



Body of Toccare (KN-15)



Sensor probe (KN-15P)

Specification

Measurement item	Regional Saturation of Oxygen (rSO ₂)		
	Total Hemoglobin index (T.Hbl)		
Measurement range	rSO ₂ (%) : 0 - 99%		
	T-Hbl : 0 - 1.0		
Sampling interval	0.5 s (fixed)		
Display time of trend graph	40 s / display		
Light Source	LED (770nm, 830nm : normal value)		
Optical output	Less than 1mW		
Measurement method	SRS-NIRS (near-infrared Spectroscopy)		
Power source	AAA battery × 2		
Rated input	DC 3V, Max. 0.2A		
battery Operating time	appx. 15h		
Sensor probe	Size S and L, made of synthetic rubber		
Sensor probe cable	40cm		
External dimensions	Width:60mm, Height:26mm, Length:82mm, Weight:0.1Kg		
Exclusive arm belt	Width:21mm, length:380mm, made of constrictive material		
Device approval number	227ADBZX00009000		
Class classification	Controlled medical device II / Medical equipment requiring specialist maintenance and management		
	Name	Model	Product code
Body	Toccare	KN-15	001
Probes	Sensor probe (L)	KN-15P (L)	002
	Sensor probe (S)	KN-15P (S)	003
Fixing belt	Fixing belt	KN-15B	004

■ Precautions of use

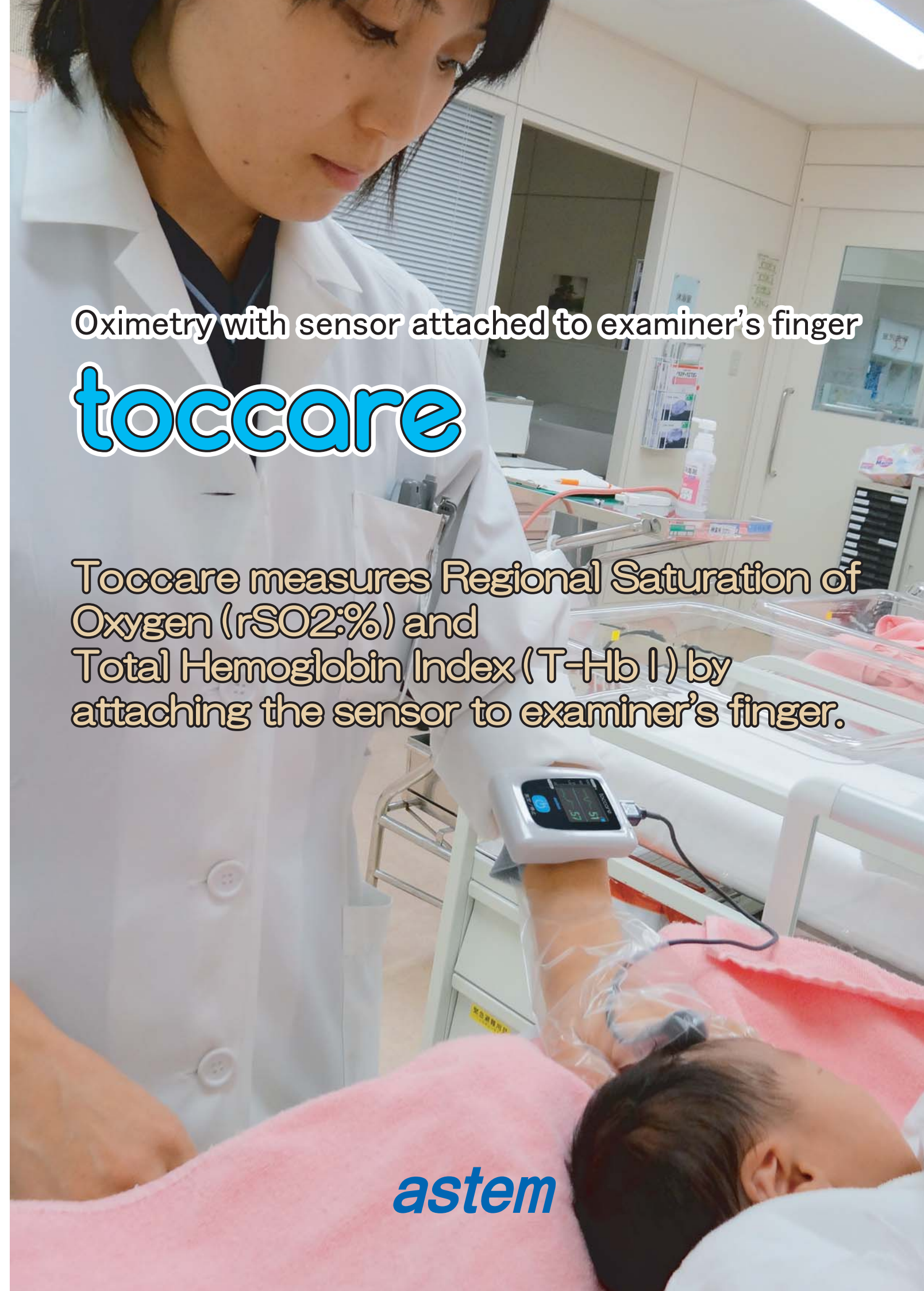
- Use transparent plastic gloves on top of the sensor probe attached to finger.
- Do not make measurements on birthmark, hematoma, fatty, hairy, boney, or injured parts.
- Do not use sensor probes intravitaly.
- Use a new sensor probe every measurement. Probes are designed for single use in terms of safety and quality.
- Turn off the switch when changing sensor probes.
- The product includes two different sized probes.

This product is developed by ASTEM Co., Ltd. based on the patent of Hamamatsu University School of Medicine and University of Shizuoka supported by Japan Science and Technology Agency.

Manufacture

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Marketing business license number of medical devices: 14B2X10026
Sales and rental business license number of specially controlled
medical devices: 745116

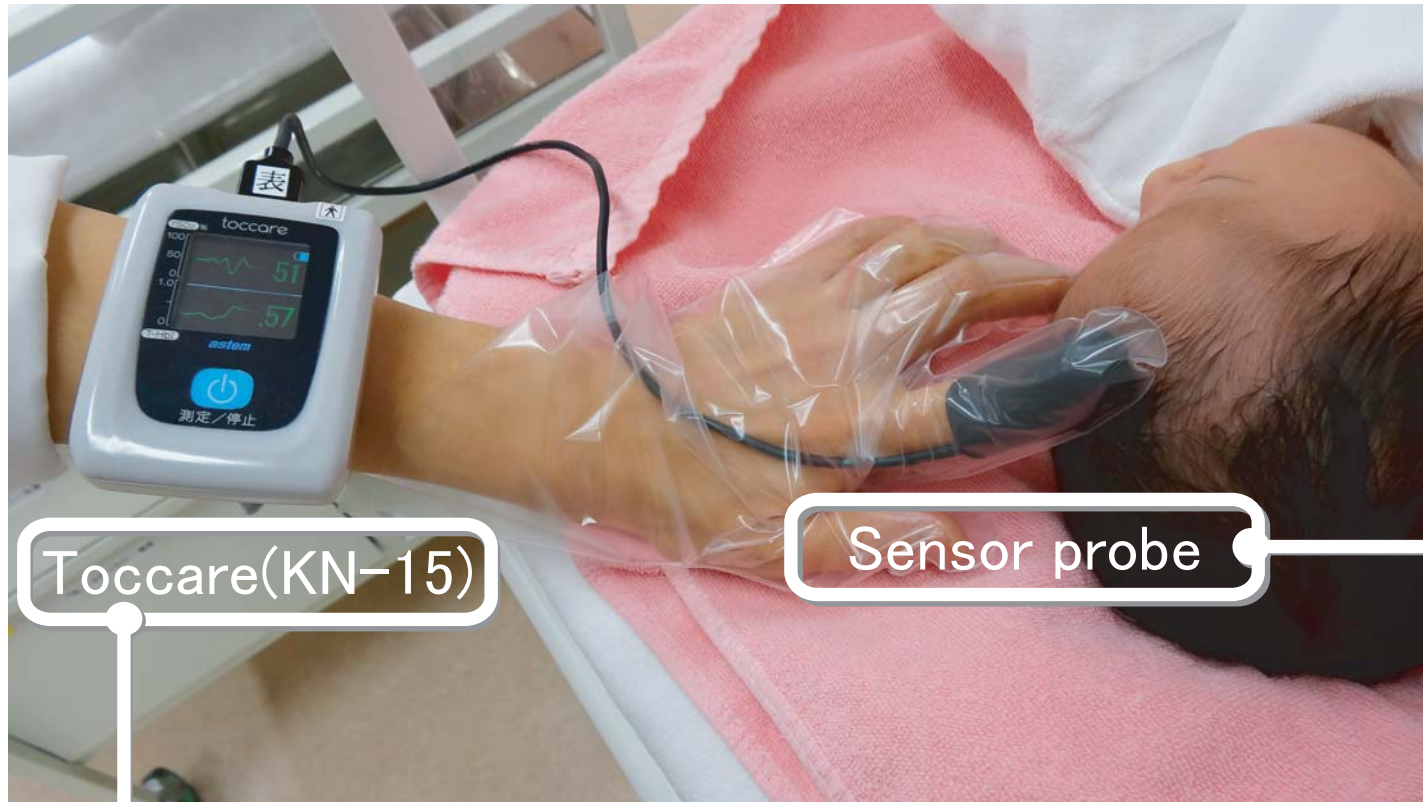


Oximetry with sensor attached to examiner's finger

toccare

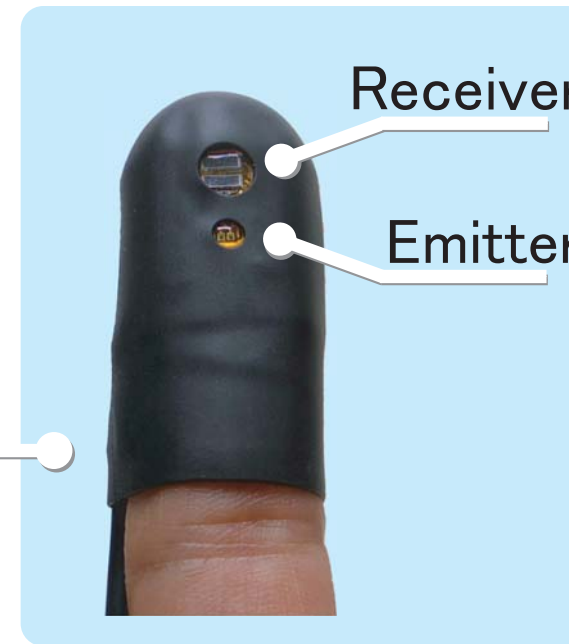
Toccare measures Regional Saturation of Oxygen (rSO₂%) and Total Hemoglobin Index (T-Hbl) by attaching the sensor to examiner's finger.

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Toccare(KN-15)

Sensor probe



Sensor probe on examiner's finger!

Features of Toccare(KN-15)

Toccare makes measurements with the sensor probe attached to examiner's finger.

This enables measurements during palpation.

Compared to the previous method which requires the attachment of sensor probe to patients, Toccare enables early diagnosis of various diseases as it shows patient's oxygen saturation and the amount of hemoglobin in blood in real time.

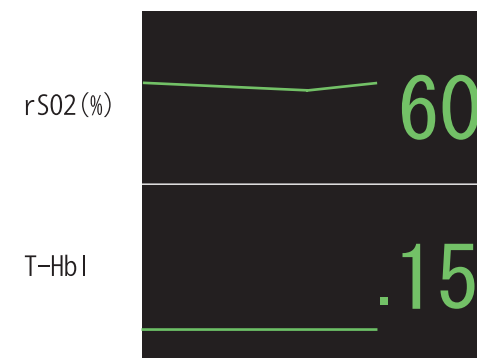


Toccare non-invasively measures oxygenation conditions of biological tissues which are approximately 5mm below from body surface. It uses special light which does not provide any adverse effects to human health.

Measurement process

1. Attach the body of Toccare to upper part of examiner's arm using the fixing belt.
2. Attach the sensor probe to examiner's pointing finger. Make sure that the light receiving/emitting side touches finger pulp.
3. Turn on the device by holding the power button. The measurement mode starts after showing calendar for 10 seconds.
4. Measurement results of rSO2 and T-HbI will be shown when the sensor probe touches a part of patient's body.
5. Short press of the power button interrupts the measurement, and it resumes by another short press.

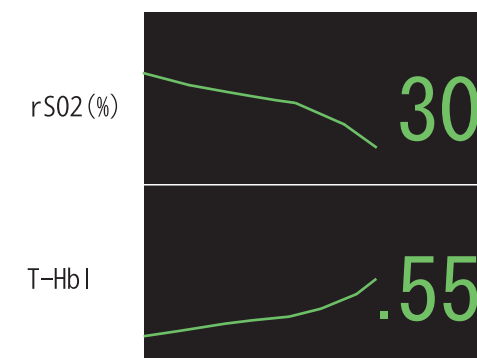
Examples



■ The picture in the upper left shows the measurement result of healthy adult. The value of rSO2 and T-HbI are shown as 60% and 0.15, respectively. Normal values of rSO2 differ between neonates, infants, and adults. Measurement points affect the value of T-HbI.

■ Oxygen saturation in the brain can be measured in neonatal cranial.

■ Low rSO2 value with normal T-HbI may be considered as oxygenation shortage or increase in oxygen consumed.



■ High T-HbI with normal value of rSO2 may indicate the first stage of congestion of blood near the measured part (The picture in lower left).

■ Low rSO2 value and high T-HbI may indicate congestion of blood near the measured part and hypoxia in tissues.

■ Low rSO2 value and T-HbI may indicate peripheral circulatory failure due to ischemia in tissues.