

Summary of Safety and Performance for Blood Glucose Monitoring System (Model: 1004, 1004+)

Foreword

This Summary of Safety and Performance (SSP) is intended to provide public access to an updated summary of the main aspects of the safety and performance of the Blood Glucose Monitoring System.

The SSP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions.

The SSP is not intended to give general advice on the diagnosis and/or treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation.

1. Device Identification and General Information

1.1. Device Name

Device Name: Blood Glucose Monitoring System

Model Name: Exactive Vital, Exactive Vital +

Model No: 1004, 1004+

1.2. Manufacturer

MicroTech Medical(Hangzhou) Co., Ltd.

No. 108 Liuze St., Cangqian, Yuhang District, Hangzhou, 311121 Zhejiang

P.R.China.

SRN: CN-MF-000001157

1.3. Basic UDI-DI and EMDN Code

Product Name	Trade Name	Model No.	Basic UDI-DI	EMDN Code
Blood Glucose Monitoring System	Exactive vital	1004	69585903W0201061004SC6	/
Blood Glucose Monitoring System	Exactive vital+	1004+	69585903W0201061004+SM9	/
Blood Glucose Meter	Exactive vital Exactive vital+	1004 1004+	69585903W0201061004W5	W0201060102
Blood Glucose Test Strip	Exactive Exactive+	1005	69585903W0201061005W7	W0101060101
Glucose Control Solution	Exactive	1005	69585903W0101061005GCMY	W0101060108

1.4. Risk Class

Class C (IVDR Annex VIII, Rule 4a, Rule 4b combined with Rule 3k)

1.5. Year when the device was first CE-marked under Regulation EU 2017/746

Not listed yet

1.6. Authorised representative

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595 AA, The Hague, Netherlands

Tel : +31644168999(Dutch)

Email:peter@lotusnl.com

Authorised Representative SRN: NL-AR-000000121

1.7. Notified Body

BSI Group The Netherlands B.V.

Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

Notified Body Identification Number: 2797

2. Intended use

2.1. Intended Purpose

The Blood Glucose Monitoring System is a quantitative assay designed for measuring glucose levels in fresh capillary whole blood samples. The system is intended for in vitro diagnostic home-use by patients with diabetes or by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. The system requires manual application of blood samples while providing automated readings.

2.2. Intended Patient Population

Diabetes patients who need to measure the glucose concentration and take the test results as reference only.

2.3. Contra-Indications and Limitations

- The Exactive Vital meters, test strips and other components of the Exactive Vital Blood Glucose Monitoring System 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 Vital Test Strips are for testing with fresh capillary whole blood.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 1.1-33.3mmo/L(20 to 600 mg/dL).
- The packed cell volume (hematocrit) should be between 30% and 55%. Outside of range may cause false results. Talk to your healthcare professional to find out your hematocrit level.
- At normal therapeutic level and up to high-test concentration level of Acetaminophen , Bilirubin, Cholesterol, Creatinine, EDTA, Galactose, Genstisicacid, Glutathione, Haemoglobin, Heparin, Ibuprofen, L-DOPA,Maltose, Methyl-DOPA, Pralidoxime Iodide, Salicylicacid, Tolbutamide, Triglycerides, Uric acid, will not significantly affect blood glucose results.
- Fatty substances (triglycerides up to 3,000 mg/dL or cholesterol up to 500 mg/dL have no major effect on blood glucose test results.
- Severely ill persons should not run the glucose test with the Exactive Vital Blood Glucose Monitoring System.
- 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 Exactive Vital 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.

3. Device description

3.1. General device description

The Exactive Vital/ Exactive Vital+ Blood Glucose Monitoring System is a quantitative assay for the detection of glucose in whole blood sample. Amperometric technology is used for the detection of glucose from testing the strip (with whole blood sample) on the meter.

Each system including meter, strip and control solution:

- The Exactive Vital Blood Glucose Monitoring System includes the Exactive Vital Blood Glucose Meter (Model: 1004), the Exactive blood glucose test strips (Model: 1005), and the Exactive control solution (Model: 1005).
- The Exactive Vital+ Blood Glucose Monitoring System includes the Exactive+ Blood Glucose Meter (Model: 1004+), the Exactive blood glucose test strips (Model: 1005), and the Exactive control solution (Model: 1005).

The Blood Glucose Monitoring System were distributed in EU market as per IVDD with Certificate No.HL1582538-1.

3.2. Work Principle

The Blood Glucose Test Strips are thin strips with a chemical reagent system. They work to measure the glucose concentration with the blood glucose meters. 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.

3.3. Description of the components

The Blood Glucose Monitoring System are including test strips, meters, and control solutions that belong to the In-vitro Diagnosis device. The Lancing device and sterile lancets are purchased from the third-party companies with MDR certification.

3.3.1. Test Strip

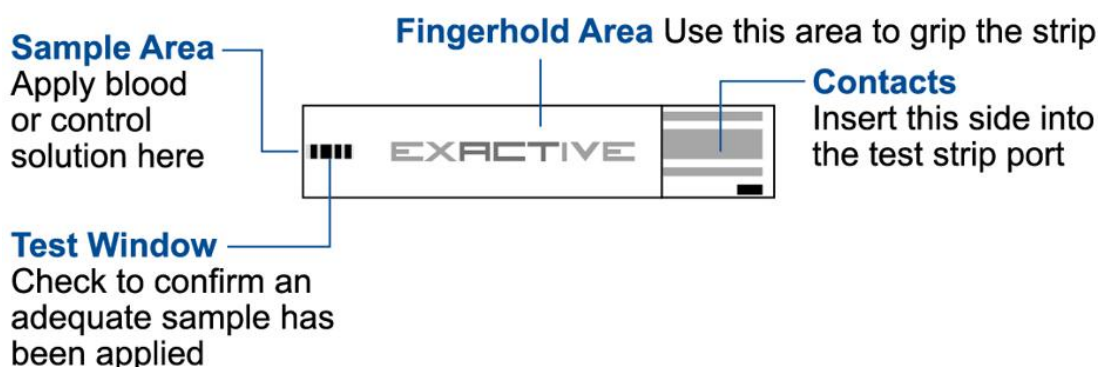


Figure 1 Blood glucose Test Strip (Illustration)

The test strip has a reagent system including glucose oxidase and mediator that reacts with the glucose in the whole blood sample to produce electrical current signal. This current is measured by the meter, and after calculation by the meter, the blood glucose concentration reading, calibrated to plasma reference, is displayed on the meter display.

3.3.2. Glucose Control Solution

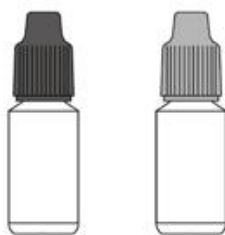


Figure 2 Glucose control solution (Illustration)

The quality control of Blood Glucose Monitoring System is performed by testing the test strip on meter with glucose control solution to confirm that the test strip and meter are working together properly. The glucose control solution contains a known concentration of glucose with preservatives in an aqueous based mixture. The control solution test result should fall within the predetermined control solution range for the given strip lot to confirm the accuracy of the Exactive Vital/ Exactive Vital +Blood Glucose Monitoring System group.

3.3.3. Meter

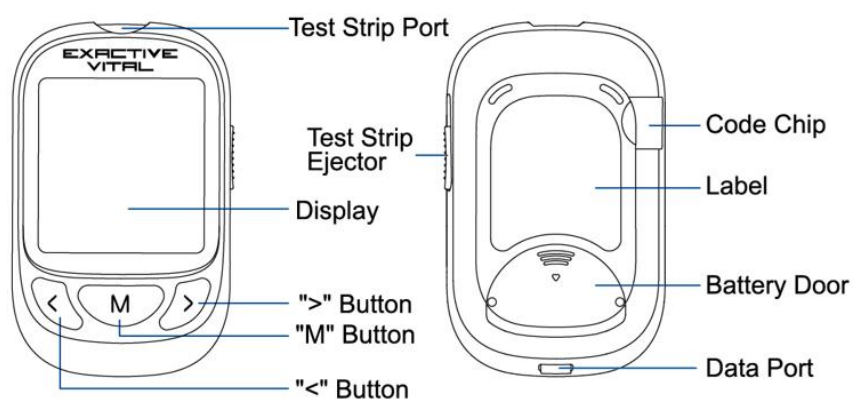


Figure 3 Blood Glucose Meter (Illustration)

The Blood Glucose Meter is mainly designed to read the Test Strips and to display the blood glucose concentration. The appearance of the meter is shown above. The meter for the Blood Glucose Monitoring System is manufactured by MicroTech Medical Co., Ltd.

3.3.4. Lancing Device

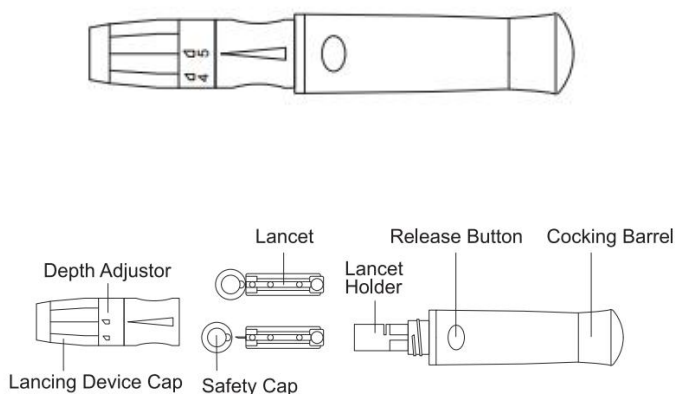


Figure 4 Lancing Device (Illustration)

The Blood Glucose Monitoring System is using for testing blood glucose levels using fresh capillary blood samples obtained from the fingertip, palm and forearm; thus, a lancing device is included in the starter kit. The lancing device included in the starter kit is manufactured by a third party vendor with sufficient CE certificates.

3.3.5. Sterile Lancets

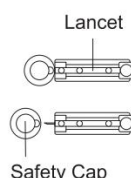


Figure 5 Sterile Lancet (Illustration)

The Blood Glucose Monitoring System is for blood glucose testing using the fingertip, palm and forearm sourced capillary blood samples; thus, lancets are included in the starter kit. The lancets included in the starter kit are manufactured by a third party vendor with sufficient CE certificates.

4. Applied Standards

No	Applicable Regulation/Directives/Standards	
1	Regulation 2017/746/EC	In Vitro Diagnostic Medical Devices Regulation
2	EN ISO 13485:2016	Medical device-Quality management system-requirements for regulatory
3	EN ISO 14971:2019	Medical devices-Application of risk management to medical devices
4	Directive 2011/65/EU	Restriction of the use of certain hazardous substances (RoHS)
5	Directive 2015/863/EU	List of Restricted Substances
6	Regulation (EU) No 1907/2006	REACH
7	ISO 18113-1:2022	In Vitro Diagnostic Medical Devices -Information Supplied by the Manufacturer (labelling) - Part 1: Terms, Definitions and General Requirements
8	ISO 18113-2:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
9	ISO 18113-3:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic

		instrument for professional use
10	ISO 18113-4:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing
11	ISO 18113-5:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing
12	EN ISO 15197:2015 (ISO 15197:2013)	In vitro diagnostic test systems Requirements for blood-glucose monitoring systems for self testing in managing diabetes mellitus
13	EN ISO 23640:2015 (ISO 23640:2011)	In vitro diagnostic medical devices-Evaluation of stability of in vitro diagnostic reagents
14	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
15	EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
16	EN 13532:2002	General requirements for in vitro diagnostic medical devices for self-testing
17	ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
18	ISO 20417:2021	Information supplied by the manufacturer of medical devices
19	ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
20	IEC 61010-1:2010+A1:2016 EN 61010-1:2010+A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements
21	IEC 61010-2-101:2018 EN 61010-2-101:2017	Standard Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic(IVD) medical equipment
22	IEC 61326-1:2020 EN IEC 61326-1:2021	Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements
23	IEC 61326-2-6:2020 EN IEC61326-2-6:2021	Electrical equipment for measurement, control and laboratory use

24	EN 62304:2006+A1:2015	Medical device software – Software life-cycle processes
25	ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems
26	ISO 9227:2017	Corrosion tests in artificial atmospheres — Salt spray tests
27	EN 13641:2002/AC:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents

5. Risks and warnings

Contact your healthcare professional if you are concerned about the use of the device or about the results. This document is not intended to replace a consultation with your healthcare professional, if needed.

5.1. Potential risks control and management

According to the requirements of CQP0801 Regulation on Risk Management, ISO 14971 and ISO/TR 24971, carried out the product risk management work, and made a systematic and comprehensive analysis of various risks of the product.

5.2. Remaining risks and undesirable effects

In accordance with the Risk Management Regulations of CQP0801, ISO 14971 and ISO/TR 24971, the risk of this product has been reduced to an acceptable standard through corrective/preventive measures.

5.3. Warnings and precautions

The related warnings and precautions are mentioned in the IFU after risks analysis.

5.4. Summary of any field safety corrective actions including field safety notices, if applicable

Not applicable.

6. Summary of Performance Evaluation and PMPF

6.1. Scientific validity of the device

According to the World Health Organization (WHO) & International Diabetes federation (IDF), American Diabetes association (ADA), and European Association for the Study of Diabetes (EASD) diagnostic definition of diabetes, diabetes is diagnosed by the result of plasma glucose or glycosylated hemoglobin. The Exactive Vital Blood Glucose Monitoring System is designed to measure the glucose concentration in a whole blood sample and present plasma blood glucose results. The test results can be used for users' daily blood glucose monitoring and provide reference for daily blood glucose control.

6.2. Performance Data

The Exactive Vital Blood Glucose Monitoring System complies with the requirements of EN ISO 15197:2015(In vitro diagnostic test systems-Requirements for blood-glucose monitoring systems for self- testing in managing diabetes mellitus)

System measurement range: 20 - 600 mg/dL (0.6-33.3 mmol/L)

Sample size:0.6 uL

Test time: 5 Seconds

System Accuracy

The capillary blood glucose measurements from at east 100 participants were taken by a trained technician using the Blood Glucose Meter(y). Capillary blood samples were obtained from fingertip, Palm,Forearm for the Exative 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 in the table below.

Fingertip Sample Site Tested by Technician			
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
398/882(45.1%)	792/882(89.7%)	882/882(100%)	882/882(100%)
System Accuracy Results for Glucose Concentration < 100 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
88/168(55.3%)	153/168(91.0%)	168/168(100%)	168/168(100%)
System Accuracy Results for both Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL			
Within $\pm 15\%$ or ± 15 mg/dL			
1050/1050(100%)			

Palm Sample Site Tested by Technician			
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
364/882(41.2%)	645/882(73.1%)	882/882(100%)	882/882(100%)
System Accuracy Results for Glucose Concentration < 100 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
73/168(43.4%)	142/168(84.5%)	168/168(100%)	168/168(100%)
System Accuracy Results for both Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL			
Within $\pm 15\%$ or ± 15 mg/dL			
1050/1050(100%)			

Forearm Sample Site Tested by Technician			
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
374/882(42.4%)	678/882(76.8%)	882/882(100%)	882/882(100%)
System Accuracy Results for Glucose Concentration < 100 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
74/168(44.0%)	150/168(89.2%)	168/168(100%)	168/168(100%)
System Accuracy Results for both Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL			
Within $\pm 15\%$ or ± 15 mg/dL			
1050/1050(100%)			

User Performance

The fingertip capillary blood glucose measurements from at least 100 participants were taken by Layperson using the Exactive Vital+ Blood Glucose Meter.

Fingertip Sample Site Tested by Layperson			
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
389/882(44.1%)	828/882(93.8%)	882/882(100%)	882/882(100%)
System Accuracy Results for Glucose Concentration < 100 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
72/168(42.8%)	164/168(97.6%)	168/168(100%)	168/168(100%)
System Accuracy Results for both Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL			
Within $\pm 15\%$ or ± 15 mg/dL			
1050/1050(100%)			

Repeatability

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

	mg/dL	44.2	90.6	142.9	240.4	368.6
Mean Value	mmol/L	2.45	5.03	7.94	13.35	20.48
95% Confidence interval	mg/dL	2.09	2.80	3.83	7.11	10.25
Lower for Standard deviation	mmol/L	0.12	0.16	0.21	0.39	0.57
95% Confidence interval	mg/dL	2.45	3.29	4.50	8.35	12.03
Upper for Standard deviation	mmol/L	0.14	0.18	0.25	0.46	0.67
Coefficient of variance(%)		5.1%	3.3%	2.9%	3.2%	3.0%

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 Value	mg/dL	39.9	119.2	347.6
	mmol/L	2.22	6.62	19.31
95% Confidence interval Lower for Standard deviation	mg/dL	1.75	3.49	9.69
	mmol/L	0.10	0.19	0.54
95% Confidence interval Upper for Standard deviation	mg/dL	2.06	4.10	11.38
	mmol/L	0.11	0.23	0.63
Coefficient of variance(%)		4.7%	3.2%	3.0%

6.3. Summary of Performance and safety

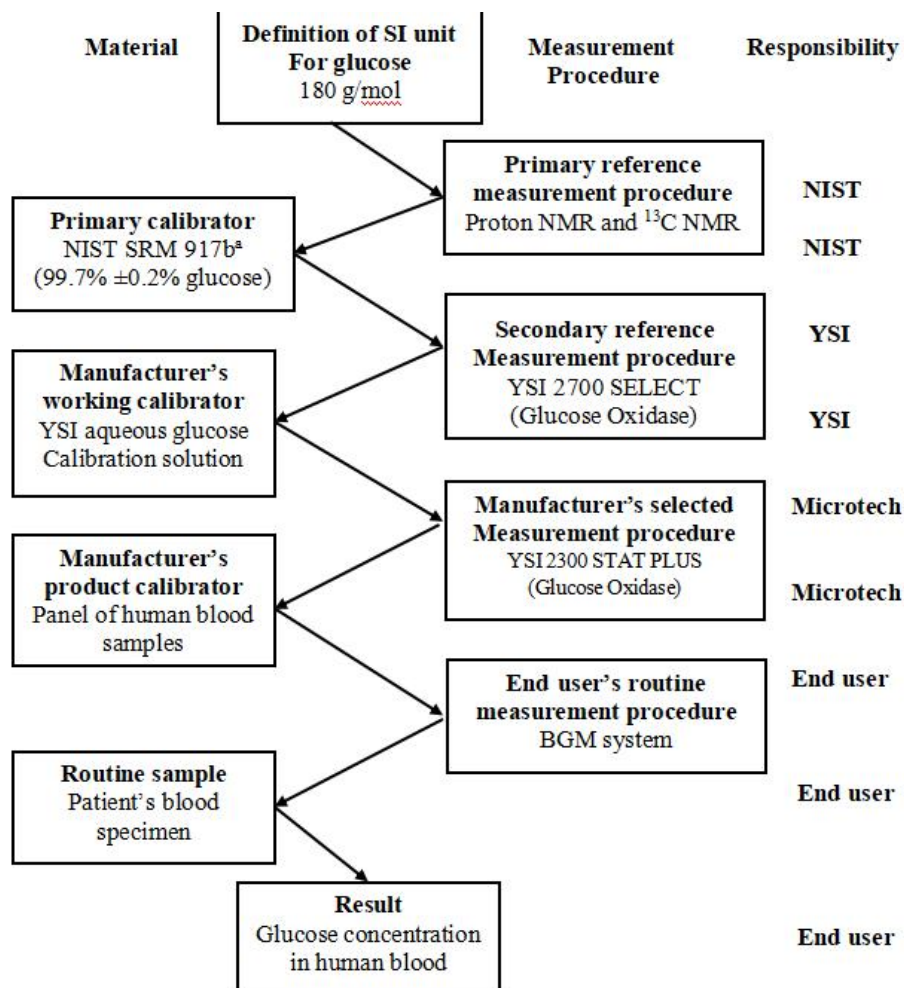
The precision, accuracy, Interference, temperature, humidity, hematocrit, drop, stability and other properties of the whole system were verified and evaluated, and the results showed that all the performance indicators of the system met the requirements of ISO 15197:2013. At the same time, safety regulations and EMC third-party testing also meet the regulatory requirements.

6.4. Post-market performance follow-up

According to the requirements of IVDR, a post-market performance follow-up plan is set to evaluate whether the product performance meets the requirements of EN ISO 15197:2015 after the devices are listed.

7. Metrological traceability of assigned values

A system traceability chain for the Blood Glucose Monitoring System is illustrated below:



^a NIST SRM917b refers to the Certificate of Analysis issued by the National Institute of Standards and Technology (NIST) for the standard reference material (SRM) 917b, D-glucose (dextrose), used for calibration in this example.

Note: This illustration was modified from a full traceability chain taken from ISO 17511:-, 4.3.3 h.

7.1. The unit of measurement

The international units “mg/dL” or “mmol/L” is used according to customer requirements.

7.2. Calibration

YSI 2300 is selected as the reference instrument. Test results for this product can be traced to NIST SRM917b and ultimately to the definition of the international Unit of glucose (180g/mol).

8. Suggested profile and training for users

The IFU and Quick Operation Card will be provided to users for profile and training.

9. Public Revision History

Version No.	Date issued	Change description	Revision validated by the Notified Body
V1.0	March 2023	Document created.	☐ YES Validation language: English ☒ No
V2.0	October, 2024	Update intended purpose, basic UDIs, Classification rules, and Performance Data. Correct the NB number	☐ YES Validation language: English ☒ No
V3.0	January, 2025	Correct the typo. Mark the NB's validation status as "YES"	☒ YES Validation language: English ☐ No