1, F2 Parameter**<br>The sample-mixing rate was not within specifications. | 1) Check the alarm and error log (see Section 7.4.1) and note the frequency of Error 16 in the log and whether it occurred during a patient test (A) or during an EQC test (E).<br>2) Call Customer Support with this information.<br>If this event occurred during an EQC test, refer to Table 10-5 for more information. |
| **17** | **Error – EQC V1 parameter**<br>This event occurs during a Failed EQC, and is logged as Error 17 in the event log. | See V1 in Table 10-5.<br>1) Use the cleaning device (see Section **Error! Reference source not found.**) then perform an EQC (see Section 5.1).<br>2) Repeat if necessary. Call customer support if EQC does not pass after three attempts. |
| **18** | **Error – EQC V2 parameter**<br>This event occurs during a Failed EQC, and is logged as Error 18 in the event log. | See V2 in Table 10-5.<br>1) Use the cleaning device (see Section **Error! Reference source not found.**) then perform EQC (see Section 5.1).<br>2) Repeat if necessary. Call customer support if EQC does not pass after three attempts. |
| **19** | **Error – EQC P1 parameter**<br>This event occurs during a Failed EQC, and is logged as Error 19 in the event log. | See P1 in Table 10-5.<br>1) Use the cleaning device (see Section **Error! Reference source not found.**) then perform EQC (see Section 5.1).<br>2) Repeat if necessary. Call customer support if EQC does not pass after three attempts. |
| **21** | **Error - Low proximal voltage**<br>Assay or EQC optical data was outside expected limits.<br>This event occurs during a Failed EQC as O1, and is logged as Error 21 in the event log. | Possible causes of this error include incomplete reagent reconstitution, a damaged EQC device, faulty optical components, or excessive time between the blood draw into a syringe and sample transfer to the sample tube or start of the assay.<br>1) If running an EQC, verify the EQC device is not damaged.<br>2) If running an assay, ensure that the sample was drawn correctly, that it was mixed sufficiently but gently, and that the assay was run within the time allotted for the assay type (see Chapter 6, *Patient Testing*).<br>3) Perform an EQC test (see Section 5.1). If the EQC is OK, attempt the assay again.<br>4) If the EQC is not OK or the problem continues, call Customer Support. |

| No. | Issue Description | Resolution |
|---|---|---|
| 22 | **Error - Low distal voltage**<br>Assay or EQC optical data was outside expected limits. | Possible causes of this error include incomplete reagent reconstitution, a damaged EQC device, faulty optical components, or excessive time between the blood draw into a syringe and sample transfer to the sample tube or start of the assay.<br>1) If running an EQC, verify the device is not damaged.<br>2) If running an assay, ensure that the sample was drawn correctly, that it was mixed sufficiently but gently, and that the assay was run within the time allotted for the assay type (see Chapter 6, *Patient Testing*).<br>3) Perform an EQC test (see Section 5.1). If the EQC is OK, attempt the assay again.<br>4) If the EQC is not OK or the problem continues, call Customer Support. |
| 23 | **Error DC agreement (IIb/IIIa only)**<br>There was significant variation between the internal controls. | A redundant assay using the same reagents is run in one of the detection wells of the IIb/IIIa assay device as a control. This error occurs when the DC values vary significantly between the two channels.<br>1) Perform an EQC test (see Section 5.1). If the EQC is OK, run WQC Level 2 (see Section 5.2.2).<br>2) If the EQC is not OK or the problem continues, call Customer Support. |
| 24 | **Attention - Channel slope agreement (IIb/IIIa)**<br>**OR**<br>**Clinical control units**<br>There was significant variation between the internal controls or the clinical control unit (CU) is out-of-range. | In these cases, the event may be associated with the blood sample and the following causes should be investigated:<br>• The patient being tested is on an interfering substance. Refer to the package insert for list of interfering substances.<br>• An improper blood collection technique was used to draw the sample.<br>• The discard tube was used to run the assay.<br>• The patient being tested has a low platelet count, a low hematocrit or an inherited platelet disorder.<br>• The assay device was exposed to excess humidity prior to running.<br>• A WQC sample was run in Assay mode rather than QC mode.<br>• The Greiner sample tube is expired.<br>If none of the above can be determined to be the cause, run WQC Level 2 (see Section 5.2.2). If the problem continues, call Customer Support. |
| 25 | **Error - Mean agreement (IIb/IIIa Only)**<br>There was significant variation between the internal controls. | For the IIb/IIIa assay, a redundant assay using the same reagents is run one of the detection wells of the IIb/IIIa assay device as a control. This error occurs when the mean values vary significantly between the two channels.<br>1) Perform an EQC test (see Section 5.1). If the EQC is OK, run WQC Level 2 (see Section 5.2.2).<br>2) If the EQC is not OK or the problem continues, call Customer Support. |

| No. | Issue Description | Resolution |
|---|---|---|
| 26 | **Attention - Premature sample tube**<br>The sample tube was inserted prior to the prompt being displayed. | 1) Discard the sample and the assay device. Do not reuse.<br>2) Re-draw sample and perform another assay with a new assay device<br>**NOTE: Make sure to wait for the sample tube prompt before inserting the tube into the assay device.** |
| 27 | **Attention - Assay type not supported**<br>The type of assay device inserted is not supported by this version of the instrument's software. | This event may occur after a software upgrade or following changes to the assay device.<br>1) Check the printing on the assay device pouch to ensure it is the type of assay device desired. If not, obtain the correct assay device type, and repeat the assay. If yes, perform an EQC test (see Section 5.1). When running EQC, make sure to select the QC prompt and not the assay prompt.<br>2) If EQC test is OK, attempt the assay again.<br>3) If the EQC is not OK or problem continues, call Customer Support. |
| 28 | **Attention - Signal saturation**<br>High light transmittance through the detection wells. | High light transmittance through the detection wells prevents the instrument from measuring a change in optical signal.<br>In these cases, the event may be associated with the blood sample and the following causes should be investigated:<br>• The patient being tested has a hematocrit outside of the applicable range. Refer to the package insert for information on the range.<br>• An improperly mixed sample was used to run the assay.<br>• The sample was not run within the specified amount of time.<br>If none of the above can be determined to be the cause, run WQC Level 2 (see Quality Controls Section 5.2.2) to confirm the integrity of the assay device and the reagents. If the problem continues, call Customer Support. |
| 29 | **Error – EQC Mask parameter**<br>This event occurs during a Failed EQC, and is logged as Error 29 in the event log. | This event occurs when the EQC test detects the unfiltered light as not within specifications.<br>Call Customer Support if the EQC device had been removed completely at the end of the EQC and it fails. |

| No. | Issue Description | Resolution |
|---|---|---|
| 32 | **Attention – Cover opened**<br>The assay port cover was opened during the assay. | Typically, this event occurs when the assay port cover is opened during the assay or when air bubbles are present in the detection wells of the assay device.<br>1) Verify that the assay port cover was not inadvertently opened while the assay was running. If so, repeat the assay using a new sample and assay device.<br>**NOTE: Close the assay port cover within 5 seconds after insertion of the sample tube. Do not open the cover until prompted.**<br>2) Keep the assay device for troubleshooting, and verify there are no bubbles in the detection wells. If bubbles are visible, use a cleaning device, repeat with a new sample and assay device.<br>**NOTE: Make sure to gently invert the sample as specified in Section 6.4 to avoid bubbles.**<br>3) If the problem continues, call Customer Support and have the assay device handy. |

## 10.3 Alarm Messages

Table 10-4 lists alarm messages and provides a brief description of the issue and instructions for resolving it.

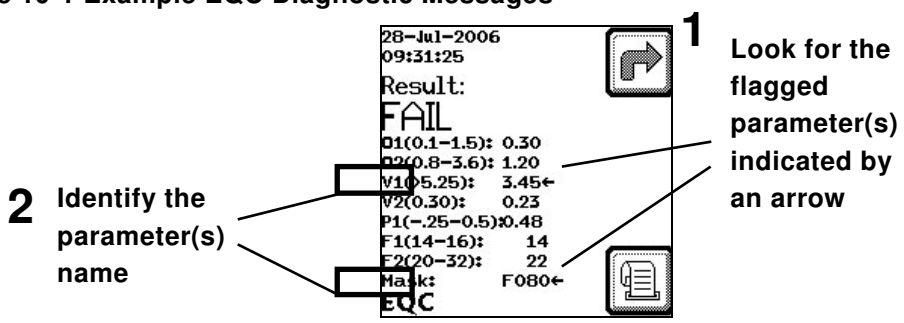
**Table 0-4 Troubleshooting Alarm Messages**

| No. | Issue Description | Resolution |
|---|---|---|
| **20** | **Alarm 20**<br>Heater Unstable: Temperature exceeds acceptable bounds for more than 10-seconds | Power instrument off. While instrument is off, remove and examine fan filter for excessive dust that may be blocking fan. Replace filter if needed. Power instrument on.<br>Verify the fan has at least 3 inches of space to ventilate properly, and that it is not being affected by airflow from a vent or another instrument.<br>Check if fan is functioning. If no airflow can be detected, call Customer Support. |
| **21** | **Alarm 21**<br>Stuck Key: Key pressed for more than 5 seconds | Power instrument off and back on. Keys should only be pressed and release, not pressed and held. |
| **31** | **Alarm 31**<br>Vacutainer Missing When Expected | Power instrument off and back on. Verify that sample tube was not removed during test. |
| **104** | **Alarm 104**<br>Heater Timeout During Heating Cycle | Power instrument off and back on. Verify the fan has at least 3 inches of space to ventilate properly, and that it is not being affected by airflow from a vent or another instrument.<br>Check if fan is functioning. If no airflow can be detected, call Customer Support. |
| **118** | **Alarm 118**<br>Emitter problem associated with an EQC filter | Power instrument off and back on. If alarm occurred during EQC, use alternate EQC device.<br>If no alternate EQC device is available, or alarm reoccurs, call Customer Support. |

## 10.4 EQC Diagnostic Messages

EQC diagnostic messages will display at the conclusion of the EQC test. Figure 10-1 provides an example of a diagnostic message that displays when the EQC test does not produce results within the expected range for a monitored parameter.

**Figure 10-1 Example EQC Diagnostic Messages**




To troubleshoot EQC diagnostic messages, first identify the parameter(s) flagged with an arrow, then look up the parameter(s) in the following table. Table 10-5 lists diagnostic messages and provides a brief description of the issue and instructions for resolution.

**Table 10-5 Troubleshooting EQC Diagnostic Messages**

| Parameter | Issue Description | Resolution |
|---|---|---|
| O1 | High optical signal level | 1) Visually inspect the EQC device to verify it has not been damaged.<br>2) If you have another EQC device, repeat EQC using the second device; otherwise, Call Customer Support. |
| O2 | Low optical signal level | 1) Visually inspect the EQC device to verify it has not been damaged.<br>2) If you have another EQC device, repeat an EQC using the second device; otherwise Call Customer Support. |
| V1 | Maximum vacuum level | This event is logged as Error 17 in the event log.<br>1) Use the cleaning device (see Section **Error! Reference source not found.**) then perform an EQC (see Section 5.1).<br>2) Repeat if necessary.<br>3) Call Customer Support if EQC does not pass after three attempts. |
| V2 | Maximum leak rate | This event is logged as Error 18 in the event log.<br>1) Use the cleaning device (see Section **Error! Reference source not found.**) then perform an EQC (see Section 5.1).<br>2) Repeat if necessary.<br>3) Call Customer Support if EQC does not pass after three attempts. |

| Parameter | Issue Description | Resolution |
|---|---|---|
| P1 | Maximum pressure level | This event is logged as Error 19 in the event log.<br>1) Use the cleaning device (see Section **Error! Reference source not found.**) then perform an EQC (see Section 5.1).<br>2) Repeat if necessary.<br>3) Call Customer Support if EQC does not pass after three attempts. |
| F1 | Mixer frequency flag count | 1) Check the alarm and error log (see Section 7.4.1) and note the frequency of Error 16 in the log.<br>2) Call Customer Support with this information. |
| F2 | Mixer frequency transitions high to low | 1) Visually inspect the EQC device to verify it has not been damaged. If you have another EQC device, repeat EQC using the second device.<br>2) Check the alarm and error log (see Section 7.4.1) and note the frequency of Error 16 in the log.<br>3) Call Customer Support with this information. |
| MASK | Failing optical element | This event is logged as an error in the event log (e.g. #4, #29). It commonly occurs when the EQC device has not been removed completely from the assay device port when prompted or when the instrument is located in adverse lighting conditions (refer to installation guidelines).<br>Call Customer Support if the EQC device had been removed completely at the end of EQC and it fails. |

# 11 Appendix

## 11.1 Technical Specifications

| Feature | Specification |
|---|---|
| Dimensions (WxDxH)<br>(See Note 1) | 9.5 x 9.3 x 6.5 in / 24 x 23 x 16.5 cm |
| Location | Clean, firm, level surface without vibration.<br>Avoid placement near sources of heat or cold, incandescent lighting or direct sunlight. |
| Service Access Perimeter | 4 in / 10.4 cm |
| Weight | 4 lb / 1.8 kg |
| AC Voltage | 100-240 VAC (50/60 Hz)<br>Printer accessory not included |
| Power Rating | 35 W |
| Fuses | Two (2) 1A/250V, 5x20mm SLO-BLO type |
| Operating Temperature | 64°-90° F / 18°-32°C (0-85% RH, non-condensing) |
| Operating Pressure | -1,000 ft to 10,000 ft |
| Shipping/Storage Temperature | 14°-113° F / -10°-45°C (0-95% RH, non-condensing) |
| Shipping/Storage Pressure | -1,000 ft to 15,000 ft. |
| Calibration | Factory set |
| Display | Dot matrix liquid crystal |

**NOTES**:

The printer accessory is recommended with the system but is not included in current dimensions.

## 11.2 Explanation of Symbols

| | | | |
|---|---|---|---|
| REF | Catalog Number |  | This End Up |
| SN | Serial Number |  | Fragile |
| EC REP | Authorized Representative in the European Community |  | Keep Dry |
|  | Manufacturer |  | Load Limit |
|  | Temperature Limits | IVD | *In vitro* Diagnostic |
| **RH** | Relative Humidity |  | Single Use |
| **P** | Atmospheric Pressure |  | Remove |
| LOT | Lot Number |  | Contains sufficient for < n > tests |

## 11.3 System Components

| Manufacturer Catalog No. | Description |
|---|---|
| 85065 | VerifyNow System |
| 85066 | VerifyNow System, International, European Community |
| 85005 | VerifyNow Instrument |
| 85053 | VerifyNow Aspirin Assay – kit of 25 aspirin assay devices |
| 85064 | VerifyNow P2Y12 Assay – kit of 25 P2Y12 assay devices |
| 85011 | VerifyNow IIb/IIIa Assay – kit of 25 IIb/IIIa assay devices |
| 85047 | VerifyNow Assay WQC – kit of 6 wet quality controls (for Level 1 or 2 wet quality control) |
| 454082 | Greiner Bio-One Vacuette Coagulation, Lithium heparin, 3 mL, 50 pcs, partial-fill tube **- ONLY for use with VerifyNow IIb/IIIa assay** |
| 454237 | Greiner Bio-One Vacuette Coagulation, Lithium heparin, 2 mL, 50 pcs, partial-fill tube **- ONLY for use with VerifyNow IIb/IIIa assay** |
| 454321 | Greiner Bio-One Vacuette 9NC Coagulation, Sodium citrate 3.2%, 2 mL, 13x75, 50 pcs, partial-fill tube **- for use with VerifyNow Aspirin, P2Y12 and IIb/IIIa (ReoPro) assays** |

### 11.3.1 Spare Parts and Accessories

The following table provides parts and accessories ordering information.

| Manufacturer Catalog No. | Description |
|---|---|
| 30005 | Power cord, US |
| 30020 | Power cord, Continental Europe |
| 30022 | Power cord, United Kingdom |
| 30028 | Fuse, 1A/250V, 5x20mm SLO-BLO type |
| 85021 | VerifyNow Printer and 3 rolls of paper |
| 37056 | Fan Filter – 1 replacement filter for the exhaust fan |
| 37060 | Fan Filter Retainer – 1 replacement plastic cover for the filter |
| 70068 | EQC Device |
| 85022 | VerifyNow Printer Labels - pack of 10 rolls |
| 85062 | VerifyNow Instrument Cleaning Device Kit - kit of 10 cleaning devices |

## 11.4 Glossary

The following table provides a definitions for common terms used in this manual.

| Term | Description |
|---|---|
| IIb/IIIa receptor | See glycoprotein (GP) IIb/IIIa receptor |
| Abciximab | Abciximab (trade name ReoPro®) is a platelet aggregation inhibitor mainly used during and after coronary artery procedures like angioplasty to prevent thrombus (blood clot) formation within the coronary artery. Its mechanism of action is inhibition of the glycoprotein IIb/IIIa complex. |
| Adenosine diphosphate | ADP. When secreted by activated platelets from storage granules, ADP activates additional platelets in circulation through two G protein-coupled P2 receptors, P2Y1 and P2Y12. |
| Anti-platelet | Platelet inhibition may be induced in response to an anti-platelet agent. Three classes of potent anti-platelet agents include acetylsalicylic acid (aspirin), P2Y12 inhibitors, and glycoprotein (GP) IIb/IIIa inhibitors. |
| Arachidonic acid | In an activated platelet, arachidonic acid is converted by cyclo-oxygenase (COX-1) to prostaglandin $G_2$ ($PGG_2$) and $PGH_2$ and then to thromboxane A2. Aspirin affects platelet function by irreversibly inhibiting the cyclo-oxygenase (COX) activity of prostaglandin (PG) H-synthase, which in turn blocks the metabolism of arachidonic acid to thromboxane A2 (TXA2). |
| Aspirin | Acetylsalicylic acid. The primary pharmacological effect of aspirin on platelets is to decrease the activation of the GP IIb/IIIa receptor and activation of other platelets. |
| Aspirin reaction units | Results for the Aspirin assay are interpreted based on the extent of platelet aggregation measured and reported in Aspirin Reaction Units (ARU). |
| Aggregation, platelets | The binding of the activated platelet IIb/IIIa receptors to fibrinogen (and vWF) results in the formation of platelet-platelet and platelet-matrix adhesive interactions and the formation of a stable, larger platelet aggregate at the site of injury. |
| Alarm | A type of message that displays after an unexpected event. Alarms are likely system problems, and in general not serviceable by the customer. |

| Term | Description |
|---|---|
| ARU | See Aspirin Reaction Units |
| Assay device | There are three types of assay devices relating to the appropriate platelet function test: Aspirin, P2Y12, and GP IIb/IIIa inhibitors (specifically abciximab or eptifibatide). Each single-use, assay device consists of a sample well, staging well, and four detection wells |
| Assay device port | The assay device port holds a VerifyNow assay device during the test. |
| Attention | A type of message that displays after an unexpected event. These events may be simple issues that can be easily addressed by the customer. |
| Bar code | A series of vertical black and white lines on the white assay device package (pouch). The label stores information about the assay type, |
| Bar code Scanner | The bar code scanner scans a bar code on the white assay device package, decodes the bar code, and passes the information to the instrument software. |
| Base result | For the P2Y12 assay, a base result using the Base channel (TRAP and PAR-4 activating peptide) serves as an estimate of baseline platelet function independent of P2Y12 receptor inhibition. The Base result is normalized to report units that are equivalent to baseline PRU. |
| Baseline | A sample can be drawn prior to drug administration, and it can be used as a baseline reading for determining percent inhibition (for IIb/IIIa assay). |
| Cleaning device | A single use, disposable plastic component with an adhesive strip. The cleaning device is used to remove debris from a pneumatic port connection inside the assay device port. |
| Clopidogrel | Clopidogrel (trade name Plavix® - clopidogrel bisulfate) is a potent oral antiplatelet agent used in the treatment of coronary artery disease, peripheral vascular disease, and cerebrovascular disease. As a thienopyridine, its mechanism of action is inhibition of the P2Y12 receptor. |
| Cover | A plastic door on the instrument that shields the assay device port from ambient light. |

| Term | Description |
|---|---|
| Date extension | When Accumetrics issues a date extension notification for a specific lot of assay devices, these devices can be used after the original expiration date. |
| Detection well | The detection wells of an assay device contain a lyophilized preparation of human fibrinogen coated beads and platelet agonist. The instrument measures platelet aggregation as an increase in light transmittance through the detection wells. |
| Diluent | An optically absorbent solution used in lieu of blood during wet quality control. |
| Diluent tube | Tube in the Assay WQC kit containing the diluent. |
| Discard tube | When collecting patient samples using direct venipuncture, the discard tube (that is later discarded) is filled before the sample tube. This tube may be plain sodium citrate, blood culture, or heparin tube. The tube cannot contain EDTA (purple top). |
| Electronic quality control | Electronic quality control (EQC) is a procedure during which the software will calibrate and verify instrument optics performance, reagent mixing, and instrument pneumatics. |
| EQC | See electronic quality control. |
| EQC device | A re-usable device that is inserted by the operator into the assay port and is used to perform a comprehensive testing routine that confirms performance of key instrument components. |
| EQC frequency | Specifies the time interval between EQC tests. When the time interval is exceeded, the instrument cannot perform patient testing until an EQC test is performed. |
| Eptifibatide | Eptifibatide (trade name Integrilin®) is a platelet aggregation inhibitor mainly used during and after coronary artery procedures like angioplasty to prevent thrombus (blood clot) formation within the coronary artery. Its mechanism of action is inhibition of the glycoprotein IIb/IIIa complex. |
| Error | A type of message that displays after an unexpected event. Typically these events occur when the instrument detects an abnormal condition, and often can be corrected by the customer. |

| Term | Description |
|---|---|
| F1 | The mixer frequency flag count parameter reported during electronic quality control diagnostics. See electronic quality control. |
| F2 | The mixer frequency transitions (high to low) parameter reported during electronic quality control diagnostics. See electronic quality control. |
| Fibrinogen | A soluble blood plasma protein which the enzyme thrombin converts into fibrin during the blood-clotting process. The binding of the activated platelet IIb/IIIa receptors to fibrinogen (and vWF) results in the formation of platelet-platelet and platelet-matrix adhesive interactions and the formation of a stable, larger platelet aggregate. |
| glycoprotein (GP) IIb/IIIa receptor | Activation induces a conformational change in the platelet glycoprotein IIb/IIIa receptors on the surface of platelets to an activated high-affinity binding site for fibrinogen and vWF. The binding of the activated platelet IIb/IIIa receptors to fibrinogen (and vWF) results in the formation of platelet-platelet and platelet-matrix adhesive interactions and the formation of a stable, larger platelet aggregate at the site of injury. |
| Humidity indicator | Part of the assay device. It is used to determine if the lyophilized reagent in the assay device has degraded after prolonged exposure to room air. |
| Icon | Icons are used to navigate through the steps in a test. Icons display along the right side of the display screen and correspond to an adjacent icon key. |
| Icon keys | The four icon keys directly to the right of the display screen correspond to the different icons displaying on the screen. Selecting an icon key displays another screen or directs the instrument to perform an action. |
| Inhibitor, glycoprotein (GP) IIb/IIIa | GP IIb/IIIa inhibitors block platelet aggregation by preventing fibrinogen and other adhesion molecules (vWF) from binding to the IIb/IIIa integrin on platelets. |

| Term | Description |
|---|---|
| Integrilin | Eptifibatide (trade name Integrilin®) is a platelet aggregation inhibitor mainly used during and after coronary artery procedures like angioplasty to prevent thrombus (blood clot) formation within the coronary artery. Its mechanism of action is inhibition of the glycoprotein IIb/IIIa complex. |
| iso-TRAP | Thrombin receptor activating peptide (iso-TRAP), a synthetic peptide, serves as a surrogate for thrombin and activates the platelet through the PAR-1 receptor in the P2Y12 (base result) and IIb/IIIa assays. |
| Keypad | The keypad contains 13 labeled keys located directly below the display screen. The “0” through “9” keys are used to enter operator and patient identification numbers, change the time and the date, and make selections from menu options. |
| Level 1 | Wet quality control Level 1 is formulated at a clinically relevant level and is representative of a sample with platelet inhibition. During Level 1 WQC, diluent is used to verify continued performance by checking that actual results are within a standard range. See also wet quality control. |
| Level 2 | WQC Level 2 is formulated at a clinically relevant level, and is representative of a sample with no platelet inhibition. During Level 2 WQC, a pink pellet is added to the diluent to verify continued performance, by checking that actual results are within a standard range. See also wet quality control. |
| Log | A running record of activity by the instrument. There are separate logs organized by patient results, QC results, and error events. |
| Mask | The optical element parameter reported during electronic quality control diagnostics. See electronic quality control. |
| Mode | The instrument supports two modes, depending on whether the instrument is running an assay or QC test. |
| Operator identification | A feature that assigns a number and matching password number to each operator. When enabled, identification is required to use the instrument. |
| P1 | The maximum pressure level parameter reported during electronic quality control diagnostics. See electronic quality control. |

| Term | Description |
|---|---|
| P2Y12 reaction units | PRU. PRU reports the amount of ADP-mediated aggregation specific to the platelet P2Y12 receptor, and is calculated as a function of the rate and extent of platelet aggregation in the ADP channel. |
| P2Y12 receptor | The P2Y12 receptor is a G protein-coupled P2 receptor on the surface of the platelet. Adenosine diphosphate (ADP) secreted from activated platelets results in the further amplification by activating additional platelets in circulation via the P2Y1 and P2Y12 receptors. |
| PAR-1 receptor | PAR-1 is one of four protease-activated receptors (PAR) located on the surface of platelets. Thrombin activates PAR-1 by cleavage of part of its extracellular domain. Thrombin receptor activating peptide (iso-TRAP), a synthetic peptide, serves as a surrogate for thrombin and activates the platelet through the PAR-1 receptor in the P2Y12 and IIb/IIIa assays. |
| PAR-4 receptor | PAR-4 is one of four protease-activated receptors (PAR) located on the surface of platelets. Thrombin activates PAR-4 by cleavage of part of its extracellular domain. PAR-4 activating peptide (PAR-4 AP), a synthetic peptide, serves as a surrogate for thrombin and activates the platelet through the PAR-4 receptor in the P2Y12 assays. |
| PAR-4 activating peptide | PAR-4 activating peptide (PAR-4 AP), a synthetic peptide, serves as a surrogate for thrombin and activates the platelet through the PAR-4 receptor in the P2Y12 assay. It is used to determine the Base result. |
| Password | When operator identification is enabled, a user identification number and a matching password number are required to use the instrument. |
| Patient Identification | A feature that assigns a patient identification (ID) to each patient sample. |
| PAU | See platelet aggregation units. |
| Pellet | A hygroscopic substance provided in the Assay WQC kit and used in Level 2 wet quality control testing. The active ingredient is a peptide that gives results that mimic platelet function in an uninhibited sample. |

| Term | Description |
|---|---|
| Percent inhibition | Percent inhibition (%) is the percent change from baseline aggregation, and is calculated from a result and a base or baseline result. |
| PGE1 | The VerifyNow P2Y12 assay uses PGE1 to increase intraplatelet cAMP and reduce the contribution of the P2Y1 receptor on activation. This makes the assay more specific for the effects of ADP on the P2Y12 receptor. |
| Platelet | Also called a thrombocyte. A discoid cell found in large numbers in blood, responsible for aggregation and contributing to haemostasis by repairing vascular wall injuries. |
| Platelet activation | Platelet activation induces a conformational change in the platelet glycoprotein IIb/IIIa receptors on the surface of platelets to an activated high-affinity binding site for fibrinogen and vWF. The platelet changes from a disc shape to a round shape with long, filopodial extensions that can bind to adhesive proteins in circulation, such as fibrinogen, to form a meshwork of platelets. |
| Platelet aggregation units | The IIb/IIIa assay reports patient results in Platelet Aggregation Units (PAU). PAU is calculated as a function of the rate and extent of aggregation. |
| Platelet function test | A laboratory or point-of-care test to measure platelet activity or platelet inhibition in patients. One method detects platelet activity by measuring *in vitro* platelet aggregation in a blood sample exposed to specific agonists. |
| Platelet inhibition | The condition in which or the process by which platelet aggregation is inhibited. Platelet inhibition may be induced in response to a potent anti-platelet agent (e.g. acetylsalicylic acid (aspirin), P2Y12 inhibitors, and GP IIb/IIIa inhibitors). |
| Plavix | Clopidogrel (trade name Plavix® - clopidogrel bisulfate) is a potent oral antiplatelet agent used in the treatment of coronary artery disease, peripheral vascular disease, and cerebrovascular disease. As a thienopyridine, its mechanism of action is inhibition of the P2Y12 receptor. |
| Pouch | The white assay device package. |
| Power indicator | When power is on, a green LED indicator on the lower left corner of the keypad remains illuminated. |

| Term | Description |
|---|---|
| PRU | See P2Y12 reaction units. |
| ReoPro | Abciximab (trade name ReoPro®) is a platelet aggregation inhibitor mainly used during and after coronary artery procedures like angioplasty to prevent thrombus (blood clot) formation within the coronary artery. Its mechanism of action is inhibition of the glycoprotein IIb/IIIa complex. |
| Sample well | An assay device has of a sample well. The instrument automatically draws whole blood into the assay device from a sample collection tube in the sample well. |
| Staging well | An assay device has of a staging well. The instrument heats the blood in the staging well (except for the Aspirin assay). |
| Spot code | The spot code consists of printed black circles on the assay device. It provides information about the assay device to determine which assay is being performed and the assay device lot number. |
| Thienopyridine | Thienopyridines are a class of therapy that has significant antiplatelet effect by inhibiting adenosine diphosphate (ADP)-mediated platelet activation. Thienopyridines irreversibly inhibit ADP binding to the P2Y12 receptor on the platelet surface. Clopidogrel (trade name Plavix® - clopidogrel bisulfate) is a thienopyridine. |
| Thromboxane A2 | A potent platelet agonist, thromboxane A2 is released by activated platelets and acts to cause vasoconstriction and amplify the platelet recruitment by binding to thromboxane receptors on the surface of circulating platelets. |
| TRAP | See iso-TRAP. |
| V1 | The maximum vacuum level parameter reported during electronic quality control diagnostics. See electronic quality control. |
| V2 | The maximum leak rate parameter reported during electronic quality control diagnostics. See electronic quality control. |
| VerifyNow | A platelet function test developed by Accumetrics. The VerifyNow system is a whole blood, point-of-care assay, which consists of a turbidimetric-based optical detection instrument, single-use assay devices, and associated quality controls. The system was formerly named Ultegra®. |

| Term | Description |
|---|---|
| Wet quality control | Assay WQC measures two levels of turbidimetric signal that verify the dynamic range of the instrument. It verifies continued performance by checking that actual results are within a standard range. |
| WQC | See wet quality control. |
| WQC kit | A kit of 6 wet quality controls (for Level 1 or 2 WQC). Controls are formulated at clinically relevant levels, and are individually packaged in tubes (Level 1 and 2) and vials (Level 2). |

## 11.5 Software Icons

The icons represent actions and prompt the operator during the activities to configure the instrument, assay patient samples, perform quality control, and troubleshoot. The following is a complete list of all screen icons and what each symbol represents:

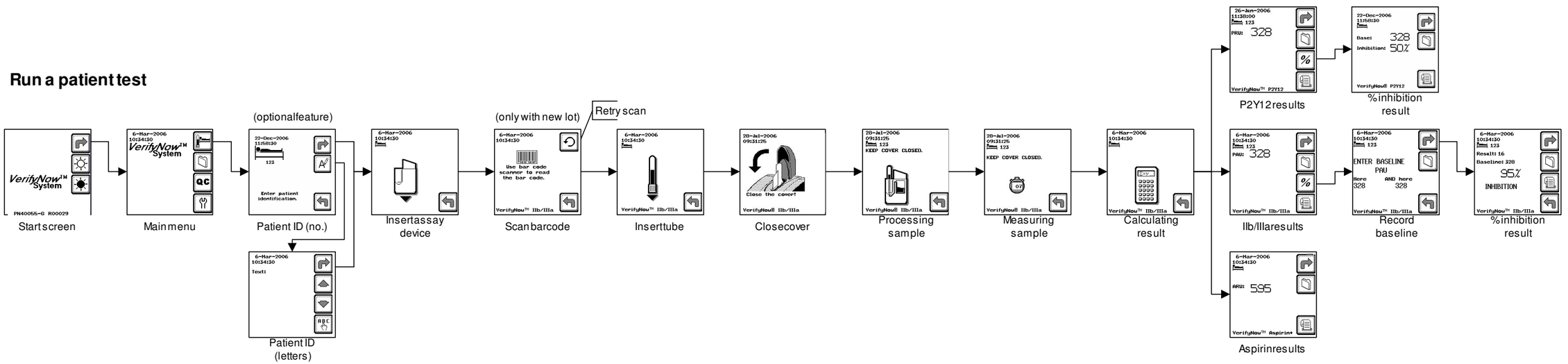
| Icon | Name | Description |
|---|---|---|
|  | Add/Update Record | Select this icon to add an operator's log-in, password, and authority information to the list. |
|  | Assay | Select this icon to begin a patient test. |
|  | Back | Select this icon to return to the prior screen. If you have made a change to an instrument setting, it will return to the prior screen without saving changes. |
|  | Backlight | Select this icon to toggle the backlight level for viewing the display. |
|  | Darken Contrast | Select this icon to adjust the contrast level for viewing the display. |
|  | Date and Time | Select this icon to change the date and time setting. |
|  | Delete | Select this icon to remove the highlighted (where cursor is positioned) information from the setting. |
|  | Edit Record | When adding or changing operator information, select this icon to add information to the operator list. |

| Icon | Name | Description |
|---|---|---|
|  | EQC Log | Select this icon to view the last 100 EQC results. |
|  | Event Log | Select this icon to retrieve information on recent alarms and errors when troubleshooting instrument performance. |
|  | Lighten Contrast | Select this icon to adjust the contrast level for viewing the display. |
|  | Maintenance Menu | Select this icon to view and edit instrument configuration settings and view assay results and logs. |
|  | Network Transfer | Select this icon to transfer information on assay results, QC tests, and errors across a network. |
|  | Next | Select this icon to proceed to the next screen. |
|  | Parameters | Select this icon to view and edit information about the instrument configuration and settings. |
|  | Password | Select this icon to view and edit information about operator ID, passwords and authority levels. |
|  | Percent | Select this icon to calculate percent inhibition (for P2Y12 and IIb/IIIa assays). |
|  | Pick Letter | Select this icon to pick the displayed letter when adding the letter to a patient identification. |
|  | Print | Select this icon to print the highlighted information (where cursor is positioned). This feature only displays if your system is configured with a printer accessory. |
|  | Print All | Select this icon to print the records starting where cursor is positioned. This feature only displays if your system is configured with a printer accessory. |
|  | QC | Select this icon to begin a quality control test (either Level 1 or 2). |
|  | Retrieve Patient | Select this icon to retrieve the last 150 patient |

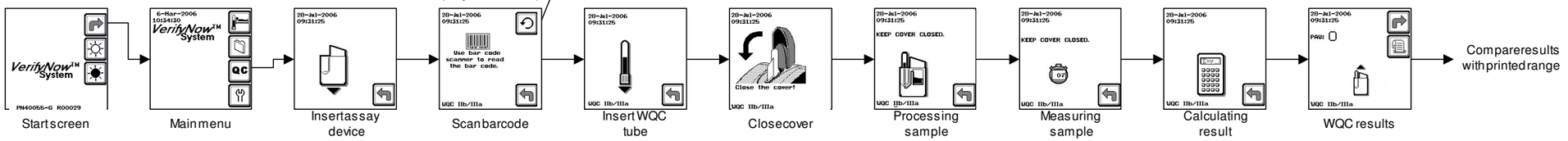
| Icon | Name | Description |
|---|---|---|
| | Results | results from earlier tests. |
|  | Retry | Select this icon to retry scanning the bar code on an assay device pouch. |
|  | Save | Select this icon to save any changes made to an instrument setting and return to the prior screen. |
|  | Scan Bar Code | Select this icon to scan the bar code on an assay device pouch. |
|  | Scroll Back | Select this icon to move down through a list of items, such as the alphabet - when looking to add a letter to a patient identification. |
|  | Scroll Forward | Select this icon to move up through a list of items, such as the alphabet - when looking to add a letter to a patient identification. |
|  | Text | Select this icon to record an alphanumeric patient identification (ID) when starting a patient test. |
|  | Usage Statistics | Select this icon to view the quantity and type of assays performed on the instrument. |
|  | WQC Log | Select this icon to view the last 100 WQC results. |

## 11.6 Instrument Software – Assay and QC

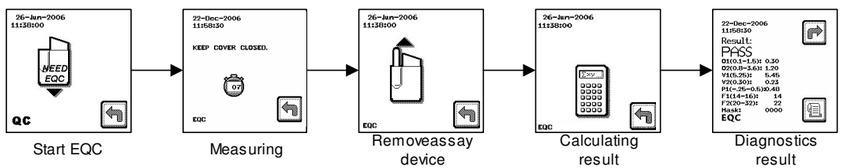
### Run a patient test




### Run a wet quality control

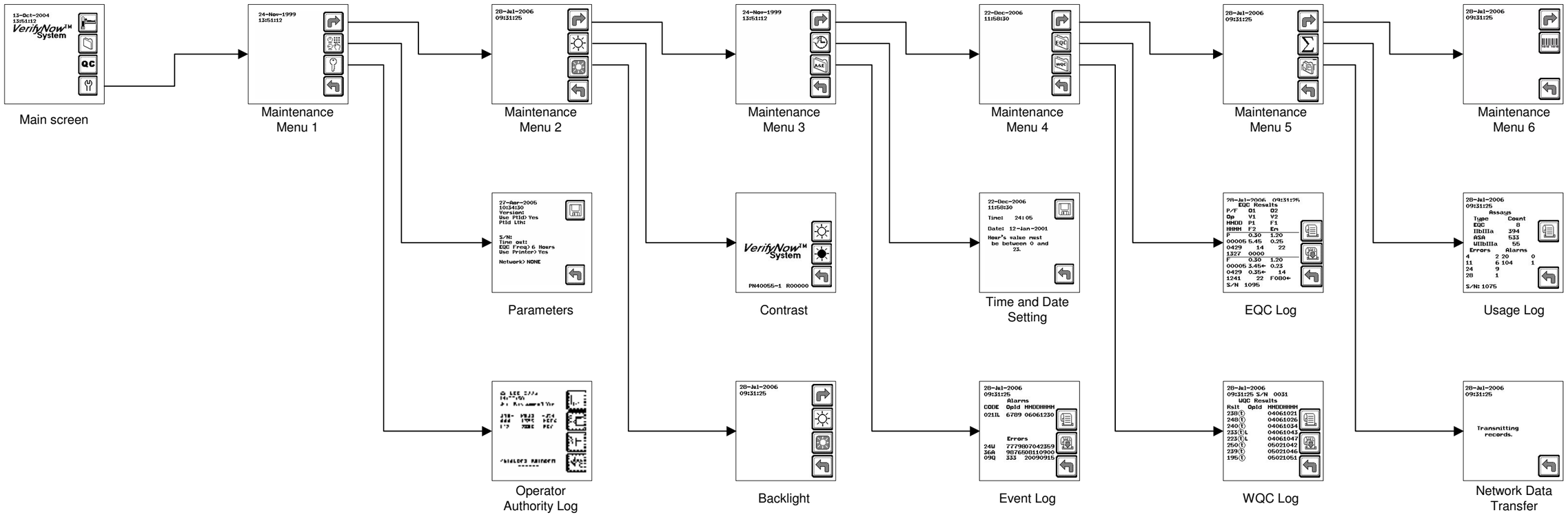



### Run an electronic quality control



## 11.7 Instrument Software – Settings and Logs

### Instrument Settings and Logs



## 11.8 VerifyNow Instrument Cleaning and Maintenance Schedule

Month_____ Year_____

| TASK Day | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Daily Maintenance** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Run Electronic Quality Control (EQC) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Bi-Weekly Maintenance (every other week)** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Use the cleaning device | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Check the fan filter for cleanliness; clean or replace if needed | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Monthly Maintenance** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Clean exterior surfaces | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| **Annual/Monthly Maintenance** | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **TASK Year 20_ _ Month** | **Jan** | **Feb** | **Mar** | **Apr** | **May** | **June** | **July** | **Aug** | **Sept** | **Oct** | **Nov** | **Dec** |
| Replace the fan filter | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |

## 11.9 Compliance with CLIA Control Requirements

The CLIA Regulation, section 493.1256 - Control Procedures, states that the laboratory must perform control procedures as specified by the test manufacturer. It goes on to state that at least once each day of patient testing, a positive and negative control must be run for qualitative tests and two controls materials at different levels must be run for quantitative tests.

These requirements have traditionally been met for batch assays by running external controls. For unitized test systems, such as the VerifyNow system, where each patient sample is its own assay run, quality control should be run for each sample. External quality controls, such as the VerifyNow WQC, are an important element of the entire QC system, but they are not the most important QC element for unit-test systems.

The VerifyNow System provides “equivalent” quality control procedures including daily (or more frequent) system checks with the Electronic Quality Control (EQC) and **two levels of quality control included in each assay device**. In addition to these equivalent QC procedures, the Wet Quality Controls (WQC) are run according to Accumetrics’ recommendations. This system provides more comprehensive quality control than can be provided by external quality control testing alone.

The quality control features of the VerifyNow System are described in detail on the following pages.

### 11.9.1 Description of the VerifyNow System Control Measures

The VerifyNow System includes a comprehensive system of quality control measures that are designed and manufactured into the VerifyNow System to provide control for the complete analytical process, as defined in the CLIA Regulation. Various QC mechanisms detect errors caused by various factors that can influence assay results and potentially lead to erroneous results:

- Instrument system failure
- Reagent system failure
- Adverse environmental conditions
- Variations in operator performance

The VerifyNow quality control measures are described in detail below.

#### 11.9.1.1 VerifyNow Instrument

- Startup Checks: The VerifyNow Instrument performs a self-testing procedure each time the instrument is turned on. These startup self–tests include: 1) a system program and data memory check to ensure memory integrity; 2) a system temperature check to ensure the assay warming plate reaches and maintains the proper temperature; 3) system check of proper operating

voltages; and 4) system intra-communication validation. These self-tests serve as one component of the quality control check of the instrument system.

- System Security and Access Controls: The VerifyNow Instrument has been designed with features that restrict instrument access and improve patient result traceability:
  - The laboratory has the option of assigning a User ID to each user, so that instrument access may be restricted to only trained operators who have demonstrated competency. If this feature is selected, a User ID and a password must be entered before an operator can use the instrument. This can facilitate CLIA compliance and prevent errors due to operator variability.
  - If the User ID feature is enabled, it is also possible to assign different authority levels to each user, depending upon the instrument functions delegated to each user (e.g. running patient samples, QC procedures or changing instrument parameters).
  - As an additional security feature, various instrument display screens may be set to time out after a default time period set by Accumetrics (2 to 5 minutes), or a time period set by the user (from 0 to 255 minutes). If the instrument is idle for a longer period, it will automatically return to the Main Menu and require re-entry of User ID if applicable.
  - The laboratory may decide to assign a Patient ID to each patient sample, to allow traceability of test results. If this option is selected, the laboratory defines the format (number of characters) for the Patient ID number and the VerifyNow Instrument will not accept a patient sample without entry of a Patient ID in the designated format.
- Electronic Quality Control: The Electronic Quality Control (EQC) is the primary quality control mechanism for the VerifyNow Instrument. It is a re-usable device that is inserted by the operator into the assay port and is used to perform a comprehensive testing routine that confirms performance of the following key VerifyNow Instrument subsystems.
  - Verifies proper performance of instrument optics.
  - Confirms proper functioning of the pneumatics system that draws the sample into the assay device and moves it into the assay device for reaction and measurement.
  - Monitors reagent mixing parameters and sample data acquisition.
  - Confirms correct calibration parameters.
  - Simulates assay testing at two levels of results, to check correct data acquisition and calculations. Specifically, the EQC measures two levels of turbidimetric signal that verify the dynamic range of the instrument. **One of these signals is at the level that would be observed in a patient with a minimal amount of platelet aggregation (Negative or Low Level**

**Control), and the other represents a patient who demonstrates a significant amount of aggregation (Positive or High Level Control).**

- The required EQC testing frequency is input into the VerifyNow Instrument by the user. Accumetrics recommends that the EQC be run at least on a daily basis, although the institution may select their preferred EQC testing frequency. When the established interval has elapsed, the user is locked out from running a patient test until the EQC test has been successfully completed.
- **When run according to Accumetrics' recommendations, the EQC meets CLIA requirements for daily QC of the instrument system.**

- System Controls for Each Sample Tested: Each time an assay device is run on the VerifyNow System, the instrument verifies the device expiration date, sample filling, optics performance, correct fluid transfer, and proper mixing. The system controls prevent the operator from running an expired assay device. The system also detects certain other operator errors, such as placing the assay device or the sample in the instrument at the wrong time, or removing the assay device before the assay is complete. These controls prevent reporting of an inaccurate test result. These controls exceed the CLIA requirement for daily QC because they are performed for each assay device.

#### 11.9.1.2 VerifyNow Assay Device

- Assay Device Internal Controls: Each assay device incorporates two levels of quality control to identify invalid test runs caused by random errors, reagent degradation or inappropriate blood samples. Before platelet activation and fibrinogen binding begin, the Negative (Aspirin) or Low-Level (P2Y12 and IIb/IIIa) Internal Control performs a test for non-specific aggregation. During the active phase of the assay, the Positive (Aspirin) or High-Level Internal Control channel monitors the reaction and calculates Clinical Control Units, which must fall within specified limits. A failure of either internal control results in an error message by the VerifyNow Instrument, which prevents the reporting of an inaccurate result.
  The assay device internal controls can detect failures of the reagent system due to improper storage or handling conditions. The internal controls will also flag an improperly collected or mishandled blood sample, or a blood sample with certain types of interfering substances. The Assay Device Internal Controls detect errors from the reagent system, adverse environmental conditions, and additional types of operator errors. **The Assay Device Internal Controls exceed the CLIA requirement of daily controls because two levels of control are run with each assay.**

- Assay Device Humidity Indicator: Each assay device contains an internal humidity sensor. If the assay device has been degraded due to exposure to excessive humidity, a color change of the humidity indicator will be observed. The user is instructed to check the color of the indicator before each test, and

to discard an assay device where a color change is evident. The Assay Device Humidity Indicator detects errors due to adverse environmental conditions.

- Assay Device Kit Temperature Indicator: Each VerifyNow Assay kit has a temperature indicator on the outside of the packaging. The user is instructed to inspect the indicator upon receipt of the kit. If the indicator has changed color, the kit has been exposed to elevated temperatures, and a Wet Quality Control (WQC) Level 2 must be run to ensure that the reagents are performing properly. The Temperature Indicator detects errors due to adverse environmental conditions.

#### 11.9.1.3 VerifyNow Assay Wet Quality Controls (WQC)

- Wet Quality Controls Levels 1 and 2 are available from Accumetrics for verifying the integrity of the VerifyNow System and for evaluating operator proficiency. WQC Level 1 and Level 2 are formulated at clinically relevant levels. In the VerifyNow Assays, Level 1 is representative of a sample with platelet inhibition, and Level 2 is representative of a sample with no platelet inhibition.

  Laboratories may elect to run these controls on a regular basis for QC of the VerifyNow Assays, although Accumetrics believes that the comprehensive QC components built into every VerifyNow assay make this unnecessary. Accumetrics recommends that Level 2 WQC be run under the following conditions:

  - Whenever a new shipment or lot number of VerifyNow Assay Devices is received.
  - When a temperature indicator changes color, indicating that a VerifyNow Assay kit has been exposed to elevated temperatures.
  - In the case of repeated failures of the Assay Device Internal Control, to rule out degradation of assay device reagents as the cause of the failure.

- VerifyNow Assay WQC may be used as a tool for other types of activities required by the CLIA Regulation, other than the daily quality control requirements. These activities include the following:

  - Proficiency testing
  - Laboratory personnel competency evaluation
  - Establishment and verification of system performance specifications (493.1253)
  - Analytical system quality assessment (493.1289)

  Accumetrics Customer Support can advise on the use of WQC as tools in meeting these CLIA requirements.

**NOTE**: The recommendation for the VerifyNow IIb/IIIa Assay only is to run Level 2 WQC with each lot or shipment, or every 30 days.

#### 11.9.1.4 Accumetrics Quality Control Procedures

To assure that VerifyNow System components are of the highest quality, Accumetrics subjects its products to rigorous quality control procedures before they are shipped to customers.

- Each VerifyNow Instrument is tested mechanically, optically and electrically throughout the manufacturing process. The instrument's performance is validated by comparing it to Accumetrics' internal reference standards. The validation process consists of the following:
  - Test results are correlated to results from a qualified reference VerifyNow Instrument
  - Each instrument is extensively tested with previously qualified lots of VerifyNow assay devices.
  - Testing includes multiple replicates of previously qualified lots of WQC control materials.
- Each lot of VerifyNow Assay devices is tested against a previously qualified lot of assay devices. Testing includes multiple replicates of WQC and blood from several normal donors.

In summary, the VerifyNow System includes a comprehensive set of quality control features, which have been designed and incorporated into the system. The VerifyNow quality control features control all aspects of the analytical process, as defined in the CLIA Regulation:

- Test system – instrument and reagent system
- Operator
- Environmental factors

Running the VerifyNow System according to Accumetrics' recommended procedures meets all the CLIA quality control requirements.

# 12 References

1. Centers for Disease Control. Perspectives in Disease Prevention and Health Promotion Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings. MMRW 1988;37(24): 377-388.

# 13 Index

# Customer Support

Accumetrics and its distribution partners are available to assist with technical support, service, and ordering.

## Technical Support and Service

For US customers or direct customers outside the US, contact Accumetrics for technical support and service at:

- **Accumetrics**: 3985 Sorrento Valley Blvd. San Diego, California 92121 USA
- Toll Free: 1 (800) 643-1640
- International (direct): 1 (858) 643-1600
- FAX number: 1 (858) 643-1605
- Email: support@accumetrics.com

For customers outside the US using a distributor partner, contact your local distributor for technical support and service:

European Community (EC)

- **Diagnostica Stago S.A.S.**: 9 rue des Fréres Chausson 92600 Asniéres sur Seine (France)
- International (direct): +33 (0)1 46 88 20 20
- Email: stago@stago.fr
- Website: www.stago.org

Korea

- **Beckdudae Co., Ltd**.: 725, Family Tower, 958-2, Youngtong-Dong, Suwon-City, Kyongki-Do, Korea 443-810
- International (direct): +82 0 31 201 1309
- FAX: +82 0 31 201 1310
- Email: sjparkuk@hotmail.com
- Website: www.beckdudae.com

## Ordering

For ordering, contact your distributor representative. For direct customers, contact Accumetrics at:

- **Accumetrics**: 3985 Sorrento Valley Blvd. San Diego, California 92121 USA
- Toll Free: 1 (800) 643-1640
- International (direct): 1 (858) 643-1600
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- Email: support@accumetrics.com

Refer to the Appendix for a complete listing of parts, accessories, and consumables.

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