# SureStep® Technology

## LifeScan makes getting accurate glucose results perfectly easy.

The **excellent performance** of LifeScan's SureStep Technology* is a reflection of our **commitment to accuracy**, the most important feature of any blood glucose monitoring device.

SureStep® Test Strips and Meters are painstakingly engineered to be **accurate** and **precise**, even at low glucose levels, and to **avoid interferences** from other substances.

Our innovative test strip holder not only helps to **promote proper strip insertion** and accurate readings, it also **repels blood** to make cleaning easier.

We recognize that great products must be **easy to use**, so we created a **touchable** test strip with an easy-to-see **pink test square** and a **confirmation dot**. And since SureStep® Meters perform an internal check each time they are turned on, **no check strip** is required.

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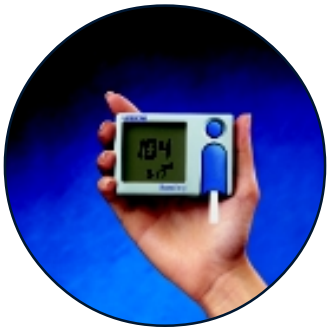
* The SureStep® Brand is marketed as Novo Assist™ or GlucoTouch® in certain international locations.

LIFESCAN
a Johnson & Johnson company

# SureStep® Technology for the entire continuum of care



## SureStep®

COMPLETE BLOOD GLUCOSE MONITORING SYSTEM

- Simple, single-button testing
- Results in as little as 15 seconds
- Confirms enough blood applied
- 150-test memory with date and time
- Compatible with IN TOUCH® Diabetes Management Software

## SureStep®Pro

PROFESSIONAL BLOOD GLUCOSE MANAGEMENT SYSTEM

- Capture and control point-of-care testing data with confidence
- Promotes caregiver and patient safety
- Helps make it easier to comply with stringent regulatory requirements
- Integrates clinical, regulatory, and utilization data from bedside to LIS
- DataLink™ enhancements provide options for remote data transfer via modem or network and a LIS interface via script or EDI

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## SureStep®Flexx

PROFESSIONAL BLOOD GLUCOSE MANAGEMENT SYSTEM

- Small, lightweight ergonomic design
- Enhanced QC and operator compliance
- Comprehensive data management and report capabilities
- Available with all DataLink connectivity options

*LifeScan's SureStep Meters provide innovative blood glucose management solutions for the entire continuum of care, from self-monitoring for individuals to integrated professional systems for clinical and institutional settings.*

## SureStep® Meters offer key advantages

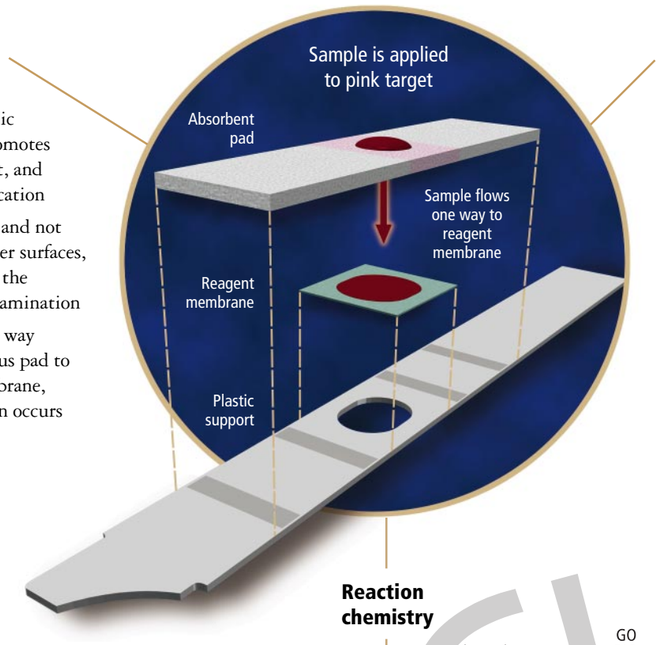
- Innovative SureStep® Test Strip Technology
- Touchable test strip for true off-meter dosing
- Plasma-calibrated glucose results
- Photoreflectance optical system
- Glucose oxidase chemistry for minimal interference

# The advanced design of SureStep® Technology provides accurate, dependable glucose results in three simple steps

## ONE
## Sample is applied to the test strip

### Absorbent pad

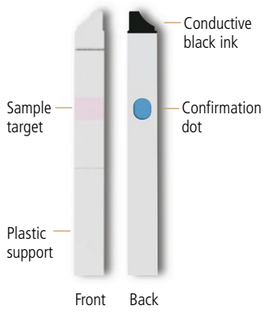
- Touchable
- Special hydrophilic polymer foam promotes quick, convenient, and safe sample application
- Blood is retained and not transferred to other surfaces, thereby reducing the potential for contamination
- Sample flows one way through the porous pad to the reagent membrane, where the reaction occurs



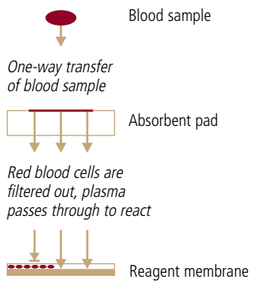

### Asymmetric black tip

- Asymmetric shape helps with the proper orientation of test strip into test strip holder
- Conductive black ink provides an indication that the test strip has been inserted and remains inserted by completing an electrical circuit

### Test strip at a glance




### Blood sample flow




## TWO
## Glucose reacts with reagents in the test strip

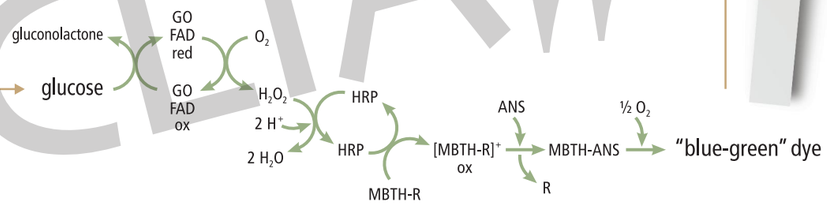
### Reagent membrane

- Reagent-impregnated microporous membrane provides the reaction site
- Filters out red blood cells while allowing plasma to move through
- Hides red blood cells and simplifies glucose measurement

### Enzymatic reaction

- Glucose in the sample is oxidized by glucose oxidase (GO) in the presence of atmospheric oxygen, forming hydrogen peroxide ($H_2O_2$)
- $H_2O_2$ reacts with indicator dyes using horseradish peroxidase (HRP), forming a chromophore or light-absorbing dye
- The intensity of the color formed at the end of the reaction is proportional to the glucose present in the sample

### Reaction chemistry




### Glucose oxidase chemistry

- High degree of specificity for D-glucose
- Very stable
- Efficiently couples to visible dye systems

### Patented indicator dye system

- Tailored specifically to absorb a particular wavelength of light where hemoglobin (red blood) does not interfere
- Stable over time
- High level of performance for accuracy and precision is achieved, especially at low glucose concentrations

### Confirmation dot

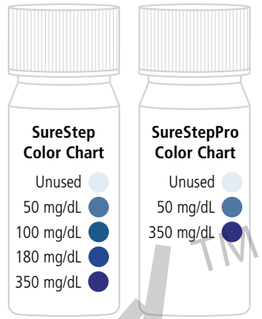
- Turns blue after the blood sample has been applied
- Allows user to see if a sufficient amount of blood has been applied correctly
- Intensity of the blue color can be compared to the optional color chart for quick reference of blood glucose concentration

### Endpoint reaction

- Glucose concentration is determined using the amount of color formed at the end of the reaction: the point at which all the glucose has reacted with the enzyme and the color stops changing
- Off-meter dosing is made possible, thereby improving infection control
- User has up to two minutes to insert the test strip once sample has been applied

## THREE
## Measurement of blood glucose concentration with SureStep® Meters

Test Strip vial color charts



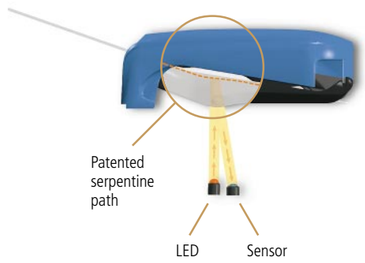

*Vial color charts are to be used as an additional check to confirm a meter reading. They are NOT a replacement for a meter test.*


### No check strip is required

- SureStep Meters automatically perform numerous internal checks each time they are turned on

### Test strip holder

- Patented design with serpentine path, which in conjunction with the unique asymmetric test strip tip, helps guide proper test strip insertion
- Teflon®-impregnated plastic repels blood




Measurement of glucose level using reflectance photometry

### Reflectance photometry quantifies the intensity of the colored product generated by the enzymatic reaction

- Light-emitting diode (LED) emits a specific wavelength of light onto the test strip
- Colored product absorbs the light—the more glucose in a sample (and thus the more colored product on a test strip), the less reflected light
- A detector captures the reflected light, converts it into an electronic signal, and translates it into a corresponding glucose concentration
- System is calibrated to give plasma glucose values
- In general, reflectance photometry methods are less sensitive to the interferences common to electrochemical technologies

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# Performance data

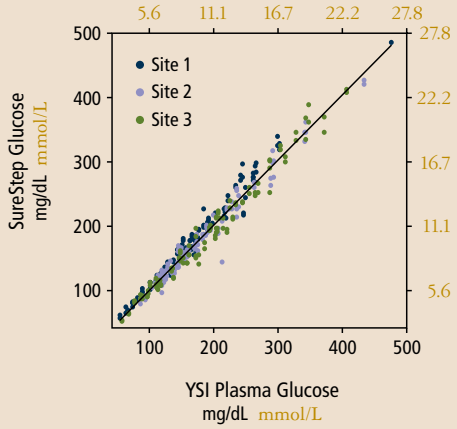
## EXCELLENT ACCURACY

*Accuracy is a measure of how close the results are to target reference values.*

### Testing by lay user[1]

**Linear regression**

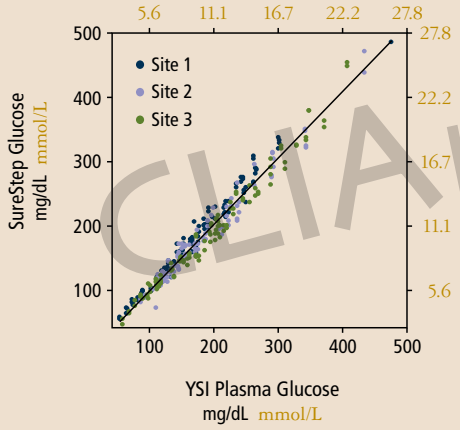
y = 1.01x – 1.02 (mg/dL)
1.01x – 0.56 (mmol/L)
$r^2$ = 0.969
r = 0.984
n = 335
Sy.x = 13.46 mg/dL
0.748 mmol/L




### Testing by laboratory technician[1]

**Linear regression**

y = 1.03x – 4.44 (mg/dL)
1.03x – 0.56 (mmol/L)
$r^2$ = 0.967
r = 0.983
n = 335
Sy.x = 14.20 mg/dL
0.789 mmol/L




## EXCEPTIONAL PRECISION

*Precision is a measure of reproducibility.*

### Within-run precision of SureStepFlexx using whole blood[2]

| Glucose concentration | Mean | | SD | | CV |
|---|---|---|---|---|---|
| | mg/dL | mmol/L | mg/dL | mmol/L | % |
| **Site 1** (n=20) | | | | | |
| **Normal** | 78.4 | 4.36 | 1.1 | 0.061 | 1.4 |
| **High** | 339.3 | 18.85 | 11.2 | 0.622 | 3.3 |
| **Site 2** (n=20) | | | | | |
| **Low** | 47.8 | 2.66 | 1.9 | 0.106 | 4.1 |
| **High** | 260.7 | 14.48 | 4.9 | 0.272 | 1.9 |

## LACK OF INTERFERENCES

### Interferences from endogenous substances[3]

*Substances produced or originating from within the body.*

NO INTERFERENCE was observed in the following substances at physiological levels up to test concentration:

| Substance | Test concentration | | Physiological level | |
|---|---|---|---|---|
| | mg/dL | mmol/L | mg/dL | mmol/L |
| Bilirubin | 20 | 0.342 | 1.2 | 0.021 |
| Cholesterol | 500 | 12.93 | 300 | 7.76 |
| Creatinine | 30 | 2.65 | 1.5 | 0.133 |
| Triglycerides | 3000 | 33.88 | 190 | 2.15 |
| Uric Acid | 20 | 1.19 | 7 | 0.42 |

### Interferences from exogenous substances[3]

*Substances originating from outside the body such as therapeutic agents or vitamins.*

NO INTERFERENCE was observed in the following substances at therapeutic levels up to test concentration:

| Substance | Test concentration | | Therapeutic level (or range) | |
|---|---|---|---|---|
| | mg/dL | mmol/L | mg/dL | mmol/L |
| Acetaminophen | 20 | 0.342 | 1–2 | 0.066–0.132 |
| Ascorbic Acid | 3 | 0.17 | 0.8–1.2 | 0.045–0.068 |
| Ephedrine | 10 | 0.61 | 0.005–0.01 | 0.0003–0.0006 |
| Ibuprofen | 40 | 1.94 | 0.5–4.2 | 0.024–0.204 |
| Methyl Dopa | 2.5 | 0.12 | 0.1–0.5 | 0.005–0.024 |
| Salicylate (aspirin) | 50 | 3.62 | 15–30 | 1.09–2.17 |
| Tetracycline | 4 | 0.09 | 0.4 | 0.009 |
| Tolazamide (Tolamide, Tolinase) | 100 | 3.21 | 2.0–2.5 | 0.06–0.08 |
| Tolbutamide (Oramide, Orinase) | 100 | 3.70 | 5.3–10 | 0.20–0.37 |
| Sodium Citrate | 500 | 19.4 | Blood drawing tube | |
| EDTA (K+) | 400 | 9.89 | Blood drawing tube | |

The following substances produced NO INTERFERENCE AT THERAPEUTIC LEVELS up to indicated threshold (i.e., exhibited supratherapeutic interference only):

| Substance | Threshold Level | | Therapeutic level (or range) | |
|---|---|---|---|---|
| | mg/dL | mmol/L | mg/dL | mmol/L |
| Dopamine | 6 | 0.392 | 0.4–1.6 | 0.026–0.104 |
| Gentisic Acid | 10 | 0.649 | 3.5–5.0 | 0.23–0.32 |
| L-Dopa (Levo-Dopa) | 20 | 1.014 | 0.02–0.3 | 0.001–0.015 |

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### References

1. Stover HM, et al. *Clinical evaluation of the enhanced SureStep System for self-monitoring of blood glucose (SMBG)*. Presented at the AADE 26th Annual Meeting, August 1999. Reprint available as LifeScan AW 056-796.
2. Weber S, Torio M, Correll G, et al. *Multicenter evaluation of a new blood glucose monitoring system for point-of-care testing*. Presented at the 52nd Annual AACC Meeting, July 2000. Reprint available as LifeScan AW 057-263.
3. *Interferences from endogenous and exogenous substances*. LifeScan Technical Bulletin, AW 056-498, 1999.


For more information, check with your sales representative or call the LifeScan Healthcare Professional Line at 1 800 524-7226.

# We designed SureStep® Products with you in mind

## Each feature of SureStep® Technology is engineered to provide you with benefits in performance, ease of use or infection control.

| Technology | Feature | Performance | Ease of use | Infection control |
|---|---|---|---|---|
| **Absorbent pad** | • Touchable | | ✓ | |
| | • Easy-to-see pink sample target | | ✓ | |
| | • Absorbs, retains, and transfers blood one-way to reagent membrane | ✓ | | ✓ |
| **Microporous reagent membrane** | • Filters out and hides red blood cells to allow for visual confirmation | ✓ | | |
| | • Glucose oxidase-based chemistry provides excellent accuracy and precision without interferences from other substances<br>– very specific for D-glucose<br>– very stable<br>– efficiently couples to visible dye systems | ✓ | | |
| | • Patented indicator dye system provides excellent accuracy and precision, especially at low glucose concentrations<br>– dye absorbs a specific wavelength of light where hemoglobin does not interfere<br>– dye absorbs light in proportion to amount of color present in the sample<br>– dye is relatively stable over time | ✓ | | |
| | • Not affected by $PO_2$ | ✓ | | |
| | • Off-meter sample application is possible since the glucose concentration is determined by the amount of color formed at the *end* of the reaction | | ✓ | ✓ |
| **Confirmation dot** | • Turns blue almost immediately after proper application of blood | | ✓ | |
| | • Provides a visual estimate of blood glucose level | | ✓ | |
| **Asymmetric black tip** | • Asymmetric shape helps with the proper orientation of the test strip (pink side up) upon insertion into the test strip holder | ✓ | ✓ | |
| | • Completes an electrical circuit, providing an indication that a test strip has been inserted and remains inserted | ✓ | ✓ | |
| **Test strip holder** | • Teflon®-impregnated plastic repels blood to make cleaning easier | | | ✓ |
| | • Patented serpentine shape maintains the test strip against the optics, promoting a constant optical reading | ✓ | | |
| | • If necessary, can be easily removed for cleaning | | ✓ | ✓ |
| **Calibration** | • SureStep® Systems are calibrated to give plasma glucose values, enabling a more direct comparison to laboratory results | | ✓ | |
| **Check strip** | • No check strip is required—SureStep® Meters perform an automatic check every time they are turned on | ✓ | ✓ | |

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