



Pura® X

Enjoy precision.



swissdesign 

mylife™ Pura® X – easy to use with side loaded test strip and large display.

- Preset blood glucose monitoring system for fast initialisation and easy training
- Side-loading test strip for hygienic strip removal without blood contact
- Solid test strip design with good grip for easy handling
- Basic functions for easy and intuitive operation
- Autocoding and High Definition Signal Transmission (HDST) for high measuring accuracy and precision^{1,2}



More freedom. More confidence. With mylife™.

YPSOMED
SELFCARE SOLUTIONS



Pura[®] X

Made for life.



A reliable and user-friendly device

For people who wish a simple and easy to use meter

In the therapy of diabetes mellitus, blood glucose self-monitoring and the resulting therapy adjustments play a central role.

Blood glucose meters can be quite different in their design and technology, but also in their performance: mylife™ Pura® X features Autocoding and the innovative High Definition Signal Transmission (HDST) technology, which offers interference-free signal transmission,

making it a very accurate and precise meter. 100 % of measurements¹ of this blood glucose monitoring system fall within the accuracy requirements of the ISO 15197:2013³.

mylife™ Pura® X is the ideal blood glucose monitoring system for people with diabetes who would like to have a simple, easy to use meter with a large display.



In a survey⁴, conducted with more than 3 200 patients, 100 % of those polled rated the usability of the mylife™ Pura® X as “very good” and “good”. A top rating achieves the display size as well as the readability: 100 % of the polled patients evaluated both criteria as “very good” and “good”. The confidence of the reliability, which has been rated by the professionals as “very important” (91 %), reaches 100 % by the patients (64 % “very good”, 36 % “good”).

mylife™ Pura® is identical in design with mylife™ Pura® X⁵

Same technology – different colour

To meet the demands of our clients, the white mylife™ Pura® is also offered in another colour. The technology of mylife™ Pura® X was retained, only the external appearance differentiates the

original version – black and green colours adorn mylife™ Pura® X. In the United Kingdom, Germany, Austria and India exclusively mylife™ Pura® X is available.

mylife™ Pura®



mylife™ Pura® X





Technology for high measurement accuracy and precision

High Definition Signal Transmission and Autocoding

High Definition Signal Transmission

Accuracy and precision of blood glucose measurements result from a combination of various elements. In principle, through biochemical substances the glucose molecules in a blood sample are translated into electrons which can be measured by creating an electric current (other technologies are also common in the market, e. g. photometry). The higher the measured current, the higher the blood glucose value.

However, the generated voltage for the measurement is extremely low and therefore sensitive to interference. The signal transmission is crucial for the quality of the measurement.⁶

The concept of the shortest possible signal path has been consistently applied. All unnecessary amounts of conductive distance were eliminated on the test strips, and gold electrodes in the device as well as in every individual test strip ensure optimal signal transmission. Furthermore, gold-plated battery contacts guarantee a stable operating voltage at all times.⁶

Autocoding

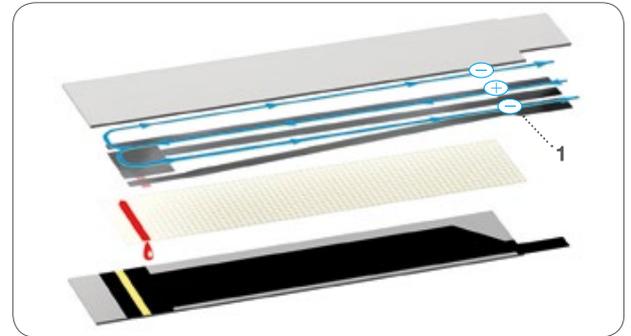
The meter automatically identifies a specific test strip lot code after the insertion of a mylife™ test strip into mylife™ Pura® X (Autocoding). This Autocoding feature allows the meter to cope with variations in test strip productions in order to ensure a high level of accuracy and precision.

mylife™ Pura® X with High Definition Signal Transmission



Short signal paths permit interference-free transmission of the signal. Gold is one of the most corrosion-resistant of all established conductive materials, ensuring optimal signal transmission from test strip to measurement device.⁶

Conventional test strip



With conventional test strips where blood is applied from the front, the signal path is significantly longer and thus more vulnerable to interference. Also, the contacts between measurement device and test strip are made from conventional metal, which will corrode faster, thus impacting the signal and leading to less accurate measurements.



According to a survey⁴ in Germany, 93 % of professionals rate accuracy and precision of a blood glucose monitoring system as “very important”. 99 % of end users value this characteristic of the mylife™ Pura® blood glucose monitoring system “very good” and “good”.

100 % of the test results fall within the accuracy requirements according to ISO 15197:2013

With the IVD standard ISO 15197:2013³ the minimal requirements for

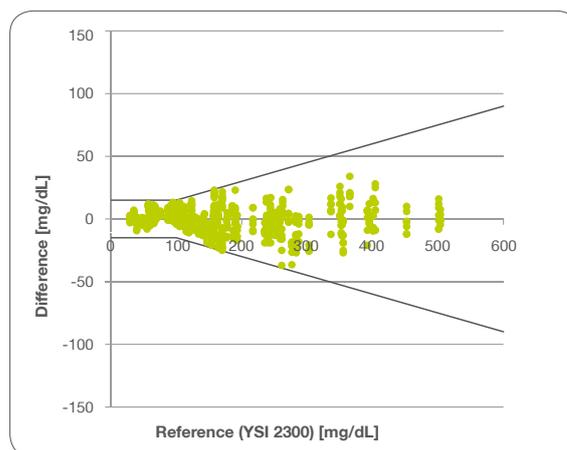
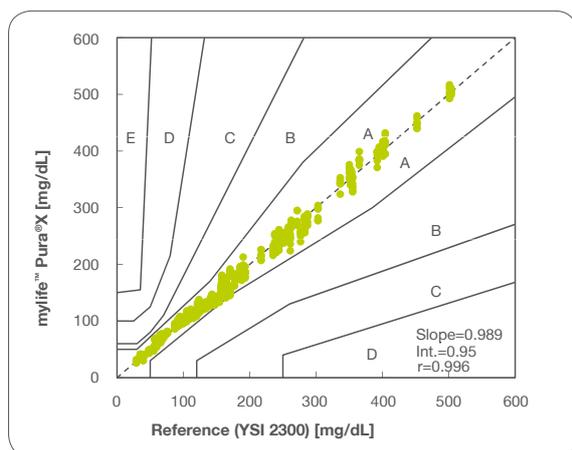
- measurement precision
- system accuracy and
- influence quantities (especially haematocrit area)

have been defined more demanding. In this more selective context, mylife™ Pura® X's advanced measuring technique leads to the following results^{1,2,7}:

System accuracy¹

ISO 15197:2013 demands $\geq 95\%$ of measurements within ± 15 mg/dL (± 0.83 mmol/L) at glucose concentration < 100 mg/dL (< 5.55 mmol/L) and $\pm 15\%$ at glucose concentration ≥ 100 mg/dL (≥ 5.55 mmol/L).

100 % of mylife™ Pura® X test results (636 of 636 pooled measurements) fall in both areas together and A-coverage of 100 % in the Consensus Error Grid (CEG) (AB zones must be $> 99\%$):



Definition of the error grid zones:

- Zone A** No effect on clinical action
- Zone B** Altered clinical action – little or no effect on clinical outcome
- Zone C** Altered clinical action – likely to affect clinical outcome
- Zone D** Altered clinical action – could have significant medical risk
- Zone E** Altered clinical action – could have dangerous consequences

Measurement precision²

mylife™ Pura® X shows strong results when tested for measurement repeatability (ten meters, three test strip lots and five glucose concentrations): $SD \leq 1.5$ mg/dL (≤ 0.08 mmol/L) (TNO⁸ acceptance criteria:

$SD \leq 10$ mg/dL (≤ 0.56 mmol/L) at glucose concentration < 100 mg/dL (< 5.55 mmol/L)) and $CV \leq 2.0\%$ (TNO criteria: $CV \leq 5\%$ at glucose concentration ≥ 100 mg/dL (≥ 5.55 mmol/L)).

Haematocrit⁷

mylife™ Pura® X achieves a hematocrit range of 30–57 % for glucose concentration between 30 and 400 mg/dL (1.67 and 22.2 mmol/L).

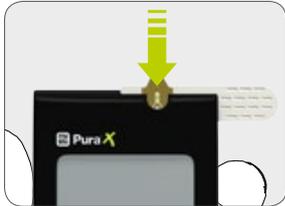
Clinical conclusion

The advanced measuring principle of mylife™ Pura® X leads to precise and accurate measuring quality which exceeds the minimal measurement requirements of the new edition of ISO 15197:2013. With 100 % of all pooled measurements in zone A of the CEG, measuring with mylife™ Pura® X leads to correct clinical conclusions.



mylife™ Pura® X

Easy to use and blood-free removal of test strips



The device automatically activates when a test strip is inserted



Autocoding automatically identifies the strip code

Safe and easy application makes mylife™ Pura® X the ideal blood glucose meter for patients of any age. The device switches itself on when a test strip is inserted and automatically identifies the strip code. There will be an audio signal when the large and solid strip is inserted correctly. When applying blood, the test strip visually indicates if enough blood has been applied.



Easy application of blood



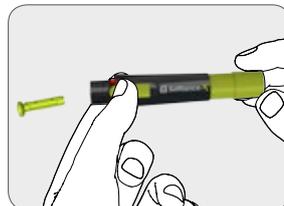
Strip removal without blood contact

Measurement results are easy to read due to large numbers and an illuminated display.

The unique test strip design simplifies application: mylife™ Pura® X is the first blood glucose meter that features lateral insertion and blood-free removal of test strips. This enables a safe and hygienic test strip handling.



Puncture depth adjustment



Lancet ejection

The mylife™ Softlance lancet device facilitates smooth and gentle collection of blood samples. The vibration-absorbing lamellae allow precise application of the lancet and thus minimal puncture injury. Seven increments support a precise adjustment of the puncture depth.

The safety concept is both unique and ingenious: mylife™ Softlance features a lancet ejection and a safety function for safe and easy lancet changes.

Moreover, mylife™ Softlance comes with an adapter that allows to collect blood samples from alternative locations.



Safety function



Adapter for alternative sampling locations



In an external customer survey⁹, conducted in April and May 2015 in Germany, 83% of the mylife™ test strip users are “extremely satisfied” to at least “satisfied” with the test strips and their handling. In fact, 29% of users were “very satisfied” and a further 29% “extremely satisfied”. Positive remarks were made in particular about the size of the test strips, the rigidity as well as the application of the blood sample and the removal of the test strip without contact to blood. Based on the high and very high satisfaction values, the quality (size, material and stiffness) of the test strips and the application of the blood sample are regarded as the strengths of the mylife™ blood glucose test strips.

Technical data

Competitive product features

Product specifications	
Measurement technology	Electrochemical: GOD
Calibration	Plasma
Sample	Full capillary blood
Blood volume / Measurement time	0.75 µL / 5 seconds
Memory capacity	500 measurements including date and time
Measurement range	10–600 mg/dL (0.6–33.3 mmol/L)
Battery-saving mode	Automatic switch-off 2 minutes after the last action
Measurement temperature	10–40° C
Relative humidity	10–90 %
Haematocrit range	30–57 %
Power supply / Battery life	2 batteries CR2032 / approx. 1,000 tests
Dimensions / Weight	90.6 mm × 46 mm × 16.5 mm (H × W × D) / 53 g incl. batteries
Display / Display size	LCD / 47 mm × 33.5 mm (H × W)
Meter storage conditions	-10 to 60° C
Test strip storage conditions	4–30° C, <90 % relative humidity
PC software	Data can be transferred to mylife™ Software, Diabass®, SiDiary, diasend® (special cable required)

mylife™ Pura® X

Product overview

	Item
Blood glucose measurement starter set	mylife™ Pura® X set
Test strips	mylife™ Pura® test strips
Lancets	mylife™ Lancets mylife™ Lancets multicolor
Safety lancets	mylife™ SafetyLancets mylife™ SafetyLancets Comfort

¹ Bionime Corporation: Test Report for the System Accuracy Evaluation of Rightest Blood Glucose Monitoring System GM550 (mylife™ Pura® X), Min-Sheng General Hospital, Taiwan, 05.2015.

² Bionime Corporation: Test Report for the Evaluation of Precision (ISO 15197:2013), Model GM550 (mylife™ Pura® X) and Strip GS550 (mylife™ Pura®), Taichung, Taiwan, 04.2015.

³ ISO 15197:2013; In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. International Organisation for Standardization, Geneva.

⁴ Ypsomed GmbH: User survey mylife™ Pura®, 06.2015. Data on file.

⁵ Bionime Corporation: Declaration Letter of Equivalence of mylife™ Pura® and mylife™ Pura® X, 2014. Available on request.

⁶ Hsu C. et al.: Fabrication of a Glucose Biosensor Based on Inserted Barrel Plating Gold Electrodes. Anal Chem 2009, 81(1): 515-518.

⁷ Bionime Corporation: Test Report for the Evaluation of Hematocrit ISO 15197:2013) of GM550 (mylife™ Pura®), Taiwan, 04.2015.

⁸ Post H. et al.: Portable In-Vitro Blood Monitor Systems for (Self)-Monitoring-Blood Glucose Monitors – Particular Requirements and Test Methods. TNO Quality Guideline PG / TG / 2001 045 2001. Delft: TNO, 2001.

⁹ 2hm & Associates GmbH: User survey on the acceptance of “mylife™ test strips and their handling” and “mylife™ AutoLance™”, Mainz, 05.2015.



Diabetescare

More **freedom.**
More **confidence.**
With **mylife™.**



Blood glucose
monitoring systems



Pen needles and
safety pen needles



Infusion systems



Accessories and
services

mylife™ is a range of products and services for people with diabetes. It offers them everything they need for easy and reliable self-treatment, giving them more freedom and more confidence for the life they want to lead.

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