



Unio™

Enjoy innovation.

A-coverage of 100%¹
in the Consensus
Error Grid (CEG)*



swissdesign+

mylife™ Unio™ – inspired by users, designed for you.

- Modern blood glucose monitoring system for intuitive operation
- Side-loading test strip for hygienic strip removal without blood contact
- Solid test strip design with good grip for easy handling
- Ultra-compact design for more discreetness
- Comfortable blood sampling with the automatic load and release function of mylife™ AutoLance™

* ISO 15197:2013 demands $\geq 99\%$ in the zones A and B together



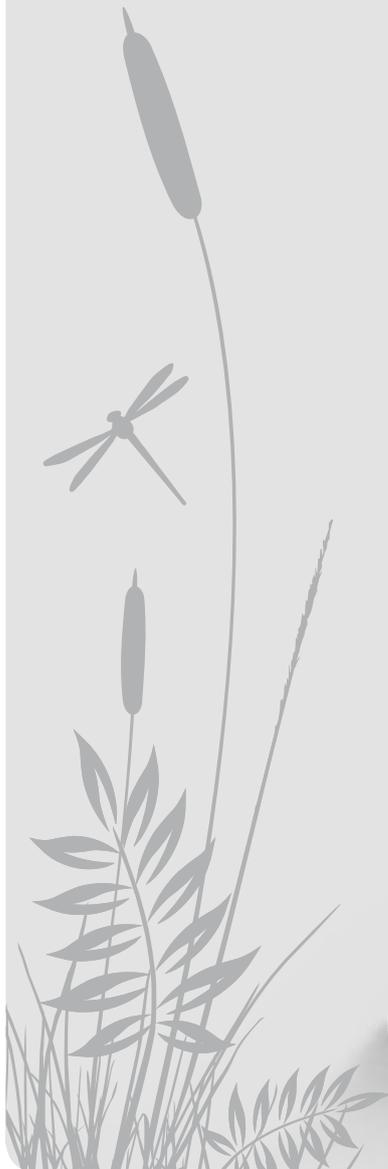
More freedom. More confidence. With mylife™.

YPSOMED
SELFCARE SOLUTIONS



Unio™

Made for life.



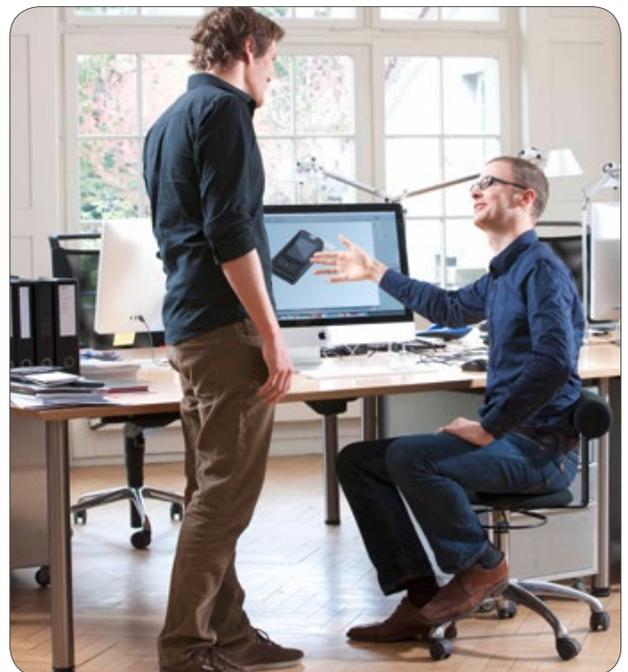


Unio™

mylife™ Unio™ Inspired by users – designed for you

We asked diabetes patients what they consider to be the ideal blood glucose meter. Based on their requests and suggestions, we developed mylife™ Unio™ – a patient focused blood glucose monitoring system that meets user requirements. Inspired by users – designed for you.

Every detail is tailored to the demands of diabetes patients: a discreet and high quality blood glucose meter with intuitive operation and hygienic test strip handling and a lancing device with comfortable blood sampling – all combined in a compact and practical case. This makes mylife™ Unio™ the optimal companion every day, whether your patients are at home, at work or on-the-go.



See handling movie

An all-embracing concept Design, technology and functionality all in one

mylife™ Unio™ will motivate your patients to enhance their blood glucose control through its innovative technology in a miniaturised format. Its centrepiece is a compact blood glucose meter that meets high standards – it is easy to handle, accurate¹, precise²

and robust. The mylife™ AutoLance™ is a high-precision lancing device. With an automatic load and release function and constant pricking pressure, it ensures easy and virtually painless blood sampling.



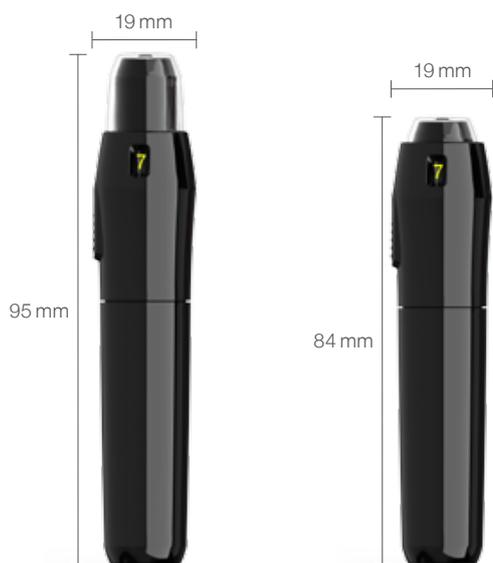
The user feedback of an ongoing survey³ of more than 740 patients show that we meet user needs: The overall satisfaction with mylife™ Unio™ achieves 97%. More than 93% of those polled rate the application of the blood sample and the size of the meter of mylife™ Unio™ as “very good” or “good”, the design of the meter and its reliability reach 98% of confidence. About 93% of the patients evaluate the almost painless pricking of the mylife™ AutoLance™ as “very good” or “good”.

 **mylife™ Unio™**
Technology in a compact format



mylife™ Unio™ blood glucose meter

- Modern design, small and handy
- Easy-to-read menu-based LCD display with intuitive operation
- Display available in different languages
- Fast and accurate¹ results
- Mini-USB: Simple plug & play diabetes software (mylife™ Software, Diabass®, SiDiary, diasend®)
- Alarm functions: 4 daily alarms
- Event markers: up to 4 markers can be selected for each measurement and be edited subsequently



mylife™ AutoLance™ lancing device

- Automatic load and release function in one step
- Automatic pressure control produces steady pricking pressure and thus ensures almost painless blood sampling
- Safety button prevents unintentional release
- 7 variable puncture depths
- Practical bayonet lock and stop function for easy lancet replacement
- AST cap available for alternative test sites



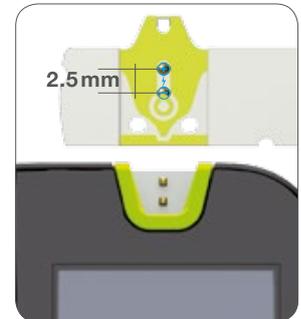
mylife™ Unio™ test strip

- High accuracy and precision with GDH-FAD enzyme^{1,2}
- Autocoding
- Interference-free measurements with High Definition Signal Transmission (HDST)
- Large and solid test strip
- Test strip removal without blood contact
- Easy taking of test strips from compact vial



High Definition Signal Transmission (HDST) and Autocoding for reliable accuracy and precision^{1,2}

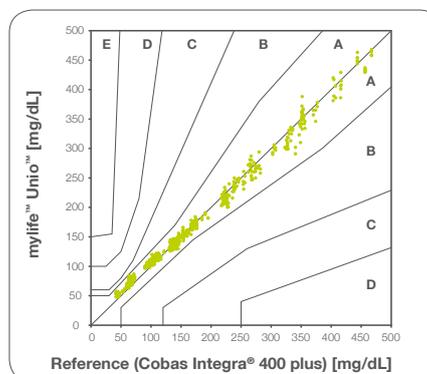
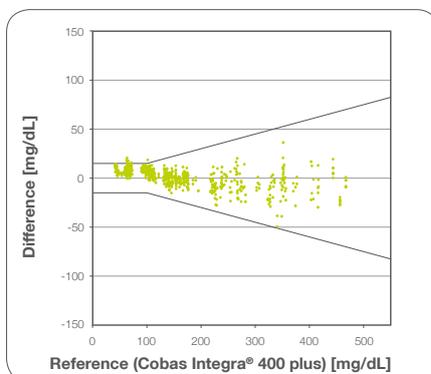
Signal transmission from the test strip to the device is crucial for the quality of measurement results. mylife™ Unio™ uses the innovative High Definition Signal Transmission (HDST) technology, which enables precise and accurate signalling. The very short signal path of just 2.5 mm and gold contacts minimise interference and thus ensure the best possible signal transmission.⁴ The meter automatically identifies a specific test strip lot code after the insertion of a mylife™ test strip into mylife™ Unio™ (Autocoding). This Autocoding feature allows the meter to cope with test strip production variations in order to ensure a high level of accuracy and precision.



In the context of the more demanding requirements of ISO 15197:2013⁵, mylife™ Unio™'s advanced measuring technique leads to convincing results:

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). The three reagent system lots achieved the following test results within ± 15 mg/dL (± 0.83 mmol/L) and $\pm 15\%$: 99.5%, 98.5% and 99%. 100% of mylife™ Unio™ test results (600 of 600 pooled measurements) cover zone A in the Consensus Error Grid (CEG) (A and B zones must be $\geq 99\%$).



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™ Unio™ shows very good results when tested for measurement repeatability (ten meters, three test strip lots at five glucose ranges): $SD \leq 2.2$ mg/dL (≤ 0.12 mmol/L) (TNO⁶ acceptance criteria:

$SD \leq 10$ mg/dL (≤ 0.56 mmol/L) at glucose concentrations < 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)).

Clinical conclusion

The advanced measuring principle of mylife™ Unio™ leads to excellent measuring quality which clearly exceeds the minimal measurement requirements of the more demanding ISO 15197:2013. With 100% of all pooled measurements in zone A of the CEG, measuring with mylife™ Unio™ leads to correct therapeutical decisions.



High measurement convenience

In just a few steps



Removing test strip

Take the large and solid test strip out of its vial and close the box again.



Applying blood

Apply the blood from above onto the test strip. The channel absorbs the blood sample while the blood sample window on the test strip shows the filling level.



Inserting test strip

The device activates automatically and recognizes the strip code (Autocoding).



Reading the measurement

Read the measurement on the LCD display and set markers.



Extracting blood

Holding down the safety button, gently push against the fingertip. Precise and almost painless lancing thanks to the automatic load and release function.



Removal of test strip without blood contact

Remove the strip and dispose.



The evaluation of user-friendliness was conducted by 85 users following a two-week test phase with mylife™ Unio™. The users were satisfied with the user-friendliness of mylife™ Unio™ and gave it a positive assessment all round. The device is evaluated as being user-friendly and easy to operate.⁷



Measurement straight from the mylife™ SmartCase™

Easy and discreet in any situation

Your patients will not only experience fast and discreet measurements with the mylife™ SoftCase, but also with the compact and practical mylife™ SmartCase™, which is available as an accessory. It's so handy to perform a check with this hard case that it can be done on-the-go.



- Compact integration of all components
- Discreet appearance without attracting attention
- Spare lancets compartment
- Easy disposal of used test strips



reddot design award
winner 2013

**Unio™**

Technical data

Competitive product features

Product specifications	
Technology	Electrochemical: GDH-FAD
Haematocrit range	20–70 % when blood glucose ≤ 200 mg/dL (11.1 mmol/L) 20–60 % when blood glucose > 200 mg/dL (11.1 mmol/L)
Calibration	Plasma
Sample	Capillary, venous and arterial whole blood
Blood volume / Measurement time	0.7 µL / 5 seconds
Memory	1000 measurements
Measurement range	10–600 mg/dL (0.6–33.3 mmol/L)
Measurement temperature	6–44 °C
PC connection	Via USB (mini-USB connection)
PC software	Data can be transferred to mylife™ Software, Diabass®, SiDiary and diasend®
Screen and operation	LCD screen with multilingual menu navigation. Simple and intuitive with helpful symbols
Illumination	Illuminated screen for good readability day and night
Error messages	Error message with symbols and suggestion for correcting the error
Alarm functions	4 alarms with possible repeat function
Event markers	Markers for preprandial and postprandial, sport, illness, special. Up to 4 markers for each measurement result
Power supply	2 CR2032 coin cell batteries (about 600 measurements)
Lancing device	mylife™ AutoLance™ with automatic load and release function



mylife™ Unio™ and accessories

Product overview

	Item	Country
Blood glucose measurement starter set	mylife™ Unio™ set	Austria, Denmark, Finland, France, Germany, India, The Netherlands, Norway, Sweden, Switzerland, United Kingdom
Test strips	mylife™ Unio™ test strips	Austria, Denmark, Finland, France, Germany, India, The Netherlands, Norway, Sweden, Switzerland, United Kingdom
Lancets	mylife™ Lancets	International
	mylife™ Lancets multicolor	International
Accessory	mylife™ Unio™ SmartCase™	International

1 IDT Ulm: System accuracy evaluation of mylife™ Unio™ blood glucose monitoring system based on ISO 15197:2013 versus Cobas Integra® 400 plus. Institute for Diabetes-Technology Research and Development Corporation at the University of Ulm, Principal Investigator: N. Jendrike, 08.2016.

2 Bionime Corporation: Test Report for the Evaluation of Precision (ISO 15197:2013), Model GM720 (mylife™ Unio™) and Strip GS720 (mylife™ Unio™), Taichung, Taiwan, 10.2015.

3 Survey Ypsomed GmbH, Patients using mylife™ Unio™, Germany, 03.2016. Data on file.

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

5 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.

6 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.

7 SKUP Scandinavian evaluation of laboratory equipment for primary health care. Report from the evaluation SKUP/2013/100, www.skup.nu.

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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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