

PRODUCT DATA SHEET

DIABETES CARE



 **SURE**TM
Sure and simple

SMART DUO

FOR SELF-TESTING AND POINT-OF-CARE-TESTING
OF WHOLE BLOOD GLUCOSE AND β -KETONE



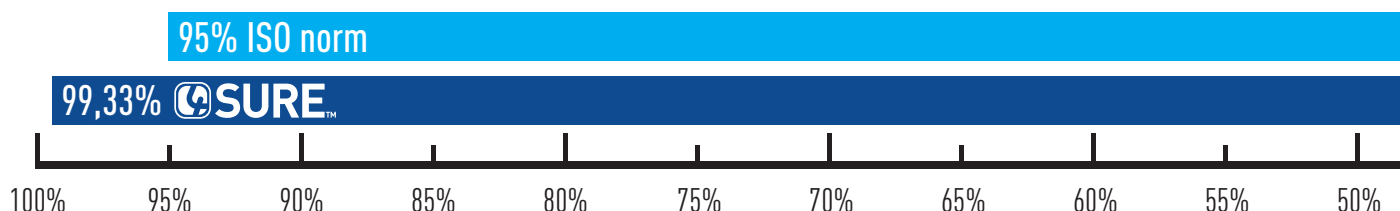
 **NIPRO**
MEDICAL EUROPE

PRODUCT FEATURES

- Memory bank holds 1000 tests with date/time
- 7, 14, 30, 60, and 90 day averaging
- Pre (AC) and post (PC) meal tagging
- Combined blood glucose and β -ketone testing (use appropriate test strips)
- β -ketone test reminder
- Results can be downloaded to the 4SURE Diabetes Manager Software (via Bluetooth or USB)
- Large, easy to read backlit display
- Test strip eject button
- Reagent enzyme: GDH-FAD (glucose) and β -Hydroxybutyrate Dehydrogenase (ketone)
- Audible fill detection
- Small sample size: 0.5 μ L (glucose) and 0.8 μ L (β -ketone)
- Wide haematocrit range: 0-70% (glucose) and 10-70% (β -Ketone)¹
- Automatic glucose control detection
- Suitable for Type 1 patients, drivers², diabetes in pregnancy³, and neonatal use (glucose testing only)¹
- Blood glucose test strip expiration date is 24 months from date of manufacture; opening of vial has no impact on expiration date⁴
- Measurement range from 0.55 to 33.3 mmol/L (glucose) and 0.1 to 8.0 mmol/L (ketone)
- Rapid reaction time: 5 sec (glucose) and 10 sec (β -ketone)

CE 0123
IVDD list b

SYSTEM ACCURACY



99.33% of 4SURE SMART DUO test results are within ± 0.83 mmol/L (low glucose levels) or $\pm 15\%$ (high glucose levels) of laboratory reference method test results.⁵

PRODUCT COMPLIANCE

- CE 0123, IVDD list b, IVD 98/79/EC
- ISO 13485
- EN 13532
- EN 13612
- ISO 14971
- ISO 15197:2013 / EN ISO 15197:2015
- ISO 15223-1
- ISO 18113-1
- ISO 18113-2
- ISO 18113-3
- ISO 18113-5
- ISO 23640
- IEC 61010-1
- IEC 61010-2-101
- EN 61326-1
- EN 61326-2-6
- EN 62304+A1
- EN 62366-1

1. ForaCare Suisse AG internal testing, Instructions For Use, 4SURE Blood Glucose Test Strip, Ver 1.0 2018/02

2. For driving with diabetes, follow DVLA guidelines

3. Follow NICE guidelines "Diabetes in pregnancy: management from preconception to the postnatal period".

4. ForaCare Suisse AG internal testing, Owner's Manual, 4SURE Smart Duo, Ver 1.0 2018/02

5. Assessment of System Accuracy, Intermediate Measurement Precision, and Measurement Repeatability of a Blood Glucose Monitoring System Based on ISO 15197. Jendrike N, et al., J Diabetes Sci Technol. 2018 Dec 14.

MANUFACTURING DETAILS

Legal manufacturer: Foracare Suisse AG, Switzerland

STERILIZATION AND SHELF LIFE

Sterilization

(Lancets only)

Gamma



Maximum Shelf Life

(from date of manufacture)

Glucose strips: 24 months

Ketone strips: 18 months



MATERIALS USED



PRODUCT RANGE OVERVIEW

Included in meter kit (individual box)

Reference code	Description
4S-800-4183400-005	4SURE Smart Duo meter kit, mmol/L, UK 4SURE Lancets, 30 G, 10 ct, EN/DE 4SURE Ketone strip, 1 ct, UK
4S-810-0000001-115	4SURE Glucose strips, 10 ct, UK
4S-716-5010200-016	4SURE Lancing device, UK/DE

Weight: 50 g (not including AAA battery)

Dimensions (L x W x H): 9 x 1.8 x 5.8 cm

Consumables available with prescription

Reference code	Description
4S-810-0000001-112	4SURE Glucose strips, 50 ct, UK
4S-810-4183401-001	4SURE Ketone strips, 10 ct, UK
4S-815-5084100-047	4SURE Lancets, 30 G, 100 ct, EN/DE/ES/FR/IT
4S-815-5084100-048	4SURE Lancets, 33 G, 100 ct, EN/DE/ES/FR/IT

PACKAGING DETAILS

Quantity per individual box	1 unit
Quantity per outer box	12 units
Number of outer boxes per Euro-pallet	72 (sea pallet), 54 (air pallet)

	Length	Width	Height	Weight	Quantity
Individual box	13.5 cm	5.5 cm	15.7 cm	0.32 kg	An individual box contains 1 unit
Outer box	37.7 cm	30.1 cm	21.2 cm	5.0 kg	An outer box contains 12 individual boxes (12 units total)

Languages

English (EN)







Storage conditions

Meter Storage Condition: -20°C to 60°C, RH <85% (Non-condensing)

System Operating Condition: 8°C to 45°C, RH 10-90% (Non-condensing)

Label details

	Individual box	Outer box
Product name	✓	✓
Product size	✓	✓
Quantity (pieces)	✓	✓
REF	✓	✓
LOT	✓	✓
	✓	✓
IVD	✓	—
CE	✓	✓
	✓	✓
	✓	✓

	Individual box	Outer box
	—	✓
	—	✓
	—	✓
	✓	—
	✓	✓
	✓	✓
	—	✓
	—	✓
	—	✓

For more information on products or how Nipro can help you switch patients to the 4SURE portfolio, please contact Nipro Customer Service at **0800 08 588 08**.

