TRUE METRIX™ PRO

Professional Monitoring Blood Glucose System

(using TRUE METRIX™ PRO Test Strips with GDH-FAD Enzyme)

Comprehensive Resource Guide for Healthcare Professionals

(Policies, Processes, and Procedures)

Information in this guide is specific for healthcare professionals using the TRUE METRIX™ PRO Professional Monitoring Blood Glucose System* in a multiple-patient clinical setting.

For assistance please call:
Customer Care 1-800-803-6025
www.niprodiagnostics.com

TRUE METRIX™ PRO

NIPRO DIAGNOSTICS™

*TRUE METRIX is intended for self-monitoring blood glucose only and not for multiple patient use. Only TRUE METRIX PRO is intended for multiple-patient use.

Table of Contents

Introduction

Introduction

The purpose of this document is to provide you with specific manufacturer's information on using the TRUE METRIX™ PRO System in a multiple-patient, clinical use setting. The information includes manufacturer's processes and procedures for:

- Understanding system intended use, safety information and testing method.
- Reviewing System components and key design features.
- Examining clinical white papers on proven product performance.
- Reviewing limitations of use including physiological and pharmacological interfering substances.
- Performing the blood glucose testing process using various specimens.
- Reviewing processes for Quality Control Testing, product maintenance, system operating temperature and storage ranges.
- Selecting diabetes data management options for data retrieval and management.
- Training program for your staff focused on safe use of the product in a clinical setting.

Most clinical sites already have clearly defined policies and procedures that address bedside blood glucose testing, safety, quality control, clinical evaluations and other processes. This document is intended to be an adjunct to already established policies and procedures within a facility and not as a replacement for the policies and procedures.

Intended Use Statement

The TRUE METRIX™ PRO Blood Glucose Monitoring System is intended for the quantitative determination of glucose in human whole blood taken from the fingertip or forearm (capillary) or from the vein (venous). The system is not to be used for neonates. The system is intended for multiple-patient use in professional healthcare settings.

Safety

Healthcare professionals should adhere to standard precautions and disinfection procedures when handling or using this device. ALL parts of the TRUE METRIX™ PRO Blood Glucose Monitoring System are considered potentially infectious and capable of transmitting blood-borne pathogens.[1,2] Only use auto-disabling, single-use lancing devices with this product.

- **NEVER** re-use test strips. **NEVER** wipe test strips with water, alcohol, or any cleaner.
- **DO NOT** attempt to remove blood or control solution sample from test strips or clean test strips and re-use. Reuse of test strips will cause inaccurate results.
- **NEVER** add a second drop of sample to the test strip. Adding more sample gives an error message.

A point-of-care blood testing device, such as a blood glucose meter, should be used only on one patient and not shared. If dedicating one blood glucose meter to a single patient is not possible, the meter must be properly cleaned and disinfected after every use following the guidelines found in System Maintenance and Cleaning and Disinfecting sections of this Resource Guide.

Clean and disinfect the meter after each use to prevent the transmission of blood-borne pathogens. Healthcare professionals should wear gloves when cleaning and disinfecting the meter. Wash hands after taking off gloves. Contact with blood presents a potential infection risk. A new pair of gloves should be worn before testing each patient.

Note: *Clean to remove blood or soil from the surface of your meter and disinfect. Disinfecting removes most but not all possible infectious agents (bacteria or virus) from the meter, including blood-borne pathogens.*

To Clean and Disinfect the Meter

1. Wash hands thoroughly with soap and water. Wear a clean pair of gloves.

2. Make sure meter is off and a test strip is not inserted. With ONLY PDI Super Sani Cloth Wipes (or any disinfectant product with EPA* reg. no. 9480-4), rub the entire outside of the meter using 3 circular wiping motions with moderate pressure on the front, back, left side, right side, top and bottom of the meter. Repeat as needed until all surfaces are visibly clean. Discard used wipes. (*Environmental Protection Agency.)

3. Using fresh wipes, make sure that all outside surfaces of the meter remain wet for 2 minutes. Make sure no liquids enter the Test Port or any other opening in the meter.

Super Sani-Cloths may be purchased at the following places:
- Amazon.com
- Officedepot.com or visit your local Office Depot store for other options
- Walmart.com

4. Let meter air dry thoroughly before using to test.

5. Verify that the system is working properly by performing an Automatic Self-Test.

Note: *Other disinfectants have not been tested. The effect of other disinfectants used interchangeably has not been tested with the meter. Use of disinfectants other than Super Sani Cloth Wipes may damage meter.*

Note: *Super Sani Cloth Wipes have been tested on the meter for a total of 10,950 cleaning and disinfecting cycles, which is equal to cleaning and disinfecting the meter 10 times per day for a 3 year period.* Life of the meter is 3 years.

EMC Safety Information

This meter meets the electromagnetic immunity requirements as per ISO 15197 Annex A[3]. It meets the electromagnetic emissions requirements as per EN 61326 series. Interference from the meter to other electronically driven equipment is not anticipated. The electromagnetic environment should be evaluated prior to operation of the device.

Do not use the meter in a very dry environment, especially one in which synthetic materials are present. Do not use the meter close to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

System Specifications

Meter Specifications

Result Range: 20-600 mg/dL

Sample Size: Minimum 0.5 microliter (0.5 µL)

Sample Type: Fresh capillary whole blood, venous whole blood collected in sodium heparin blood collection tubes only, or control solution

Test Time: Results in as little as 4 seconds

Result Value: Plasma equivalent values

Assay Method: Amperometric

Reference Method: Yellow Springs Instrument Glucose oxidase reagent

Power Supply: One 3V lithium battery #CR2032 (non-rechargeable).

Battery Life: Approximately 1,000 tests or 1 year

Automatic Shut-Off: After two minutes of non-use

Weight: 1.66 ounces

Size: 3.44" x 2.16" x 0.69"

Memory Size: 500 glucose and control results

Operating Conditions

System Operating Range (meter & test strips):

Relative Humidity: 10-90% (Non-condensing)

Temperature: 41°F-104°F

Hematocrit: 20-70%

Altitude: Up to and including 10,200 feet

Note: *Use within specified environmental conditions only.*

Chemical Composition

TRUE METRIX™ PRO Test Strips: Glucose dehydrogenase-Flavin adenine dinucleotide (GDH-FAD) (*Aspergillus sp.*), mediators, buffers and stabilizers.

TRUE METRIX™ Control Solution: Water, d-glucose, buffers, viscosity enhancing agent, salts, dye and preservatives.

Note: *Material Safety Data Sheets can be found in the Appendix.*

CLIA Requirements

Self-testing and point-of-care testing of blood glucose has been classified by the Clinical Laboratory Improvement Amendments (CLIA) as a waived test. CLIA requires all entities that perform even one test, including waived tests, [on materials derived for the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings] to meet certain Federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory and must register with the CLIA program.

Waived laboratories must meet the following requirements:

- Complete the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Application for Certification. Form CMS-116. The form and instructions on completing and mailing the form are found on http://www.cms.hhs.gov/CLIA/06 How_to_Apply_for_a_CLIA_Certificate_Including_ Foreign_Laboratories.asp#TopOfPage.
- Pay applicable certificate fees biennially.
- Follow manufacturer's test instructions, including instructions for Quality Control, maintenance, and storage instructions.

Upon approval of Form CMS-116, a Certificate of Waiver is forwarded to the laboratory.

For more information on the CLIA program, see http://www.cms.hhs.gov/CLIA/.

For a comprehensive look at waived testing, see http://www.cdc.gov/mmwr/preview/mmwrhtml/ rr541a1.htm.

System Components

System Components

Meter

Test Strip Vial

Test Strips

Control Solution

Meter Key Features

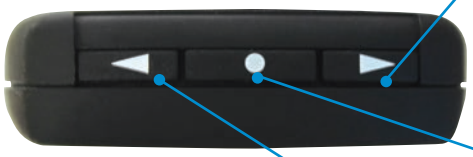
Front of Meter

Display Screen
Shows test results, messages, user prompts, information

Strip Release Button
Releases test strip after testing for disposal

Test Port
Insert TRUE METRIX™ PRO Test Strip here, contact blocks facing up

Top of Meter



"▶" Button
Increase numbers in Meter Set Up; add ALT Symbol; move forward by date/time when viewing results and Averages in Memory; scroll through Event Tags to mark results (if feature on); turn on Event Tags, Ketone Test Alert and Test Reminders during Meter Set Up

" • " Button
Turn meter on to view Average values, to view results in Memory, to access Meter Set Up, and turn on Event Tags in Meter Memory

"◀" Button
Decrease numbers in Meter Set Up; remove ALT symbol; move backward by date/time when viewing results and Averages in Memory

Back of Meter

Battery Door
Use one non-rechargeable 3V lithium battery (#CR2032), positive ("+") side up

Meter Label
Contains serial number of meter

Data Contacts
Connects meter with computer via docking station for data upload

Meter Design

Event Tagging
helps identify trends associated with blood glucose results

High quality bezel
for exclusive look; scratch resistant

Strip Release Button
safely releases test strip without user coming in contact with contaminated test strip

Time/date
for convenient tracking and trending of data

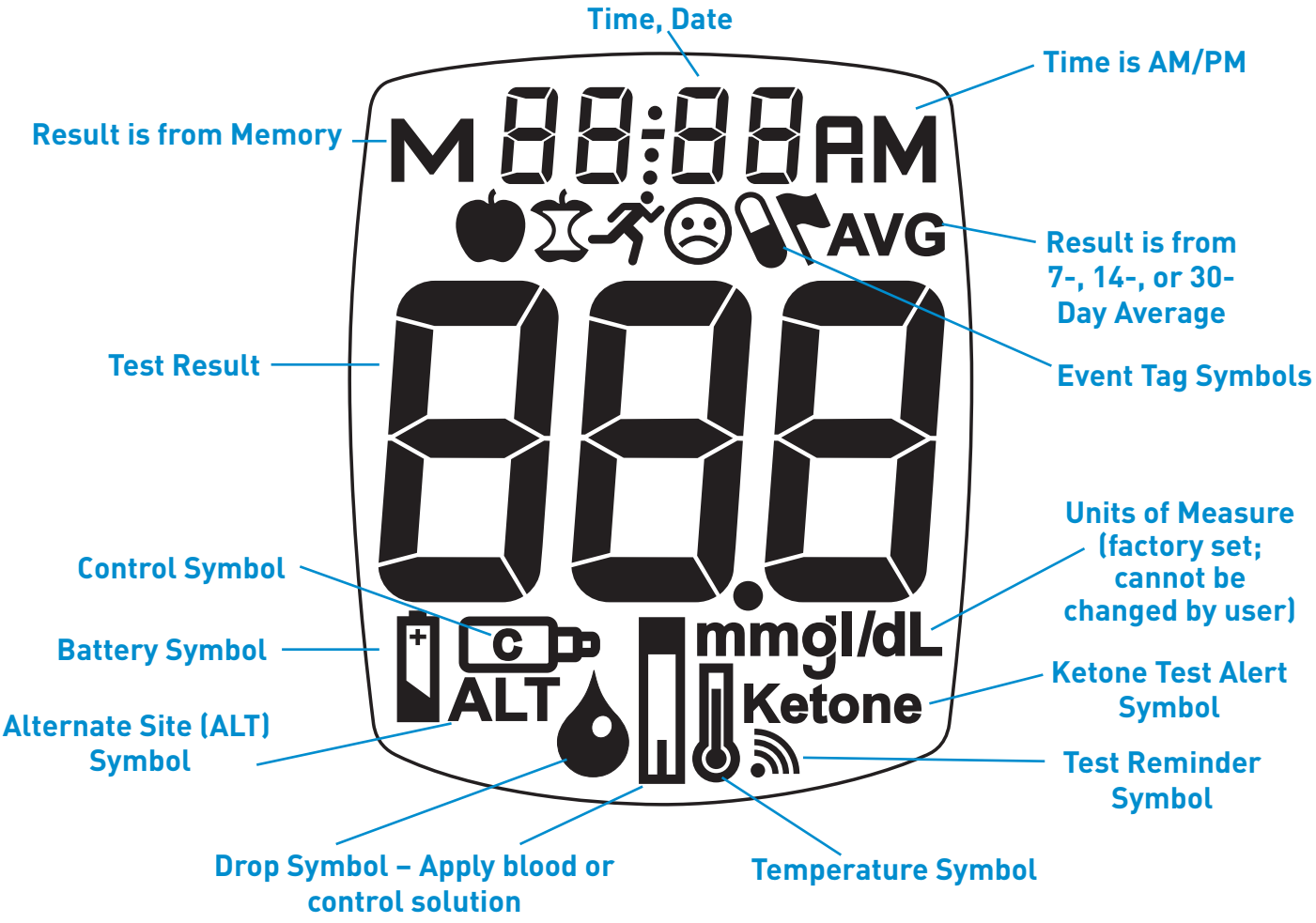
Large display
and digits for easy legibility

Elegant black
soft touch surround material/coating for easy grip of meter

Test strip guide
for easy test strip insertion

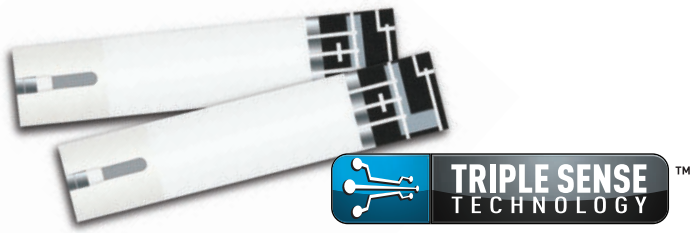
Meter Display Screen

Full Display Screen



Test Strip Design

TRUE METRIX™ PRO Test Strips – Featuring TRIPLE SENSE TECHNOLOGY™



No Coding Technology eliminates the need for coding of the meter.

- Code is assigned during manufacturing process
- Code is printed onto contacts on end of test strip
- Meter reads code on insertion

Advanced technologies – the meter, a complex algorithm, chemistry and electrodes – on the test strip work together as part of the TRUE METRIX™ PRO system to produce accurate results.

Featuring TRIPLE SENSE TECHNOLOGY™, the system provides proven accuracy and confidence in results.

DETECT

Sample Environment
- An electrode pair on the test strip detects hematocrit
- An internal unit in the meter detects temperature

Sample Size
- System triggers proper fill detection eliminating errors due to improper sample size

Control
- Detects control solution and automatically identifies results in memory for accurate data trending

ANALYZE

Environmental and Physiological Factors
- Every system analyzes the testing environment for hematocrit and temperature, which could impact or influence the accuracy of results
- Testing outside of specified operating temperature range is marked by an error code – eliminating incorrect results

CORRECT

Hematocrit/Temperature Variables
- Employs a Proprietary Dynamic Adaptive Algorithm, which incorporates:
  - Active hematocrit correction
  - Temperature compensation
- Combined, this algorithm corrects results based on the testing environment
- Ensures proven accuracy and confidence in results

Control Solution

What Is Control Solution?

Control solution is a red liquid containing a known amount of glucose.

Test Principle:

Use control solution instead of blood to make sure your system is working.

Storage and Handling:

Control solution must be stored upright, tightly sealed, at 36°F-86°F, room temperature.

DO NOT REFRIGERATE OR FREEZE

3 Levels of Control Solution

- Use **ONLY** TRUE METRIX™ Control Solution to perform Control Tests.

Control Test

Use **ONLY** TRUE METRIX™ Control Solution to check the performance of the system. It is important to perform control tests with more than one level of control solution to assure that the system is working properly and testing technique is good. Three levels of TRUE METRIX™ Control Solution (Levels 1-3) are available. Call 1-800-803-6025 for assistance in obtaining different levels of control solution.

Control Test(s) should be performed:

- Before using the system for the first time.
- For practice to ensure that testing technique is good.
- When opening a new vial of test strips.
- If results seem unusually high or low based on the patient's condition.
- If test strip vial has been left open or exposed to extreme heat, cold or humidity.
- Whenever a check on the performance of the system is needed.
- If meter damage is suspected (meter was dropped, crushed, wet, etc.).

Ranges printed on the test strip vial label are for Control Test results only. These ranges are not suggested levels for blood glucose. DO NOT drink control solution.

Clinical Information

Performance Characteristics[4] for Healthcare Professionals

Introduction

The International Organization for Standardization (ISO) develops standards in response to an identified need in the community that will eventually be suitable for implementation on as broad a basis as possible. ISO developed the standard for blood glucose monitoring performance – 15197:2003 – based on a consensus of professionals around the world.[3] It is recognized as the standard in many countries.

Standard Reference Results	ISO Bias Limit	Criteria for Accuracy
Less than 75 mg/dL	± 15 mg/dL from laboratory reference result	95% of all results
Greater than or equal to 75 mg/dL	± 20% from laboratory reference result	

Clinical data obtained by healthcare professionals on the TRUE METRIX™ PRO Blood Glucose Monitoring System exceeded the minimum accuracy criteria for ISO 15197:2003.

Accuracy:
TRUE METRIX™ PRO accuracy was assessed against the Yellow Springs Instrument. Studies were conducted at 3 clinical sites by healthcare professionals;

100% of healthcare professionals (HCP) TRUE METRIX™ PRO fingertip values fell within 15 mg/dL of the YSI results at glucose level <75 mg/dL and within 20% at glucose levels ≥ 75 mg/dL.

Fingertip Capillary Blood < 75 mg/dL (HCP finger vs. YSI)

±5 mg/dL	13/17 = 78%
±10 mg/dL	16/17 = 94%
±15 mg/dL	17/17 = 100%

Fingertip Capillary Blood ≥ 75 mg/dL (HCP finger vs. YSI)

±5%	130/216 = 60%
±10%	194/216 = 90%
±15%	213/216 = 99%
±20%	215/216 = 99.5%

99% of TRUE METRIX™ PRO forearm values fell within 15 mg/dL of the YSI results at glucose levels <75 mg/dL and within 20% at glucose levels ≥ 75 mg/dL

Forearm Capillary Blood < 75 mg/dL
(HCP forearm vs. HCP finger)

±5 mg/dL	5/9 = 56%
±10 mg/dL	9/9 = 100%
±15 mg/dL	9/9 = 100%

Forearm Capillary Blood ≥ 75 mg/dL
(HCP forearm vs. HCP finger)

±5%	42/103 = 41%
±10%	74/103 = 72%
±15%	97/103 = 94%
±20%	102/103 = 99%

Performance Characteristics[4] for Healthcare Professionals cont.

The TRUE METRIX™ PRO System was also tested by healthcare professionals at a research center. The data was compared to parallel results obtained on a Yellow Springs Instrument (YSI). The table below shows how often TRUE METRIX™ PRO Blood Glucose System venous values obtained by healthcare professionals achieve the accuracy goals.

Venous samples drawn into sodium heparin anticoagulant tubes.

Glucose concentrations < 75 mg/dL

Within ±5 mg/dL	7/7 = 100%
Within ±10 mg/dL	7/7 = 100%
Within ±15 mg/dL	7/7 = 100%

Glucose concentrations ≥ 75 mg/dL

Within ±5%	66/114 = 58%
Within ±10%	103/114 = 90%
Within ±15%	112/114 = 98%
66/114 = 58%	114/114 = 100%

Precision (Repeatability):
Precision describes the variation between results. Precision results were performed in a laboratory.

Blood (Within Run): N=100

Mean (mg/dL)	40	87	137	211	318
SD (mg/dL)	1.6	3.4	4.4	5.8	9.2
%CV	4.0	3.9	3.2	2.7	2.9

Blood (Between Day): N=100

Mean (mg/dL)	40	87	137	211	318
SD (mg/dL)	1.8	3.5	4.6	5.8	10.5
%CV	4.5	4.0	3.4	2.8	3.3

Control Solution: N=100

Mean (mg/dL)	30	99	275
SD (mg/dL)	1.1	3.0	11.8
%CV	3.5	3.0	4.3

Limitations of Use

- Please read all product Instructions for Use carefully before referencing or using this guide.
- Use only TRUE METRIX™ PRO Blood Glucose Test Strips and TRUE METRIX™ Control Solution with the TRUE METRIX™ PRO Meter.
- Do not leave test strips or control solution where the storage temperature printed on vial label may be exceeded.
- Perform control tests **before** performing a blood glucose test for the first time (See the Quality Control Testing section of this Resource Guide).
- Perform control tests with more than one level of control solution. Three levels of TRUE METRIX™ Control Solution are available for control tests. Contact place of purchase or call for assistance to obtain control procedure/policy.
- TRUE METRIX™ PRO is an in vitro (outside the body) quantitative system that is used for point-of-care testing of human whole blood only.
- The most accurate results are obtained using fresh, capillary whole blood from the fingertip or forearm. Venous whole blood drawn using only sodium heparin tubes may be used. Mix well before use.
- Do not use venous whole blood collected in sodium fluoride (grey top) vacutainer tubes for testing, as this may cause false low reults.
- Capillary blood from the forearm may be used. Check with the doctor or healthcare professional to see if forearm testing may be used for glucose testing on the patient. Results from the forearm are not always the same as results from the fingertip. Use fingertip instead of forearm:[5]
  - Within 2 hours of eating, exercise, or taking insulin;
  - If the patient's blood glucose may be rising or falling rapidly or their results often fluctuate;
  - If the patient is ill or under stress;
  - If the glucose result may be low or high;
  - If symptoms of low or high glucose levels are not evident.
- Alternate site (forearm) testing should not be used to calibrate continuous glucose monitors (CGMs).
- Alternate site (forearm) testing should not be used for insulin dose calculations.
- Do not use for the diagnosis of or screening for diabetes mellitus or for measuring blood glucose in newborns.
- When comparing results between TRUE METRIX™ PRO and a laboratory system, TRUE METRIX™ PRO blood tests should be performed within 30 minutes of laboratory test. If a patient has recently eaten, fingerstick results from the TRUE METRIX™ PRO System can be up to 70 mg/dL higher than venous laboratory results.[5] Diabetes experts have suggested that glucose meters should agree within 15 mg/dL of a laboratory system when the glucose concentration is less than 75 mg/dL, and within 20% of a laboratory system when the glucose concentration is 75 mg/dL or higher.[3]
- The device has not been validated for use in the critically ill. Capillary blood glucose levels in critically ill patients with reduced peripheral blood flow may not reflect the true physiological state. Reduced peripheral blood flow may result from the following conditions (for example):[7]
  - shock,
  - severe hypotension,
  - severe dehydration,
  - hyperglycemia with hyperosmolarity, with or without ketosis.
- Testing at altitudes up to and including 10,200 feet will not affect accurate results.[4]
- Hematocrit levels between 20% and 70% will not affect accurate results.[4]
- Do not use the TRUE METRIX™ PRO System during a xylose absorption test. This may falsely raise glucose results. Please check with patients doctor before using the TRUE METRIX™ PRO System.
- Do not use the TRUE METRIX™ PRO System if blood concentrations of ascorbic acid are > 2 mg/dL
- Do not use the TRUE METRIX™ PRO System if blood concentrations of uric acid > 5 mg/dL

Interference Testing

Interference testing was performed using the concentrations recommended by Clinical and Laboratory Standards Institute (CLSI) procedure EP7-A2; Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition.[8] Potential interferents were added to whole blood samples at 10 to 50-fold concentrations depending on solubility characteristics. Where no recommendation was given, the potential interferents were added at concentrations higher than normal or therapeutic ranges. Blood samples containing each of the potential interferents were tested concurrently with control blood samples containing no added potential interferents. All blood samples originated from normal healthy donors. The highlighted interferents below are listed as interferents in the Owner's Booklet and Test Strip Instructions For Use.

Potential Interferent	Normal/Therapeutic Concentrations	High/Toxic Concentrations	Concentrations Determined That Will Affect Meter Glucose Results
Acetaminophen	2.0 mg/dL	30 mg/dL	-------
Acetone	2.0 mg/dL	20 mg/dL	-------
Ascorbic Acid	1.5 mg/dL	6.0 mg/dL	2 mg/dL
Bilirubin	1.0 mg/dL	15 mg/dL	-------
Caffeine	1.25 mg/dL	6.0 mg/dL	-------
Ceflriaxone	20 mg/dL	60 mg/dL	-------
Cholesterol	150 mg/dL	250 mg/dL	-------
Creatinine	1.5 mg/dL	5.0 mg/dL	-------
Dopamine	0.03 mg/dL	0.1 mg/dL	-------
EDTA	0.1 mg/dL	360 mg/dL	-------
Ethanol	150 mg/dL	400 mg/dL	-------
Flouride, Sodium	0.05 mg/dL	429 mg/dL	108 mg/dL
Galactose	5.0 mg/dL	15 mg/dL	-------
Gentistic acid	0.4 mg/dL	1.8 mg/dL	-------
Glipizide	0.1 mg/dL	0.2 mg/dL	-------
Glutathione	0.15 mg/dL	10 mg/dL	-------
Hemoglobin	150 mg/dL	1400 mg/dL	-------
Heparin, Lithium	0.675 U/mL	31.7 U/mL	-------
Heparin, Sodium	0.675 U/mL	31.7 U/mL	-------
Ibuprofen	4 mg/dL	50 mg/dL	-------
Icodextrin	-------	20 mg/dL	-------
L-Dopa	1.3 mg/dL	4.0 mg/dL	-------
Maltose	125 mg/dL	250 mg/dL	-------
Maltotetraose	30 mg/dL	70 mg/dL	-------
Maltotriose	90 mg/dL	180 mg/dL	-------
Metformin	0.4 mg/dL	4.0 mg/dL	-------
Methyl-Dopa	0.42 mg/dL	1.5 mg/dL	-------
Naproxen Sodium	7.5 mg/dL	50 mg/dL	-------
PAM	1.0 mg/dL	21 mg/dL	-------
Salicylic acid	2.0 mg/dL	70 mg/dL	-------
Tetracycline	0.35 mg/dL	1.5 mg/dL	-------
Tolazamide	2.5 mg/dL	5.0 mg/dL	-------
Tolbutamide	8.1 mg/dL	64 mg/dL	-------
Triglyceride	150 mg/dL	1000 mg/dL	-------
Uric acid	3 mg/dL	9.0 mg/dL	5 mg/dL
Xylose	5.0 mg/dL	58 mg/dL	7 mg/dL

Meter Setup

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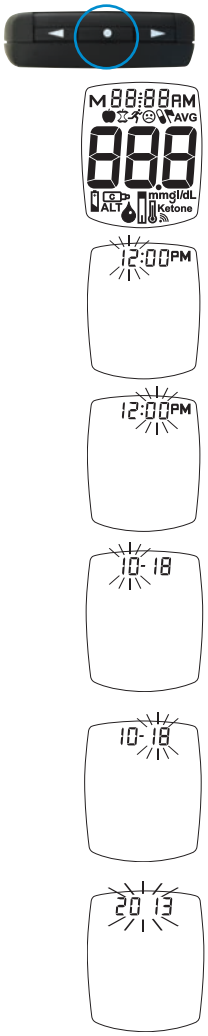
Meter Setup

Meter Setup is to be used if changes need to be made to the time and date, Event Tags, Ketone Test Alert, or if settings need to be reset because of battery change.

Note: *Setting up the time, date, Event Tags, Ketone Test Alert and Test Reminders may not be suitable for a multiple-patient use of the system. Check with the facility procedures and policies before performing Set Up.*

Note: *If the meter turns off at any time during Set Up, go back to Step #1 under Meter Set Up and begin again.*



1. Press and hold "•" Button until the full display is shown and a tone sounds (around 10 seconds). Release "•" Button. Meter goes into Set Up.

Set Up of Time and Date

2. The hour flashes. To change, press " ▶" or " ◀" Button on top of the meter to select the hour. Like many alarm clocks, to set "AM" or "PM", scroll through the hours until "AM" or "PM" appears in the Display. Press " • " Button to set.
3. The minutes flash. To change, press " ▶" or "◀" Button to select the minutes. Press " • " Button to set.
4. The month (number) flashes. To change, press " ▶" or "◀" Button to select the month. Press " • " Button to set.
5. The day (number) flashes. To change, press " ▶" or "◀" Button to select the day. Press " • " Button to set.
6. The year flashes. To change, press " ▶" or "◀" Button to select the year. Press " • " Button to set.

Note: *Meter beeps every time a setting is confirmed (" • " Button is pressed).*

Meter Setup cont.

Set Event Tags, Ketone Alert and Test Reminders

Meter comes with Event Tags, Ketone Test Alert and all Test Reminders turned off.

Note: *If the meter turned off at any time during Set Up, go back to Step #1 under Meter Set Up and begin again.*

Event Tags

Event Tags are used to mark a test result that was taken during a specific event.

1. After setting the year, press " ▶" or "◀" Button to turn Event Tags on or off. Press " • " Button to set. The meter goes to set Ketone Test Alert.

Event Tags may be used after each blood glucose result. Event Tags are as follows:

Before meal –test was taken just before a meal,

After meal – test was taken 2 hours after the start of a meal,

Exercise – test was taken during or after exercise,

Medications – medication taken may have affected test result,

Sick – test was taken when sick,

Other – any other reason that the test is unique or different in some way (example: stress, drinking alcohol).

Ketone Test Alert

When a blood glucose result is over 240 mg/dL, the Ketone Test Alert is a reminder to check the patient's ketones per the treatment plan prescribed by the doctor or diabetes healthcare professional.

2. Press "▶" or "◀" Button to turn Alert on or off. Press " • " Button to set. Meter goes to set Test Reminder.

When a Ketone Test Alert sounds, it does not mean that ketones have been detected in the patient's blood. Perform a ketone test per the treatment plan, as prescribed by their Doctor or Diabetes Healthcare Professional.

Test Reminder

Up to four Test Reminders per day may be set. Reminder sounds at set time for 10 seconds. Meter comes with all Test Reminders off. To set the Test Reminders:

1. After pressing " • " Button to set Ketone Test Alert, Display shows first Reminder setting (A-1). To turn Reminder on, press "▶" Button. Press "◀" Button to turn Reminder back to off. Press " • " Button to set.

Test Reminder

2. When "on" is chosen, press " • " Button. The hour flashes. Press "▶" or "◀" Button to set the hour. To set AM/PM, scroll (press "▶" or "◀" Button) until "AM" or "PM" is next to correct time. Press " • " Button to set.

3. The minutes flash. Press "▶" or "◀" Button to set the minutes. Press " • " Button to set. Meter goes to the next Test Reminder.

4. Turn Reminders on and repeat setting the time for next 3 Reminders (if needed).

Exit Setup

Press and hold " • " Button until meter turns off. Meter also turns off after 2 minutes of non use. Set-up choices are saved.

Note: *If Test Reminders are set, the Alert Symbol appears in all Displays. If battery dies or is replaced, Ketone Test Alert and Test Reminders may have to be reset.*

Quality Control Testing

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Quality Control Testing

Quality Control Testing is used to detect errors that may occur due to test system errors, product defects, adverse environmental conditions and variance in operator performance. Ongoing Quality Control Testing is also used to detect any performance issues of the system over time. Facility Quality Control Testing Policy and Procedure should adhere to the manufacturer's instructions for use and regulatory guidelines.

TRUE METRIX™ PRO is a no-coding system, which means the meter does not have to be coded to each lot of test strips. To assure accurate and reliable results, TRUE METRIX™ PRO offers two kinds of Quality Control Tests. These tests ensure that the TRUE METRIX™ PRO System is working properly and the user's testing technique is good.

3 Levels of Control Solution

- Use **ONLY** TRUE METRIX™ Control Solution to perform Control Tests.
    - Write date opened on control solution label. Discard if either 3 months after first opening or after the date printed next to the EXP on the bottle label has passed, whichever comes first.

- Control Test ranges are printed on the TRUE METRIX™ PRO Test Strip vial label.

Quality Control Testing cont.

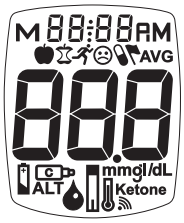
Automatic Self-Test

An Automatic Self-Test is performed by the meter each time a test strip is inserted correctly into the Test Port.

Insert a test strip into Test Port. The meter is working properly if:

Contact Blocks Face Up

~ the full Display appears, then



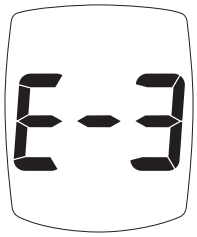
Full Display

~ the time appears in the upper part of the Display, and then,

~ the Drop Symbol begins to blink.

Drop Symbol

If an error message appears in the Display, the meter will not perform a test. See Troubleshooting or call for assistance.



Error Message

If any segments are missing in the Display when meter is first turned on, do not use the meter for testing.

Control Test

Use **ONLY** TRUE METRIX™ Control Solution to check the performance of the system. It is important to perform Control Tests with more than one level of control solution to assure that the system is working properly and testing technique is good. Three levels of TRUE METRIX™ Control Solution (Levels 1-3) containing known amounts of glucose are available.

Control Test(s) should be performed:

- Before using the system for the first time.
- For practice to ensure that testing technique is good.
- When opening a new vial of test strips.
- If results seem unusually high or low based on the patient's condition.
- If strip vial has been left open or exposed to extreme heat, cold or humidity.
- Whenever a check on the performance of the system is needed.
- If meter damage is suspected (meter dropped, crushed, wet, etc.).

Ranges printed on the test strip vial label are for Control Test results only and are not suggested levels for your blood glucose. DO NOT drink control solution.

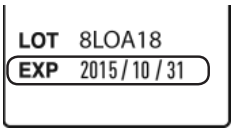
Quality Control Testing cont.

How to Perform a Control Test

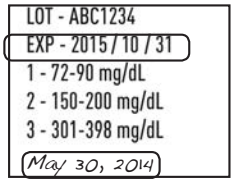
Use the Quality Control Record Form located in the Appendix D, or the form provided by your facility, to record Control Test results.

1. Allow control solution, vial of test strips and meter to adjust to room temperature 68°F-77°F.

2. Check dates on control solution label and test strip vial label.



   - Write date first opened on control solution bottle.
   - Do not use control solution if 3 months past written opened date or after EXP date printed on control solution bottle label, whichever comes first.



   - Do not use test strips 4 months past written opened date or after EXP date printed on test strip vial label, whichever comes first.
   - Discard out-of-date products and use new products.

3. Gently swirl or invert control solution to mix. **DO NOT SHAKE!**

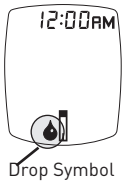
4. Remove one test strip from vial. Close test strip vial immediately. Use test strip quickly after removal from vial.

5. Insert test strip into Test Port. Meter turns on.

Note: *If test strip has been out of the vial too long before testing, an error message appears upon insertion of the test strip into the meter. Release and discard old test strip. Use new test strip for testing.*

Contact Blocks Face Up

6. Wait until Drop Symbol appears in Display. Keep test strip in meter until testing is finished.



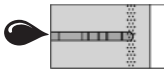
Drop Symbol

Note: *If test strip is removed before testing is finished, an error message appears. Release and discard old test strip. Test with new test strip.*

7. With cap removed, turn control solution bottle upside down. Gently squeeze one drop of control solution onto a clean tissue. Wipe off bottle tip with the tissue.

8. Gently squeeze a drop of control solution onto a small piece of unused aluminum foil or clear plastic wrap. Dispose after use.

9. With test strip still in meter, touch edge of Sample Tip to top of control solution. Allow drop to be drawn into test strip. Remove test strip from drop when meter beeps.

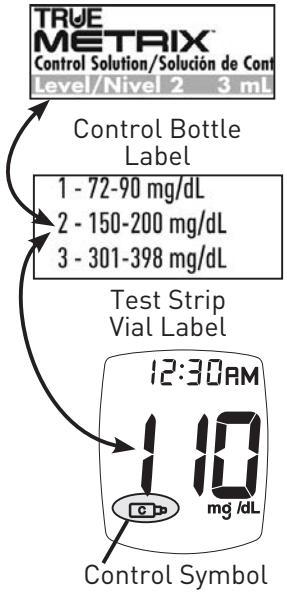


10. Dashes appear across the Display to show meter is testing.

Meter testing

Note: *If meter does not beep or begin testing soon after drawing up sample, release and discard test strip. Repeat test with new test strip. If problem persists, see the Troubleshooting section of this Resource Guide.*

Quality Control Testing cont.



11. Compare result to Control Test range printed on test strip vial label for control solution level you are using. If result is in range, system can be used for testing blood. If result does not fall within range, repeat test using a new test strip.

Note: *Control Test result shows the Control Symbol in the Display*

If Control Test result is outside range, test again. If result is still outside range, the system should not be used for testing blood. Call for assistance.

12. After result is shown, Strip Release Button flashes. Hold meter with test strip pointing down. Press Strip Release Button to release and discard test strip in appropriate container. Meter turns off.

Note: *Removing test strip before result displays cancels the test. An error message appears and the result is not stored in Memory. Retest with a new test strip and do not remove before result is displayed.*

QUALITY CONTROL TESTING DATA FORM

Meter Serial Number _____ (see number on Meter label below the bar code) ***Note any problems in Troubleshooting section below.**

Date	Time	Test Strips			Control Solution - Level _____					Control Solution - Level _____					Control Solution - Level _____					Initials	*
		LOT	EXP	Date Opened	LOT	EXP	Date Opened	Acceptable Range	Result	LOT	EXP	Date Opened	Acceptable Range	Result	LOT	EXP	Date Opened	Acceptable Range	Result		
		On TRUE METRIX™ PRO Test Strip vial label, write date vial opened. Discard vial if either 4 months after opening or EXP date printed on the vial label has passed, whichever comes first.			On TRUE METRIX™ PRO Control Solution bottle label, write date bottle opened. Discard bottle if either 3 months after opening or after EXP date printed on the bottle label has passed, whichever comes first.			Printed on vial label of test strips being used.		On TRUE METRIX™ PRO Control Solution bottle label, write date bottle opened. Discard bottle if either 3 months after opening or after EXP date printed on the bottle label has passed, whichever comes first.			Printed on vial label of test strips being used.		On TRUE METRIX™ PRO Control Solution bottle label, write date bottle opened. Discard bottle if either 3 months after opening or after EXP date printed on the bottle label has passed, whichever comes first.			Printed on vial label of test strips being used.			

*TROUBLESHOOTING			
Date	Problem	Action	Initials

Quality Control Testing Data Form (located in Appendix)

Blood Glucose Testing

TRUE METRIX PRO

NIPRO DIAGNOSTICS

Blood Glucose Testing

Type of Blood Sample Information

Fresh, capillary whole blood from the fingertip or forearm is the recommended sample to be used for testing blood glucose. Capillary forearm sampling must not be used when the blood glucose levels are rapidly changing (see Obtaining a Capillary Forearm Blood Sample below). Venous blood samples may also be used for testing on the TRUE METRIX™ PRO Blood Glucose Monitoring System. If using venous blood for testing, careful consideration must be taken when collecting and handling the venous sample (see Obtaining a Venous Blood Sample below). Follow the facility policy and procedure for obtaining samples for testing blood glucose levels. Always wear clean gloves prior to testing to decrease risk of direct contact with blood.

- Never use arterial or neonatal blood samples.
- Never use clotted blood, plasma or serum as a sample for testing on the meter.

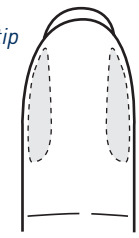
How to Perform a Blood Glucose Test

The TRUE METRIX™ PRO is a no-coding system, which means the meter does not have to be coded to each lot of test strips.

Use test strips quickly after removal from test strip vial. Test strips that have been left out of the vial too long will give an error message. If error message displays, release and discard the old test strip and test with a new test strip.

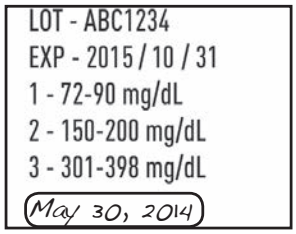
1. To obtain a blood sample for blood glucose testing refer to your facility approved methods and our recommendations listed in the table below. Follow the facility's established policy and procedure for handling blood and biohazard safety (contaminated biological materials and sharps).

   Note: *A new pair of gloves should be worn before obtaining a blood sample. Contact with blood presents an infection risk.*

Obtaining a Capillary Fingertip Blood Sample	**Obtaining a Capillary Forearm Blood Sample**	**Obtaining a Venous Blood Sample**
1. Wash hands and put on a new pair of gloves. 2. Select subject's fingertip. Clean area with soap and warm water, rinse or use an approved disinfectant to clean the area. Dry thoroughly. ***Note:*** *Do not squeeze the fingertip for the blood sample. This will damage the surrounding tissues and the fluid can dilute the blood sample.*  3. To help blood drop form, lower the hand to a level below the heart and gently massage the finger from palm to fingertip. 4. Lance subject's fingertip. 5. Allow the blood drop to form before attempting to apply the test strip. 6. Discard all biohazard materials into appropriate container. 7. Wash hands after taking off gloves.	***Note:*** *Results from the forearm are not always the same as results from the fingertip. Use fingertip instead of forearm:*[5] • Within 2 hours of eating, exercise, or taking insulin. • If the subject's blood glucose may be rising or falling rapidly or their results often fluctuate. • If the subject is ill or under stress. • If the glucose result may be low or high. • If symptoms of low or high glucose levels may not be evident. 1. Wash hands and put on a new pair of gloves. 2. Select subject's forearm area. Clean area with soap and warm water, rinse or use an approved disinfectant to clean the area. Dry thoroughly. 3. Rub area vigorously or apply a warm, dry compress to increase blood flow. 4. Lance subject's forearm. 5. Allow the blood drop to form before attempting to apply the test strip. 6. Discard all biohazard materials into appropriate container. 7. Wash hands after taking off gloves.	***Note:*** *Do not collect venous specimens from the arm that has an active intravenous infusion site. Do not collect samples from an indwelling line that has an intravenous infusion.*[9] 1. Clean site for venipuncture with soap, water or cleansing agent. Dry thoroughly. 2. Always collect sample into test tubes containing only sodium heparin. ***Note:*** *Do not use, serum, clotted blood, or plasma for testing on meter.* 3. If using venous blood for testing on a laboratory device, it must be used within 30 minutes of laboratory test. Mix well before use. ***Note:*** *Do not use sodium fluoride blood collection tubes. This may cause a false low glucose results.*

Blood Glucose Testing cont.

2. Check dates on test strip vial being used. Do not use test strips 4 months past written opened date or after date printed on test strip vial label, whichever comes first.



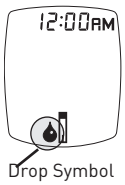
3. Remove one test strip from vial. Close vial immediately. Use test strips quickly after removal from vial.

Note: *Test strips that have been left out of the vial too long before use will give an error message. If error message displays, release and discard the old test strip and test with a new test strip.*

4. With meter off, insert test strip Contact End (blocks facing up) into Test Port. Meter turns on. Keep test strip in meter until testing is finished.

Note: *Removing the test strip before the result is displayed cancels the test. An error message appears. Retest with a new test strip and do not remove the test strip from the meter before the result is displayed.*

5. Wait until the Drop Symbol appears in the Display.



Drop Symbol

6. With test strip still in meter, touch Sample Tip of test strip to top of blood drop from sample obtained in Step 1 and allow blood to be drawn into test strip. Remove Sample Tip from blood drop immediately after the meter beeps and dashes appear across meter Display.

Note: If meter does not beep and show dashes in the Display soon after touching the sample to the Sample Tip, release and discard the test strip. Repeat the test with a new test strip and a new sample. If problem persists, see the Troubleshooting section of this Resource Guide.

7. After the test is finished, the Test Strip Release Button flashes and the result is displayed.
8. Hold the meter with the test strip pointing down. Press the Strip Release Button to release and discard the test strip into the appropriate container. Meter turns off. Result is stored in Memory with date and time.
9. Discard all biohazard materials into appropriate container. Wash hands after taking off gloves.
10. Record the result as required by your facility.

Note: *If blood glucose test result is greater than 240 mg/dL and the Ketone Test Alert is turned on, the Ketone Test Alert Symbol appears in the Display with the result. Test ketones per the treatment plan. The Ketone Test Alert may be turned on or off during Setup.*

When a Ketone Test Alert Symbol appears, it does not mean that ketones have been detected in patient's blood. The Ketone Test Alert is a reminder to perform a ketone test as prescribed in the treatment plan.

Memory

Memory

Note: *The use of Memory features (Averages, test results) may not be suitable for multiple-patient use of the system. Check with the facility procedures/ policy before use.*

View Averages (7-, 14-, and 30-Day)

The Averages feature allows viewing of the average of all blood glucose results within a 7-, 14-, and 30-day period. Control Test results are not included in the Averages.

7-Day Average

1. Start with meter off. Press and release "•" Button. Display scrolls through 7-, 14-, and 30-day Average values.

14-Day Average

2. Meter turns off after 2 minutes if no buttons are pressed.

30-Day Average

Note: *If a Control Test is performed outside the recommended testing temperature (See the Quality Control Testing section of this Resource Guide), the control solution may read as a blood test and be included in the Averages.*

Note: *If there are no Average values, three dashes are displayed for 7-, 14-, and 30-day Averages.*

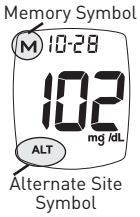
No Average

View Results

Memory stores 500 results. When the Memory is full, the oldest result is replaced with the newest result.

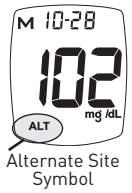
1. Press and release "•" Button. Meter displays 7-, 14-, and 30-day Averages.

2. Press and release "•" Button again to view most recent Control Test result in Memory. If there are no results in Memory, dashes appear with the Memory Symbol.

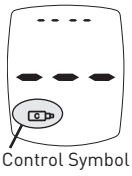


3. Press "▶" Button and release to advance to the most recent blood test. Press "▶" Button to scroll forward through blood results or "◀" Button to scroll backwards through results.

- Test results marked as alternate site display ALT Symbol.



- Control Test results display the Control Symbol. If no Control Test has been done Display shows dashes and the Control Symbol.



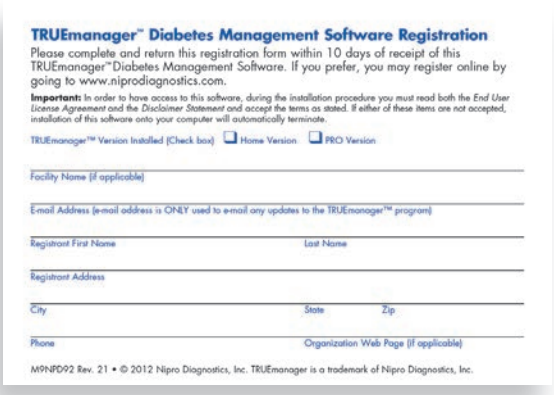
- Test results above 240 mg/dL display Ketone Test Alert Symbol, when Ketone Test Alert is turned on during meter Set Up.

Diabetes Management Software

TRUE METRIX PRO

NIPRO DIAGNOSTICS™

Diabetes Management Software


TRUEmanager™ Diabetes Management Software Registration

Please complete and return this registration form within 10 days of receipt of this TRUEmanager™ Diabetes Management Software. If you prefer, you may register online by going to www.niprodiagnostics.com.

Important: In order to have access to this software, during the installation procedure you must read both the *End User License Agreement* and the *Disclaimer Statement* and accept the terms as stated. If either of these items are not accepted, installation of this software onto your computer will automatically terminate.

TRUEmanager™ Version Installed (Check box) ❑ Home Version ❑ PRO Version

Facility Name (if applicable)

E-mail Address (e-mail address is ONLY used to e-mail any updates to the TRUEmanager™ program)

Registrant First Name Last Name

Registrant Address

City State Zip

Phone Organization Web Page (if applicable)

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TRUEmanager® Diabetes Management Software

TRUEmanager® Diabetes Management Software provides an easy way for patients with diabetes and healthcare providers to understand and manage blood glucose results. Results can be downloaded from the TRUE METRIX® PRO Meter or results can be manually entered into the program.

TRUEmanager® Diabetes Management Software gives you the tools to help your patients achieve target blood glucose levels. The design makes it easy and convenient to quickly identify glucose results that are out of target range, so you can consult with your patients to help them understand how various lifestyle and behavior choices may be affecting their blood glucose levels. With this information and your expertise, patients are empowered to make better choices in daily self-management.

TRUEmanager® Diabetes Management Software (DMS) is a stand-alone software program for a single user or multiple user/multiple patient setting.

- The single user (Home) version is installed from the TRUEmanager® DVD onto a single Windows-based personal computer (PC). It can hold an unlimited number of individual patient records and meter results.
- The multiple user version (TRUEmanager® PRO Diabetes Management Software) easily installs from a TRUEmanager® DVD to a network server and offers a separate Health Level 7 (HL7) interoperability module for data exchange with electronic medical records or other data management systems.

Nipro Meter

Home Version

- Single PC


Patient


Clinic with no server

PRO Version

- Multiple
  - PC
  - PC
  - PC

Multiple PC

HL7

Diabetes Management Software cont.

TRUEmanager™ Diabetes Management Software lets you establish and maintain valuable testing records that include demographics, health insurance information, medications, testing regimen recommendations, and results history. It is an all-in-one, easy-to-access diabetes data management system.

TRUEmanager™ Diabetes Management Software offers nine comprehensive reports two additional administrative reports are available in the PRO version. Each report interprets test results from varied, valuable perspectives and packages them in easy-to-view, printable reports for evaluation and discussion.

Comprehensive reports include:

- Summary Report
- Glucose Trend Report
- Logbook Report
- Extended Logbook Report
- Conformance Report
- Modal Day Report
- Modal Week Report
- Clinical Indicators Patient Report
- Clinical Indicators Population Report

Administrative reports available in the PRO version include:

- Login Audit Report
- Patient Audit Report

TRUEmanager™ PRO Diabetes Management Software is available in the following languages that are all available on one DVD (language preference is chosen during installation process):

- English
- Spanish
- French
- Portuguese
- Croatian
- German
- Greek
- Italian
- Russian
- Serbian

HL7 Interface Overview

- The HL7 interoperability module is installed after TRUEmanager™ PRO Diabetes Management Software and provides the ability to send information stored in the program to an Electronic Medical Record system using HL7 standard language.
- TRUEmanager™ PRO is compatible with Windows 2003 or 2008 Server operating systems.
- An administrative application is included and allows for configuration of HL7 messages and other administrative functionality.

TRUEmanager™ PRO Minimum Hardware and Software Requirements

Client

- DVD-ROM
- IBM Compatible PC with one of the following operating systems installed:
  - Windows XP 32/64bit (Service Pack 3 or later)
  - Windows Vista (Service Pack 2 or later)
  - Windows 7 32/64bit
  - Windows 8.1 32/64 bit
- 1GB of memory or greater
- 2GB free disk space or greater
- 1 free USB 2.0/3.0 port
- Pentium 4 Processor minimum 2GHz or greater (unless using a multi-core processor)
- Graphics card that supports 1024 x 768 or higher
- Docking station and USB Cable
- Acrobat Reader
- Optional color printer for printing reports

Diabetes Management Software cont.

Server

- IBM Compatible PC with one of the following operating systems installed:
  - Windows 2003 Server (Service Pack 2 or later)
  - Windows 2008 Server (Service Pack 2 or later)
- Pentium 4 Processor minimum 2GHz or faster (unless using a multi-core processor)
- 2GB Memory or greater
- 10GB free disk space or more
- Graphics card that supports 1024 x 768 or higher
- Minimum Structured Query Language (SQL) Server 2005 2008 or 2012 Express Edition (Standard or Enterprise Edition recommended for larger facilities)

TRUEmanager Home Version Minimum Hardware and Software

Requirements

- Pentium IV or higher
- Microsoft Windows operating system XP Professional with Service Pack 3 (SP3), Vista (Service Pack 2 [SP2] or later), Windows 7 (Service Pack 1 [SP1] or later) or Windows 8.1
- USB port
- DVD-ROM drive
- Docking Station and USB cable

System Maintenance

TRUE METRIX PRO

NIPRO DIAGNOSTICS

Troubleshooting

Troubleshooting

Troubleshooting

The following is a brief guide for Troubleshooting the most common errors when using TRUE METRIX™ PRO. If any problems arise that cannot be resolved by using the guide or the Display Messages, please call for assistance.

1. After inserting test strip into Test Port, meter does not turn on.

Test strip is inserted upside down or backwards.

- Remove test strip. Re-insert test strip correctly.

Test strip not fully inserted.

- Remove test strip. Re-insert test strip fully into meter.

Test strip error.

- Remove test strip. Repeat with new test strip.

Dead or no battery.

- Replace battery.

Battery in backwards.

- Check placement of battery. Battery positive ("+") side must face up.

Meter error.

- Call for assistance.

2. After applying the sample to the test strip, test does not start/meter does not begin testing.

Sample drop too small.

- Repeat test with a new test strip and a larger sample drop.

Sample applied after two minute automatic shut-off of meter.

- Repeat test with a new test strip and apply sample within 2 minutes of inserting test strip.

Problem with test strip.

- Repeat test with a new test strip.

Problem with meter.

- Call for assistance.

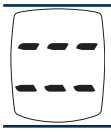
Troubleshooting
Display Messages

TRUE METRIX PRO

NIPRO DIAGNOSTICS™

Troubleshooting Display Messages

Display Messages

Display	Reason	Action
	**Invalid Hematocrit**	Repeat with new test strip, using capillary whole blood from the finger or forearm or venous whole blood collected with sodium heparin blood collection tube. If error persists, call for assistance.
	**Temperature Error** **Too Cold/Too Hot**	Move meter and test strips to area between 41°F-104°F; wait 10 minutes for System to reach room temperature before testing.
	**Sample Not Detected or Using Wrong Test Strip**	Retest with new TRUE METRIX™ PRO Test Strip and larger sample.
	**Used Test Strip, Test Strip outside of vial too long, Sample on top of Test Strip.**	Repeat with new test strip. Make sure sample is touched to edge of test strip (not top). If error persists, call for assistance.
	**Meter Error**	Call for assistance.
	**Test Strip Error, Very high blood glucose result - higher than 600mg/dL**	Retest with new Test Strip. If error persists, call for assistance. If you have symptoms such as fatigue, excess urination, thirst, or blurry vision follow your healthcare professional's advice for high blood glucose.
	**Test Strip Removed During Test**	Retest with new test strip. Make sure result is displayed before removing test strip.
	**Communication Error**	Call for assistance.
	**Low or Dead Battery**	**Low:** About 50 tests can be done before battery dies. **Dead:** Battery Symbol appears and beeps before meter turns off.
	**WARNING!! Out of Range - High Results > 600 mg/dL**	**WARNING!!** Retest with new test strip. If result is still **"Hi" (High)** or **"Lo" (Low)** contact Doctor immediately.
	**Out of Range - Low Results < 20 mg/dL**	
	**Broken Display**	Do not use meter for testing. Call 1-800-803-6025.

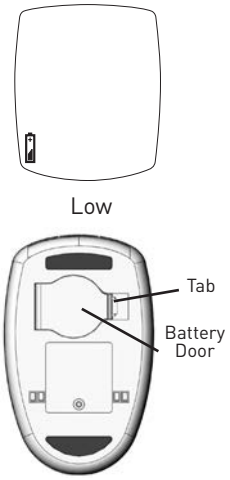
If error message still appears, any other error message appears, or troubleshooting does not solve the problem, call for assistance.

Battery Replacement

TRUE METRIX PRO

NIPRO DIAGNOSTICS

Battery Replacement



Battery Replacement

A low battery displays Battery Symbol while continuing to function. A dead battery displays Battery Symbol, beeps, and then turns off. To replace battery:

1. Lift tab on Battery Door.
2. Turn meter over, tap gently on the palm of your other hand to loosen and remove battery.
3. Discard the old battery in an appropriate container.
4. Insert new battery with positive ("+") side facing up. Close Battery Door.
5. Press " • " Button to turn meter on and check time, date, and Testing Alerts and Reminders (see *Meter Set Up*). If meter does not turn on, check that battery was installed properly. If not, remove and reinsert battery and turn meter on by pressing " • " Button. Call for assistance if problem persists.

Batteries may explode if mishandled or incorrectly replaced. Do not dispose of battery in fire. Do not take apart or attempt to recharge battery. Dispose according to local/country regulations.

Cleaning and Disinfecting

TRUE METRIX PRO

NIPRO DIAGNOSTICS

Cleaning and Disinfection

If system is to be used on multiple patients, cleaning and disinfection of the meter should be done between patients.

Healthcare professionals should wear gloves when cleaning the meter. Wash hands after taking off gloves as contact with blood presents a risk of infection.

Cleaning removes blood and soil from the meter. Disinfecting removes most, but not all possible infectious agents (bacteria or virus) from the meter, including blood-borne pathogens.

- Clean and disinfect immediately after getting any blood on the meter or if meter is dirty.
- Meter should be cleaned and disinfected between patients.
- Do not clean the meter during a test.
- Clean and disinfect the meter before allowing anyone else to handle them.

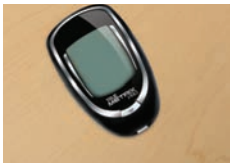
To Clean and Disinfect the Meter:

1. Wash hands thoroughly with soap and water. Wear a clean pair of gloves.
2. Make sure meter is off and a test strip is not inserted. With ONLY PDI Super Sani Cloth Wipes (or any disinfectant product with the EPA* reg. no. 9480-4), rub the entire outside of the meter using 3 circular wiping motions with moderate pressure on the front, back, leftside, rightside, top and bottom of the meter. Repeat as needed until all surfaces are visibly clean. (*Environmental Protection Agency.)

Using fresh wipes, ensure that the outside surfaces of the meter remain wet for 2 minutes.
NEVER put meter in liquids or allow any liquids to enter the test port.

3. Let meter air dry thoroughly before using to test.
4. Verify that the system is working properly by performing an Automatic Self-Test.
5. Properly dispose of gloves and wipes after cleaning. Wash hands after removing gloves.

Note: *Other disinfectants have not been tested. The effect of other disinfectants used interchangeably has not been tested with the meter. Use of disinfectants other than Super Sani Cloth Wipes may damage meter.*



Note: *Super Sani Cloth Wipes have been tested on the meter for a total of 10,950 cleaning and disinfecting cycles, which is equal to cleaning and disinfecting the meter 10 times per day for a 3 year period. The use life of the meter is 3 years.*

Stop using the meter and Call Customer Care for assistance at 1-800-803-6025 if:

- Meter display appears cloudy or any display segments are missing,
- Markings on meter, including back meter label, are coming off or are missing,
- Buttons are hard to push on the meter or do not work,
- Unable to insert test strip into Test Port,
- Automatic Self-Test gives an error message.

System Storage

System Storage

TRUE METRIX™ PRO System

- Store the system (meter, control solution, test strips) in carrying case to protect from liquids, dust and dirt.
- Store the system in a dry place at temperatures between, 40°F-86°F. **DO NOT FREEZE.**
- Allow System to sit at room temperature for 10 minutes before testing

TRUE METRIX™ PRO Test Strips

- Store test strips in original vial only. Do not transfer old test strips into new vial or store test strips outside of vial.
- Write the date first opened on test strip vial. Discard unused test strips from vial if either 4 months after first opening or after date printed next to EXP on vial label has passed, whichever comes first. Use of test strips past expiration dates may give incorrect results. Discard out of date test strips and use new test strips.
- Close test strip vial immediately after removing one test strip.
- Store in a dry place at temperatures between, 40°F – 86°F. **DO NOT FREEZE.**
- Do not reuse test strips.
- Do not bend, cut or alter test strips in any way.

TRUE METRIX™ Control Solution

- Write the date first opened on control solution bottle label. Discard if either 3 months after first opening or after date printed next to EXP on vial label has passed, whichever comes first.
- After use, wipe bottle tip using a clean, dry cloth and recap tightly.
- Store at temperatures between, 36°F-86°F. **DO NOT FREEZE.**

Training Program

TRUE METRIX PRO

NIPRO DIAGNOSTICS

Training Program

TRUE METRIX™ PRO Blood Glucose System Training Program Information

The training program provided in this section of this Resource Guide is recommended to supplement already established facility policies and procedures. It is recommended that facility personnel be trained on the TRUE METRIX™ PRO Blood Glucose Monitoring System prior to performing quality control testing and testing blood samples collected from patients for the first time.

This training program includes the following documents to assist in the setup of a training session for facility personnel

- Product Training Agenda (example)
- Materials Checklist
- Training Checklist

During the training of facility personnel on the TRUE METRIX™ PRO Blood Glucose Monitoring System, we also recommend including a review of the following established facility specific policies and procedures:

- Collection of capillary fingertip, capillary forearm, and venous blood samples
- Quality control testing and documentation
- Blood glucose testing and interpreting patient glucose values
- Medical Device Cleaning and Disinfection Guidelines
- Handling blood and biohazard safety (contaminated biological materials and sharps)

Training Program cont.

Product Training Agenda (example)

	Training Topic	Estimated Time to Complete	Source of Information
1.	Purpose of Training Overview	5 minutes	Technical Overview located in Appendix E of this Resource Guide
2.	Overview of System Components	5-10 minutes	Technical Overview located in Appendix E of this Resource Guide and the System Components section of this Resource Guide
3.	Performing Quality Control Testing	10 minutes	Technical Overview located in the Appendix E of this Resource Guide, Quality Control Testing section of this Resource Guide, and Facility Policy and Procedure on quality control
4.	Documenting and Reviewing Quality Control Results	5 minutes	Meter Setup and Quality Control Testing section of this Resource Guide, and Facility Policy and Procedure on quality control
5.	Sample Collection	10 minutes	Owner Booklet/test strip Instructions for Use located in Appendix B of this Resource Guide, Blood Glucose Testing section of this Resource Guide, and Facility Policy and Procedure for collection and handling of blood samples
6.	Performing Blood Glucose Testing	5-20 minutes	Technical Overview located in Appendix E of this Resource Guide, Blood Glucose Testing section of this Resource Guide, and Facility Policy and Procedure for blood glucose monitoring
7.	Interpreting Blood Glucose Results	5 minutes	Facility Policy and Procedure
8.	Interpreting Meter Display Messages/Troubleshooting	5 minutes	Technical Overview located in Appendix E of this Resource Guide and the System Maintenance section of this Resource Guide
9.	System Maintenance/Storage	5 minutes	Technical Overview located in Appendix E of this Resource Guide, System Maintenance section of this Resource Guide, and Facility Policy and Procedure on Medical Device Cleaning and Disinfection
	Total Time to Complete All Sections	55-75 minutes	

Materials Checklist

Materials for Blood Glucose/Control Testing	Available
TRUE METRIX™ PRO system(s)-we recommend one meter for every 2 participants	
TRUE METRIX™ PRO test strips 1 vial (25 or 50 count) shared between every 1-2 participants	
TRUE METRIX™ Control Solution (Level 1, Level 2, and Level 3 – one bottle of each level) can be shared between every 2 participants	
Auto disabling, single use lancets	
Gauze or tissue for performing blood or control testing	
Personal Protective Equipment (PPE) gloves, etc.	
Biohazard container	
Alcohol wipes	
Cleaning and disinfecting supplies if desired	
Other Training Materials	
TRUE METRIX™ PRO Owners Booklet	
TRUE METRIX™ PRO Test Strips Instructions for Use	
Copies of Checklist, Post-test and Answer Key (for all participants)	
Copies of Quality Control Testing Data Form (located in Appendix D of this Resource Guide or the form provided by your facility)	
Facility Policy and Procedure for blood glucose testing and interpreting glucose results	

Training Checklist

TRUE METRIX™ PRO Blood Glucose System Training Checklist (Please print)

Name_____ **Date** ____/____/____

Title_____

Facility _____

1. The Facility Personnel has completed the following:

    _____ Read the Owner's Booklet
    _____ Read the test strip Instructions for Use
    _____ Read the Control Solution Instructions for Use
    _____ Read the sections in the Comprehensive Resource Guide located prior to the Training Program section

2. The Facility Personnel understands the following:

    _____ Use of the TRUE METRIX™ PRO System in a clinical setting
    _____ System specifications
    _____ Limitations and critical safety information, including that the TRUE METRIX™ PRO System must not be used for certain patients (neonate)

3. Familiarization with the components of the system.

    a. Meter

        _____ Location of serial number for the meter
        _____ Review of meter buttons and functions

    b. Test strips

        _____ Identifies lot number
        _____ Writes open date on test strip vial label
        _____ Understands the use by dates, both printed and written
        _____ Reviews proper handling of test strips including recapping of the test strip vial immediately after removing test strip
        _____ Demonstrates proper insertion of the test strip into the meter

    c. Control Solution

        _____ Identifies lot number
        _____ Writes open date on control solution bottle label
        _____ Understands the use by dates, both printed and written
        _____ Identifies control test level
        _____ Identifies control test ranges

Training Checklist cont.

Name_____

4. Quality Control Tests

_____ Understands manufacturer's instructions for quality control testing
_____ Understands the purpose of the automatic self-check of the meter upon insertion of test strip into Test Port
_____ Understands the purpose of control tests, the frequency of testing, and the number of control solution levels to be tested
_____ Understands the testing temperature range and what may result if testing temperature is out of range
_____ Identifies correct (unopened vs. opened) use by dates on the control solution bottle
_____ Identifies the correct control test range for the control solution level and understands the troubleshooting if the control test result is not within the acceptable range
_____ Demonstrates the procedure using the control solution
_____ Records the control test result on the TRUE METRIX™ PRO Quality Control Testing Data Form

5. Blood Collection

_____ Understands the proper technique of capillary blood collection for both fingertip and forearm samples
_____ Understands when fingertip should be used instead of forearm
_____ Demonstrates the ability to obtain a sufficient amount of blood for testing from both a fingertip and forearm
_____ Understands facility's procedure on obtaining blood samples
_____ Understands the importance of the use of the recommended type of blood collection tube for collecting a venous blood sample for the testing on the TRUE METRIX™ PRO Blood Glucose Monitoring System

6. Demonstration of Blood Glucose Testing

_____ Demonstrates proper blood glucose testing procedure for the TRUE METRIX™ PRO System
_____ Understands the proper blood application to the Sample Tip and the significance of the symbols in the Display

7. Patient Blood Glucose Test Results

_____ Demonstrates the proper documentation of test results
_____ Understands that use of Memory, Averages, and Ketone Test Reminder features may not be appropriate for multiple-patient facilities
_____ Proper disposal of biohazardous materials (contaminated biological materials and sharps) per facility policy and procedures

8. Care, Cleaning/Disinfection, Storage of System

_____ Understands recommended procedures for cleaning and disinfecting the TRUE METRIX™ PRO Meter
_____ Understands facility policy and procedure for Medical Device Cleaning and Disinfection
_____ Demonstrates battery replacement
_____ Understands proper storage of meter, test strips, and control solution

Training Post Test

TRUE METRIX™ PRO Blood Glucose System Training Written Test (Please print)

Name_____ **Date** _____/_____/_____

Title_____

Facility Name _____

Address_____

Phone/Fax _____

True or False

1. It is recommended that healthcare personnel complete the training program prior to using the TRUE METRIX™ PRO Blood Glucose Monitoring System for the first time in a facility.

   _____True _____False

2. The TRUE METRIX™ PRO System can be used on neonates.

   _____True _____False

3. Quality Control Testing should be performed per your facility's policies and procedures.

   _____True _____False

4. Any control solution can be used with the TRUE METRIX™ PRO System.

   _____True _____False

5. Capillary blood testing of critically ill patients with reduced peripheral blood flow (for example: shock, severe hypotension, severe dehydration, hyperglycemia with hyperosmolarity, with or without ketosis) should be tested with the TRUE METRIX™ PRO System.

   _____True _____False

6. If the meter becomes soiled, wipe it off with PDI Super Sani Cloth Wipes.

   _____True _____False

7. The battery should be replaced with an AAA alkaline battery.

   _____True _____False

Training Post Test cont.

TRUE METRIX™ PRO Blood Glucose System Training Written Test (Please print)

Name_____

Multiple Choice (choose only one answer for each question)

1. Training on the use of the TRUE METRIX™ PRO System consists of reviewing the following:

    a) The Comprehensive Resource Guide
    b) The Owner's Booklet
    c) Test strip Instructions for Use
    d) Control solution Instructions for Use
    e) All of the above

2. If a point-of-care blood glucose test is ordered on a patient, the healthcare professional performing the test must:

    a) Identify treatment(s) patient may be on or starting
    b) Identify drug therapy(ies) patient may be on or starting
    c) Identify and use appropriate point-of-care blood glucose testing system
    d) All of the above

3. The TRUE METRIX™ PRO System utilizes the following enzyme to test for glucose:

    a) Glucose oxidase (GO)
    b) GDH-FAD
    c) GDH-NAD
    d) GEH-PDQ

4. The following sample(s) is/are appropriate for testing on the TRUE METRIX™ PRO System:

    a) Capillary whole blood from fingertip or forearm
    b) Venous whole blood collected in a Sodium Flouride tube
    c) Plasma
    d) Urine
    e) Venous whole blood collected using ONLY a sodium heparin tube.
    f) a and c
    g) b and d
    h) a and e

5. The following recommended Quality Control Tests are performed on the TRUE METRIX™ PRO:

    a) One level of control solution and a patient sample
    b) One level of control solution
    c) A low level of control solution and a high level of control solution
    d) Meter automatic self-test and a minimum of 2 levels of control solution

Training Post Test cont.

TRUE METRIX™ PRO Blood Glucose System Certified Training Written Test (Please print)

Name_____

6. The Control solution open bottle use by dates (expiration date) is:

a) One week after opening
b) 120 days after opening
c) 3 months after opening
d) The date pre-printed on the bottle next to the EXP
e) c and d

7. If the Control Test result is out of range, it may be because:

a) The control solution has expired
b) The test strip has expired or the vial was left open for too long
c) The cap was left off the control solution bottle
d) The open date written on the control solution bottle or test strip vial has passed
e) All of the above

8. Forearm testing may not be appropriate in the following situations:

a) Within 2 hours of exercise
b) If the patient's glucose result often fluctuates
c) If the patient is under stress
d) All of the above

9. TRUE METRIX™ PRO Test Strips open vial use by date (expiration date) is:

a) The date pre-printed on the bottle next to the EXP
b) 12 months
c) 6 months
d) 4 months
e) a and d

10. If after inserting the test strip into the Test Port, the meter does not turn on, the reason could be:

a) The test strip was inserted upside down
b) The test strip was not fully inserted
c) The battery is dead
d) All of the above

Training Post Test
Answer Key

TRUE METRIX™ PRO Blood Glucose System Training Written Test Answer Key

True or False

Q 1. True

Q 2. False

Q 3. True

Q 4. False

Q 5. False

Q 6. True

Q 7. False

Multiple Choice

Q 1. e) All of the above

Q 2. d) All of the above

Q 3. b) GDH-FAD

Q 4. h) a and e

Q 5. d) Meter automatic self-test and a minimum of 3 levels of Control Solution

Q 6. e) c and d

Q 7. e) All of the above

Q 8. d) All of the above

Q 9. e) a and d

Q 10. d) All of the above

References

1. FDA Public Health Notification: *Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood Borne Pathogens: Initial Communication Update 11/29/2010* [Electronic Version]. Retrieved February 22, 2012 from http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm.
2. CDC Clinical Reminder: *Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens* [Electronic Version]. Retrieved February 22, 2012 from http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.
3. International Organization for Standardization. In vitro diagnostic test systems. Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus. Reference number ISO 15197:2003 (E). Geneva: International Organization for Standardization; 2003.
4. Data on file.
5. U.S. Food and Drug Administration. *Blood Glucose Meters, Getting the Most Out of Your Meter.* [Electronic Version]. Retrieved July 6, 2009: www.fda.gov/MedicalDevices/Safety/ AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109371.htm.
6. Larsson-Cohn U: *Difference between capillary and venous blood glucose during oral glucose tolerance tests.* Scand J Clin Lab Invest 36:805-808, 1976.
7. Atkin, S.H., et. al. Fingerstick Glucose Determination in Shock. Annals of Internal Medicine, 114:1020-1024 (1991).
8. Clinical and Laboratory Standards Institute. Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition. CLSI document EP7-A2 [ISBN 1-56238-584-4]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.
9. CLSI POCT12-A3 Point of Care blood glucose testing in acute and chronic care facilities; Approved Guideline – Third Edition, January 2013.
10. International Organization for Standardization. In vitro diagnostic test systems. Requirements for blood-glucose monitoring system for self testing in managing diabetes mellitus. Reference number ISO 15197:2013 (E). Geneva: International Organization for Standardization; 2013.

Appendix A
Clinical Studies

Appendix B
Product Labeling

Note: *Your Distributor will provide copies of product labeling. (Owner's Booklet, Test Strip Instructions for Use and Control Solution Instructions for Use)*

Appendix C
Material Safety Data Sheets

Test Strip – Safety Data Sheet

Section 1: Product Information
Product Name: TRUE METRIX™ PRO Blood Glucose Test Strips

Section 2: Composition / Information on Ingredients
Vial: Silica Gel, polypropylene, polyethylene

Test strips: Glucose dehydrogenase-Flavin adenine dinucleotide (GDH-FAD) (Asperigillus, sp.), mediators, buffers and stabilisers

Test strip Box and Package Insert: Paper

Section 3: Hazard Identification
No significant immediate hazards for emergency response are known.

Section 4: Emergency First Aid Procedures
Eye: No first aid required.

Skin: No first aid required for contact with skin.

Ingestion: No first aid required from ingestion.

Inhalation: No first aid required.

Section 5: Fire and Explosion Hazard Data
Flash Point (Method Used): Vial - > 232°C (450°F) (estimated), test strips - N/A

Flammable Limits: N/A

General Hazard: Solid material may burn at or above the flashpoint. If thermally decomposed, flammable/toxic gases may be released. Toxic gases will form upon combustion. Hazardous combustion products may include and are not limited to: carbon monoxide, carbon dioxide.

Special Fire Fighting Procedures: Use water spray to cool fire exposed surfaces and to protect personnel. Isolate "fuel" supply to fire. Extinguish the fire by cooling with water spray. Respiratory and eye protection required for fire fighting personnel.

Unusual Fire and Explosion Hazards: None determined.

Section 6: Spill or Leak Procedures
Steps to be taken in case material is released or spilled: Contain material to prevent contamination of soil, surface water and ground water. May be slipping hazard.

Section 7: Handling and Storage
Store at temperatures and conditions as indicated on the product label.

Section 8: Personal Protection
Ventilation: Use general room ventilation.

Respiratory Equipment: None

Protective Gloves: None

Eye Protection: None

Other Protective Equipment/Clothing: None

Section 9: Physical Data
Appearance and odor: Vial - vial with desiccant liner, test strips - Plastic strip with reaction area.

pH: N/A

Specific Gravity: N/A

Boiling Point: N/A

Melting Point: N/A

Vapor Pressure: N/A

Evaporation Rate: N/A

Solubility in Water: N/A

Section 10: Reactivity Data
Stability: Stable if at storage temperature and original vial closed.

Conditions to Avoid: Product can oxidize and decompose at elevated temperatures. Avoid putting water inside of vial, exothermic reaction will occur. Temperatures above 149°C (300°F) may cause product degradation and self combustion.

Substances to Avoid: Avoid contact with strong acids and oxidizing materials.

Hazardous Decomposition Products: Flammable hydrocarbons.

Hazardous Polymerization: Will not occur.

Section 11: Toxicological Information
Chronic Effects of Overexposure: None currently known.

Carcinogen or Suspected Carcinogen: None of the compounds present are listed as a carcinogen or suspected carcinogen.

Medical Conditions Aggravated by Exposure: None currently known.

Acute Toxicity Values: Not applicable.

Section 12: Ecological Information
Ecological effects of this product have not been determined.

Section 13: Disposal
Primary Container Type: Vial with 50 test strips.

Waste Disposal Method: Each disposal facility must determine proper disposal methods to comply with local, state, and federal environmental regulations.

Control Solution – Safety Data Sheet

Section 1: Product Information
Product Name: TRUE METRIX™ Control Solution – Levels 1, 2, and 3

Section 2: Composition / Information on Ingredients
Bottle: Polypropylene, polyethylene

Control Solution: Water, d-glucose, buffers, viscosity enhancing agents, salts, dyes, and preservatives.

Control Solution Box and Package Insert: Paper

Section 3: Hazard Identification
No significant immediate hazards for emergency response are known.

Section 4: Emergency First Aid Procedures
Eye: Flush with copious amounts of water.

Skin: Flush with water.

Ingestion: Contact physician.

Inhalation: Contact physician.

Section 5: Fire and Explosion Hazard Data
Flash Point (Method Used): Bottle - N/A, control solution - N/A

Flammable Limits: N/A

General Hazard: N/A

Special Fire Fighting Procedures: N/A

Unusual Fire and Explosion Hazards: None determined.

Section 6 : Spill or Leak Procedures
Steps to be taken in case material is released or spilled: Contain material to prevent contamination of soil, surface water and ground water. May be slipping hazard.

Section 7 : Handling and Storage
Store at temperatures and conditions as indicated on the product label. Keep bottle tightly closed when not in use.

Section 8 : Personal Protection
Ventilation: Use general room ventilation.

Respiratory Equipment: None.

Protective Gloves: None

Eye Protection: None

Other Protective Equipment/Clothing: None

Section 9 : Physical Data
Appearance and odor: Bottle - plastic bottle with cap, control solution - Red liquid.

pH: N/A

Specific Gravity: N/A

Boiling Point: N/A

Melting Point: N/A

Vapor Pressure: N/A

Evaporation Rate: N/A

Solubility in Water: N/A

Section 10 : Reactivity Data
Stability: Stable at storage temperature. Keep bottle closed when not in use.

Conditions to Avoid: N/A

Substances to Avoid: Avoid contact with strong acids and oxidizing materials.

Hazardous Decomposition Products: Flammable hydrocarbons.

Hazardous Polymerization: Will not occur.

Section 11 : Toxicological Information
Chronic Effects of Overexposure: None currently known.

Carcinogen or Suspected Carcinogen: None of the compounds present greater than 0.1% are listed as a carcinogen or suspected carcinogen.

Medical Conditions Aggravated by Exposure: None currently known.

Acute Toxicity Values: Not applicable.

Section 12 : Ecological Information
Ecological effects of this product have not been determined.

Section 13 : Disposal
Primary Container Type: Bottle with 3 mL Control Solution.

Waste Disposal Method: Each disposal facility must determine proper disposal methods to comply with local, state, and federal environmental regulations.

Appendix D
Forms

QUALITY CONTROL TESTING DATA FORM

Meter Serial Number _____ (see number on Meter label below the bar code) ***Note any problems in Troubleshooting section below.**

Date	Time	Test Strips			Control Solution - Level _____					Control Solution - Level _____					Control Solution - Level _____					Initials	*
		LOT	EXP	Date Opened	LOT	EXP	Date Opened	Acceptable Range	Result	LOT	EXP	Date Opened	Acceptable Range	Result	LOT	EXP	Date Opened	Acceptable Range	Result		

*TROUBLESHOOTING			
Date	Problem	Action	Initials

Appendix E
Technical Overview