EXACTVE Series
Blood Glucose Test Strips Package Insert

EXACTIVE

EXACTIVE EASY EXACTIVE EQ

English

PRINCIPLE AND INTENDED USE

The EXACTIVE series Blood Glucose Test Strips are thin strips with a chemical reagent system. They work with the EXACTIVE series Blood Glucose Meters to measure the glucose concentration in whole blood. Specifically, EXACTIVE strip works with EXACTIVE Vital meter, EXACTIVE EQ strip works with EXACTIVE EQ Simple meter, EXACTIVE EQ Impulse meter or Equil insulin patch pump PDA (Personal Diabetes Assistant), and EXACTIVE Easy strip works with EXACTIVE Easy meter. Blood is applied to the end tip of the test strip. The blood is then automatically absorbed into the reaction cell. The reaction takes place in the reaction cell. A transient electrical current is formed during the reaction which is detected by the meter. The blood glucose concentration is then calculated based on the electrical current. The result is then shown on the meter display. The meters are calibrated to display plasma equivalent results. For in vitro diagnostic use.Test strips are to be used only outside the body for testing purposes. For self-testing and professional use.

COMPOSITION

Each test strip contains the following reactive chemicals: Glucose Oxidase <25 IU, Mediator <300 µg.
Each test strip vial contains a drying agent.

STORAGE AND HANDLING

- Test strips should be stored in their protective vial. The vial's cap must be tightly closed.
- Store test strips in a cool, dry place at room temperature, 5-30°C (41-86°F). Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- To ensure accurate results, use the test strips at room temperature.
- Keep the 'EXACTIVE/EXACTIVE EQ/EXACTIVE EASY logo side up and blank white side down when you insert the strip contact bars into the strip port.
- Do not store or use the test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners that contain bleach.
- Do not transfer the test strips to a new vial or any other container.
- Replace the vial cap immediately after removing a test strip.
- Use the test strip immediately after removing it from the vial.
- Do not use your test strips past the unopened expiration date. The expiration date is printed on the vial. Using test strips past the expiration date may produce incorrect test results.

Note:All expiration dates are printed in Year-Month format. 2016-01 means January 2016.

- A new vial of test strips must be used within 6 months after first being opened. The opened vial expiration date is 6 months after the date the vial was first opened. Write the opened vial expiration date on the vial label after opening.

PRECAUTIONS

- For in vitro diagnostic use. The test strips are to be used only outside the body. The test strips are to be used only for testing purposes.
- Do not use test strips after the expiration date that is shown on the vial. Expired test strips may give incorrect blood glucose readings.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- The sample must only be applied to the tip of the test strip. Do not apply blood or control solution to the top of the test strip as this may result in an inaccurate reading.
- Discard the vial and any unused test strips 6 months after you first opened it. Constant exposure to air may destroy chemicals in the test strip.This damage can result in incorrect readings.
- Keep the test strip vial away from children and animals.
- Consult your healthcare professional before making any changes to your treatment plan.

MATERIALS PROVIDED

- Test Strips
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Sterile Lancets
- Lancing Device
- Control Solution

INSTRUCTIONS FOR USE

See your User Manual for complete instructions for blood sample collection before use.

1. Open the cap of the test strip vial. Remove a test strip for testing. Close the cap immediately. This is to protect the remaining test strips from moisture in the air.
2. Run the blood glucos test following the User Manual.
3. The blood glucose test result will be shown on the meter display window or Equil insulin patch pump PDA (Personal Diabetes Assistant). This result should fall within the target range. Your healthcare professional should recommend your target range. If your blood glucose test results are higher or lower, ask your healthcare professional what to do. Always consult your healthcare professional before making any changes to your treatment plan.

IMPORTANT: EXACTIVE Series Blood Glucose Monitoring Systems allow alternative site testing for forearm and palm testing in addition to fingertip testing. There are important differences between forearm, palm and fingertip samples that you should know. Important information about forearm and palm blood glucose testing:

- When blood glucose levels are changing rapidly such as after a meal, insulin dose or exercise, blood from the fingertips may show these changes more rapidly than blood from other areas.
- Fingertips should be used if testing is within 2 hours of a meal, insulin dose or exercise and any time you feel blood glucose levels are changing rapidly.
- Fingertip testing should be used if hyperglycemia or hypoglycemia unawareness is a concern.

RANGE OF EXPECTED VALUES

Blood glucose monitoring requires the help of a healthcare professional. Together you can set your own range of expected blood glucose values, arrange your testing times, and discuss the meaning of your blood glucose results.
Expected blood glucose levels for people without diabetes:[1]

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70 – 100	3.9 – 5.6
2 Hours After Meal	Less than 140	Less than 7.8

CHECKING THE SYSTEM

Your blood glucose meter must be handled carefully. See your User Manual for detailed instructions for meter care. The quality control test should be used to check that the meter and test strips are working together properly. Follow the test procedure in your User Manual to run a quality control test. Two ranges CTRL1 and CTRL 2 are shown on the test strip vial label (or on the foil pouch). Control Solution 1 is sufficient for most self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 2 test. Contact your supplier for information on purchasing a control solution.
For confirmation of results, Control Solution 1 tests should fall within the CTRL 1 range and Control Solution 2 tests should fall within the CTRL 2 range. When testing with Control Solution 1, make sure you are matching the results to the CTRL 1 range on the vial label.
CAUTION: If your quality control test result falls outside the control range shown on the test strip vial, DO NOT use the system to test your blood, as the system may not be working properly. If you cannot correct the problem, contact your supplier for assistance.

LIMITATIONS

- The EXACTIVE series meters, test strips and other components of the EXACTIE series Blood Glucose Monitoring Systems have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- The EXACTIVE series Test Strips are for testing with fresh capillary whole blood. Do not use with serum or plasma samples.
- Not to be used for neonatal blood glucose testing.
- Very high (above 55%) and very low (below 30%) hematocrit levels can result in false readings. Talk to your healthcare professional to find out your hematocrit level.
- Abnormally high levels of vitamin C, Acetaminophen, Uric Acid, L-Dopa, Tolazamide or other reducing substances will produce false high blood glucose measurements.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 1.1-33.3 mmol/L (20 to 600 mg/dL).
- Fatty substances (triglycerides up to 95 mmol/L (3,000 mg/dL) or cholesterol up to 13 mmol/L (500 mg/dL) have no major effect on blood glucose test results.
- The EXACTIVE series Blood Glucose Monitoring Systems show to work properly in studies at altitudes up to 3048 meters.
- Severely ill persons should not perform the blood glucose test with the EXACTIVE series Blood Glucose Monitoring Systems.
- Blood samples from patients in shock or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis) have not been tested and are not recommended for testing with the EXACTIVE series Blood Glucose Monitoring System.
- Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions when disposing of materials.

PERFORMANCE CHARACTERISTICS

Reproducibility, Precision

Ten replicate assays were each run on ten *EXACTIVE Vital* Blood Glucose Meters. Heparinized venous blood samples at five concentration levels were used in the testing. The results provided the following estimates for reproducibility, precision.

MEAN	2.1 mmol/L	4.4 mmol/L	7.7 mmol/L	11.3 mmol/L	17.0 mmol/L	25.5mmol/L
Standard Deviation (mmol/L)or Coefficient of Variation(CV)	0.12mmol/L	3.2%	2.4%	2.1%	1.4%	1.4%

Intermediate Precision

Ten replicate assays drawn from three strip lots were run on ten *EXACTIVE* Vital Blood Glucose Meters. These tests were run each day for a total of ten days. Control solutions at three concentration levels were used in the testing. The results provided the following intermediate precision estimates.

#	MEAN	Standard Deviation(mg/dL) or Coefficient of Variation(CV)
Strip Lot 1	2.2 mmol/L	0.06 mmo/L
	6.5 mmol/L	2.5%(CV)
	18.0mmol/L	2.9%(CV)
Strip Lot 2	2.2 mmol/L	0.07 mmol/L
	6.5 mmo/L	2.4%(CV)
	18.0 mmol/L	2.6%(CV)
Strip Lot 3	2.3 mmol/L	0.06 mmol/L
	6.4 mmol/L	3.2%(CV)
	18.0 mmol/L	2.8%(CV)

System Accuracy

The capillary blood glucose measurements from 200 participants were taken by a trained technician using the *EXACTIVE Vital* Blood Glucose Meter (y). Capillary blood samples were obtained from fingertip, palm and forearm sampling sites for the *EXACTVE Vital* Blood Glucose Meter testing. Fingertip samples from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x).The results were compared.

Linear Regression Results: *EXACTIVE Vital* (y) vs. YSI Reference(x)				
Sample Site	Slope	Intercept	R	N
Fingertip	0.976	2.0435	0.9907	200

Fingertip samples were used for YSI reference measurement.
The sample range was 1.4 to 29.1 mmol/L for *EXACTIVE Vital* Blood Glucose Meter testing with blood sampled from fingertip sites.

Fingertip Site: System Accuracy Results for Glucose Concentration ≥ 4.2mmol/L			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
88(55.0%)	128(80.0%)	152(95.0%)	156(97.5%)
Fingertip Site: System Accuracy Results for Glucose Concentration <4.2mmol/L			
Within ± 0.28mmol/L (± 5mg/dL)	Within ± 0.57mmol/L (± 10mg/dL)	Within ± 0.83mmol/L (±15mg/dL)	
16（40.0%）	22（55.0%）	40（100%）	

Consumer Study

A consumer study was performed by testing three test strip lots. Participants and a trained technician used the *EXACTIVE Vital* Blood Glucose Monitoring System. This study showed that the patient can run the test as well as the trained technician.

EXACTIVE tests: Linear regression of Participant (y) versus YSI Reference value and Linear regression of Technician (y) versus YSI Reference value					
Strip Lot	Tested By	Slope	Intercept	R	N
Lot 1	Layperson	1.017	-0.033	0.9840	200
Lot 1	Technician	1.020	-0.061	0.9840	200

For complete instructions, please refer to the User manual included with your meter. For additional queries regarding this product, please contact your supplier for assistance.

REFERENCES

1. ADA Clinical Practice Recommendations. 2010.

INDEX OF SYMBOLS

	Attention, see instructions for use		Use by	CODE	Code Number
IVD	For *in vitro* diagnostic use only	LOT	Lot Number	CTRL	Control Range
5°C 30°C	Store between 5-30°C		Manufacturer	REF	Catalog #
Σ	Contains sufficient for <n> tests	EC REP	Authorized Representative		

CE 0197

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