mylife 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

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® features Autocoding and the innovative High Definition Signal Transmission (HDST) technology, which offers interference-free signal transmission, making it one of the most accurate and precise meters in its class.[1,3] Even if the acceptance criteria of the new ISO 15197:2013 are applied, mylife™ Pura® delivers excellent measurement accuracy.[1]

mylife™ Pura® 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 survey, conducted with more than 14 000 patients, 97 % of those polled rated the reliability of the mylife™ Pura® device as “very good” and “good”. A top rating achieves the display size as well as the readability: 99 % of the patients evaluated both criteria as “very good” and “good”. The confidence of the user-friendliness, which has been rated as important, reaches 93 %.[4]

mylife™ Pura® is identical in design with mylife™ Pura® X[2]
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

mylife™ Pura® fullfills high accuracy and precision standards

The accuracy requirements of ISO 15197:2013 are met by 99.5 %[1]

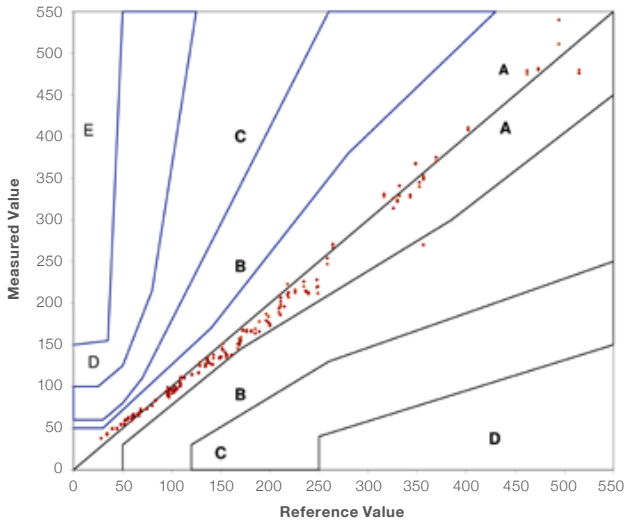
Evaluation of the system accuracy[1] according to DIN EN ISO 15197

To assess the accuracy of mylife™ Pura®, measurements were taken from 100 capillary blood samples of different subjects and compared to the reference YSI 2300 STAT Plus glucose analyzer. The distribution of blood samples corresponded to the glucose concentration categories required by the ISO standard. Samples were measured with one test stripe lot and two meters.

The latest study results show that mylife™ Pura® fulfills not only the requirements of DIN EN ISO 15197:2003 (99.5 % of the test results fall within the accuracy requirements) but also the more stringent limits of the new ISO 15197:2013 which requires that at least 95 % of the measurements under and above 100 mg/dL have a maximum deviation of 15 mg/dL respectively 15 % from the reference. With mylife™ Pura® this requirement is exceeded: 100 % of the measurements had a deviation of less than 15 mg/dL (for glucose < 100 mg/dL) and 99 % are within 15 % deviation at glucose levels > 100 mg/dL.

Consensus Error Grid Analysis[1]

The Consensus Error Grid Analysis based on the data shows that mylife™ Pura® had 100 % of the results within Zone A and Zone B. 99.5 % of the data pairs (199 / 200) are in zone A which corresponds to exceptional clinical accuracy. The exceptional measurement performance of mylife™ Pura® has also been confirmed by a further study.[6]



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

Evaluation of the reproducibility[1] according to TNO guideline

The evaluation of measurement precision was conducted on the basis of the criteria of the TNO guideline[7]. The quality criteria require a standard deviation of ≤ 10 mg/dL for glucose concentrations of < 100 mg/dL and a coefficient of variation of ≤ 5 % for glucose concentrations of ≥ 100 mg/dL. The investigation was conducted with two test strip batches using 10 blood samples from different volunteers in 5 glucose concentration ranges. The investigation shows that mylife™ Pura®'s maximum standard deviation of 2 mg/dL (for glucose levels of < 100 mg/dL) and maximum coefficient of variation of 2.4 % (for glucose levels of ≥ 100 mg/dL), falls well short of the limits and achieve a very high level of measurement precision.

my life Pura X

Made for life.

High Definition Signal Transmission (HDST)

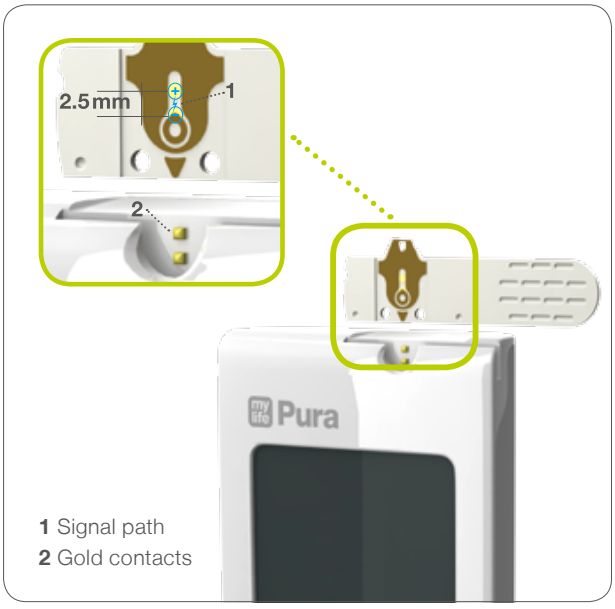
Technology for high measurement accuracy and precision

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 potential (other technologies are also common in the market, e.g. photometry). The higher the voltage measured, the higher the blood glucose value.

However, the voltage generated for the measurement is extremely low and therefore sensitive to interference. The signal transmission is crucial for the quality of the measurement. The shorter the conduction path and the better the conductive material, the more accurate the measurement will be.[5]

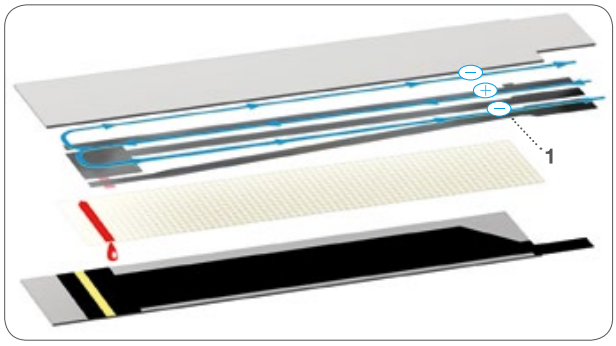
The concept of the shortest possible signal path has been consistently applied. All unnecessary amounts of conductive distance were eliminated on the test strips, and gold electrodes in the device as well as in every individual test strip ensure optimal signal transmission. Furthermore, gold-plated battery contacts guarantee a stable operating voltage at all times.[5]

mylife™ Pura® with High Definition Signal Transmission



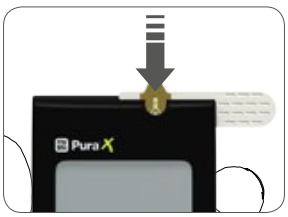
Short signal paths permit interference-free transmission of the signal. Gold is one of the most corrosion-resistant of all established conductive materials, ensuring optimal signal transmission from test strip to measurement device.[5]

Conventional test strip



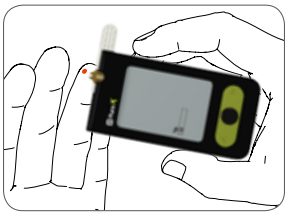
With conventional test strips where blood is applied from the front, the signal path is significantly longer and thus more vulnerable to interference. Also, the contacts between measurement device and test strip are made from conventional metal, which will corrode faster, thus impacting the signal and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

mylife™ Pura® X
Easy to use and blood-free removal of test strips

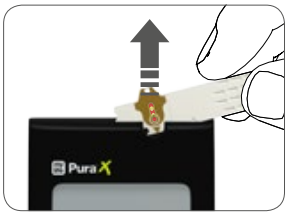


Autostart automatically switches on the device when a test strip is inserted

Autocoding automatically identifies the strip code



Easy application of blood



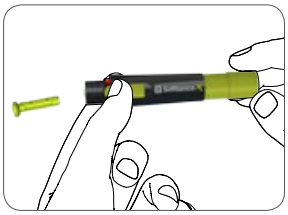
Strip removal without blood contact

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.

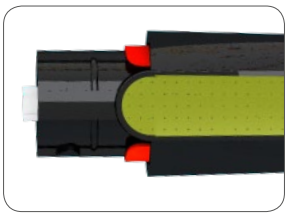
Measurement results are easy to read due to large numbers and an illuminated display.

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

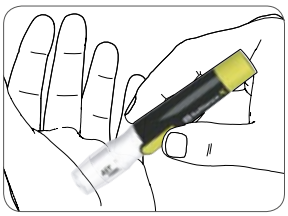
Puncture depth adjustment



Lancet ejection



Safety function



Adapter for alternative sampling locations

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 precise adjustment of the puncture depth.

The safety concept is both unique and ingenious: mylife™ Softlance features 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.

Technical data
Competitive product features

Product specifications	
Measurement technology	Glucose oxidase, electro-chemical sensor
Signal transmission	High definition signal transmission (HDST) via gold electrodes
Calibration	Plasma
Sample	Full capillary blood
Minimum sample volume	1.0 µl
Coding	Autocoding
Measurement range / time	10 – 600 mg/dL (0.6 – 33.3 mmol/L) / 5 seconds
Storage capacity	500 blood glucose values including date and time
Battery-saving mode	Automatic switch-off 2 minutes after the last action
Operating temperature	10 – 40° C
Relative humidity	10 – 90 %
Haematocrit range	30 – 60 %
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 read with Diabass, mylife™ SiDiary, 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, standard
	mylife™ Lancets, multicolor

1 Freckmann G. et al.: Evaluation of 12 Blood Glucose Monitoring Systems for Self-Testing: System Accuracy and Measurement Reproducibility. Diab Tech Ther 2014, 16(2): 113-122.
2 Bionime Corporation: Declaration Letter of Equivalence of mylife™ Pura® and mylife™ Pura® X, 2014. Available on request.
3 Baumstark A. et al.: Assessment of the system accuracy of the new Pura blood glucose monitoring system in accordance with EN ISO 15197 and comparison with the established system OneTouch Ultra 2. (Bewertung der Systemgenauigkeit des neuen Blutglukosemesssystems mylife™ Pura® nach EN ISO 15197 und Vergleich mit dem etablierten System OneTouch Ultra 2). Poster no 325, DDG Leipzig, 2009.
4 Survey Ypsomed GmbH, Germany in 2009 (patients using mylife™ Pura®). Data on file.
5 Cheng-Teng Hsu et al.: Zensor R&D, BIONIME Corporation, and Department of Chemistry, National Chung Hsing University, Taiwan. "Fabrication of a Glucose Biosensor Based on Inserted Barrel Plating Gold Electrodes". Analytical Chemistry, 11/2008.
6 Hasslacher C. et al.: Analytical Performance of Glucose Monitoring Systems at Different Blood Glucose Ranges and Analysis of Outliers in a Clinical Setting. J Diabetes Sci Technol 2014, 8(3): 466-472.
7 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.

mylife 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.

700000808/10051811-MSTR-en/V02

Ypsomed Distribution AG // Brunnmattstrasse 6 // 3401 Burgdorf // Switzerland //
info@ypsomed.com // www.mylife-diabetescare.com // +41 34 424 41 11

YPSOMED
SELFCARE SOLUTIONS