

PADnet™+ Data Accuracy & Security

How does PADnet+ compare to diagnostic devices utilizing Doppler ultrasound?

PADnet+ was tested for accuracy against conventional devices that use Doppler ultrasound. Like Doppler, the PADnet+ uses pressure cuffs to determine blood pressure values at the same anatomical sites: arm, ankle and toe. PADnet+ also allows for post-exercise Ankle-Brachial Index (ABI) and Pulse Volume Recording (PVR) testing.

In place of a blood flow transducer, PADnet+ uses established automated methods. Oscillations in the cuff caused by the pulsations of the patient's artery are recorded and converted to millimeters of mercury (mm HG). Software algorithms then determine systolic pressure values compared to conventional Doppler-derived models; the average variation is less than 1 mm HG.

According to a 2002 Journal of Vascular Technology paperⁱ, automated methods for taking pressure measurements are equivalent to Doppler with an average mean deviation of 2mm HG. "A major advantage of the automated technique is that it eliminates operator variability, sometimes an important factor in laboratories with several technologists, new personnel in training and/or staff changes."

PADnet+ PVRs are obtained in a way that is identical to conventional vascular lab devices. Waveforms deviated an average of less than 1mm in amplitude between comparison devices.

i. Salles-Cunha, PhD, RTV. (2002). *J Vascular Technology*, 26(1),20-26.

How is patient data protected?

Server security

- Dedicated server
- Network access limited by a firewall
- Server housed in secure data center; staffed
- Under continuous video surveillance, 24 hours per day
- Personnel access requires keycard and is monitored and logged
- Data center personnel cannot access patient data or monitor streams

Data security

- Data is compressed and password encrypted
- Secure HTTPS connection
- 128 bit SSL encryption, a level of security equal to that of secure online banking
- Access to data requires username/password authorization
- Automatic backups

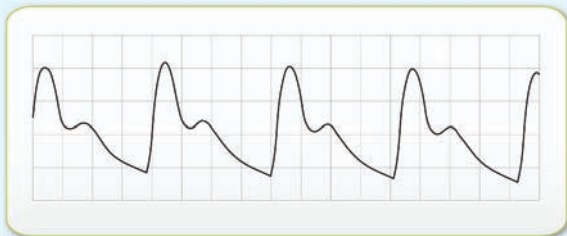


What Experts Say About PADnet™+ Arterial Testing

How does PADnet+ compare to other common diagnostic tests?

A PADnet+ arterial test involves Ankle-Brachial Indexes and Pulse Volume Recordings (PVR) technologies that have been in use for over 30 years. As noted in *Endovascular Today*, the ABI exam is the single best diagnostic test available today to predict both P.A.D. (Peripheral Arterial Disease) and major cardiovascular risk. A comparison of the ABI to other common screening tests is shown in Figure 1ⁱⁱ.

PVR waveform testing, a qualitative measure of blood perfusion, is complimentary to ABI. According to the ACC/AHA Guidelines, it is useful in patients with non-compressible vessels (ABI greater than 1.3).



ACC/AHA recommended diagnostic test	PADnet+
Ankle- and Toe-Brachial Indexes	✓
Segmental pressure measurements	✓
Pulse Volume Recordings (PVR)	✓
Post Exercise testing	✓

Figure 2ⁱⁱⁱ: PADnet+ function overview

Diagnostic test	Sensitivity (%)	Specificity (%)
Pap Smear	30-87	86-100
Fecal occult blood test	37-78	87-98
Mammography	75-90	90-95
ABI	95	100

Figure 1ⁱⁱ: Comparison of common screening tests

Which diagnostic tests are recommended by ACC/AHA for the management of P.A.D.?

Patient history and physical examination, including the existence of characteristic leg pain, are important first steps in a presumptive diagnosis of P.A.D. Non-invasive technologies like the PADnet+ arterial test can help validate and assess the severity of disease and the location of the occlusion.

Recent ACC/AHA Guidelines for the Management of PADⁱⁱⁱ support the use of vascular examinations and non-invasive vascular diagnostic techniques including those in Figure 2, which are functions of PADnet+.

ii. *Endovascular Today*. (Nov/Dec 2004). 67.

iii. Hirsch, et al. (2006). ACC/AHA Guidelines for the Management of PAD, *Circulation*, 113, e463-e465.



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PADnet is Approved