

Values of toe systolic pressure and toe brachial index (TBI)

Normal	: 100 ± 20 mmHg / mean ± SD
Pathological Threshold	: 80
Asymptomatic Arterial Disease	: 85 (66-105) mmHg / mean (lower - upper quartile)
Intermittent Claudication	: 60 (40-78)
Decubitus Pain	: 30 (10-29)
Necrosis	: 5 (0-20)
Toe / Brachial Index	: normal if between 0.65 and 1

In: F Becker. Dictionnaire des Termes de Médecine Vasculaire : Pathologie Artérielle. Masson, Paris, 2008, pp 57-58

The measurement of toe systolic pressure improves the relevance and the reliability of diagnosis

SysToe drastically improves the reliability of distal blood pressure measurement, especially in diabetic and chronic renal failure patients, since the measurement of ankle pressure and ankle brachial index may be false or impossible in these patients because of medial calcinosis. As a fully automated, totally non invasive and painless (unlike ankle pressure measurement) technique, systolic pressure measurement with SysToe is easily performed outside the Vascular Lab by diabetologists, nephrologists, general practitioners... for the follow-up of patients with peripheral arterial disease. Therefore, the use of more expensive examinations (such as complete duplex Doppler ultrasound of lower limb arteries) can now be spaced out. After an initial assessment at the time of diagnosis, the follow-up relies mainly on clinical findings and toe blood pressure. Complete ultrasound examinations are repeated with a lower periodicity and extra examinations are required only if clinical symptoms appear or worsen and/or if systolic blood pressure at the toe decreases. Thus, the social and economic burden of such a chronic disease as diabetes may be significantly alleviated whereas the number of patients with diabetes keeps increasing.

TBI is relevant for all patients

Ankle Brachial Index (ABI) has been in use for diagnosis and evaluation of peripheral arterial disease (PAD) for over half a century. Nevertheless, several problems have limited its use outside the Vascular Lab, among which the training required before the operator is able to carry out reliable measurements, the pain that some patients feel in the leg during cuff inflation, the time needed to perform the measurement and the false values that can result from medial calcinosis. On the other hand, systolic blood pressure at the toe shows a good agreement with the ABI⁽¹⁾ and remains measurable and reliable in patients with arterial wall calcification. Its easy, rapid and fully automated measurement with SysToe greatly improves clinical evaluation and follow-up of PAD in every day practice.

(1) Brooks, B.; Dean, R.; Patel, S.; Wu, B.; Molyneaux, L.; Yue, D. K. TBI or not TBI: that is the question. Is it better to measure toe pressure than ankle pressure in diabetic patients? Diabetic Medicine, Volume 18, Number 7, July 2001, pp. 528-532(5)

Specifications

- **Applied cuff pressure:** 0 to 330 mmHg
- **Pressure accuracy:**
± 2 mmHg from 0 to 70 mmHg
± 3% of the reading above 70 mmHg
- **PPG Sensor:** Infra red sensor
- **Reporting:**
- Detailed report with patient information customizable with comments and facility information
- **Electrical power:**
- Integrated NIMH battery (9 V)
- External charger (110 V or 220 V)
- Battery level indicator
- Automatic switch off of the device when not used
- **User interface:**
- LCD display
- Alphanumeric keyboard
- Control keys
- PC interface: USB 2
- **Data storage:** 32 examinations
- **Dimensions and weight:** 15 cm x 10 cm x 5.5 cm, 0.5 kg
- **Package:** delivered with all the accessories in a plastic case
- **Environmental:**
- Operating conditions: 15 to 40°C, 20-80 % Hr
- Transport & storage: 10 to 50°C, 10-100 % Hr
- **Classifications:** Class II a / Type BF
- **Quality system:** ISO 9001, ISO 13485 certified



- Assessment and diagnosis of peripheral arterial disease
- Diagnosis of critical limb ischemia
- Follow up of diabetic patients, patients with chronic renal failure, elderly patients
- Assessment of healing potential of ulcers

Assessment of lower limb arterial diseases

Ankle systolic blood pressure measurement is an essential step of the evaluation and monitoring of lower limb arterial diseases.

This measurement based on sphygmomanometry and ultrasound Doppler remains difficult and may be impossible or unreliable in patients with diabetes, patients with chronic renal failure and

elderly patients because their peripheral arteries become incompressible as a result of medial calcinosis. In this case, the systolic pressure measurement remains feasible at the first toe (hallux), where the incidence and extent of arterial wall calcification are much lower.



New prospects for non invasive measurement of toe pressure

Currently available systems for the measurement of systolic blood pressure (standard PPG, laser Doppler, mercury strain gauge, ultrasound Doppler) suffer from significant drawbacks as for ergonomics, reliability or price, which have so far limited their clinical use.

Optimized for cost, reliability, accuracy and easiness of use, **SysToe** enables toe pressure measurement to be conveniently and readily performed by all health professionals.

SysToe offers major improvements

The measurement is operator independent

SysToe is fully automated, including cuff inflation, deflation and data value display.

Once the cuff and the sensor are placed on the toe, just press on the START key to start the measurement and get the display of the toe pressure value.

The measurement is fast

The value of the toe pressure is displayed within three minutes.

The measurement is reliable, accurate and reproducible

The measurement is highly sensitive

SysToe is able to measure pressures lower than 20 mmHg.

SysToe displays the toe systolic pressure and the Toe Brachial Index (TBI)

TBI = Toe systolic pressure/ brachial systolic pressure

The user inputs the brachial pressure then **SysToe** calculates and displays the TBI.



Operating method

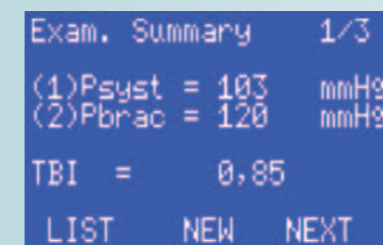
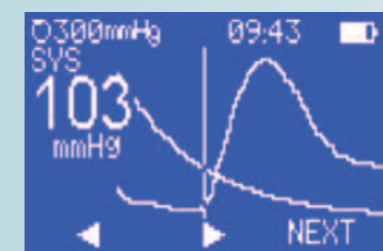
SysToe cleverly employs photoplethysmography (PPG) analysed by a unique patented algorithm designed by **Atys Medical**.

Light from an emitting diode (LED) is directed towards the skin where it is absorbed and scattered in tissues. An adjacent photosensor detects the backscattered light whose variations are related to changes of blood volume in underlying tissues.

The PPG sensor is placed on the distal pad of the toe and the occlusion cuff is wrapped on the proximal part of the toe.

The occlusion cuff is inflated automatically to a pressure sufficient to stop blood flow, then deflated slowly at a controlled rate. During deflation, resumption of blood flow downstream from the cuff is detected by the PPG sensor.

The cuff pressure at this time is the toe systolic pressure.



The measurement curves and results are stored in the **SysToe** internal memory for later transfer to a PC, printout and archiving.

