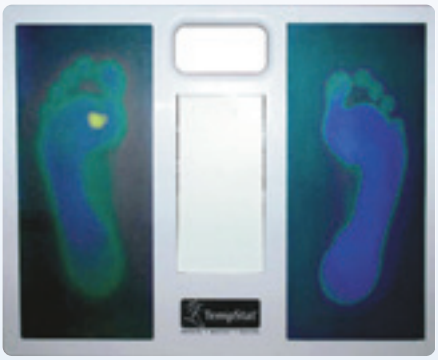
TempStat®
Thermal Imaging Device

Patient compliance and self-monitoring are key to diabetic foot care and ulceration prevention

Normal prints



Yellow "Hot spot" on the left foot

TempStat, the only FDA approved at-home/office temperature monitoring device produces a thermal image of your patient's feet to allow for quick and easy identification of yellow "hot spots" – indicative of areas of increased temperature and harbinger of inflammation or infection. A TempStat LCT (Liquid Crystal Technology) reading might be of many colors (varying temperatures) but the appearance of a yellow "hot spot" is cause for concern. On observing and then retesting for verification, your patient should be instructed to make an appointment for a foot exam as the inflammation can be a precursor to the development of a diabetic foot ulcer.

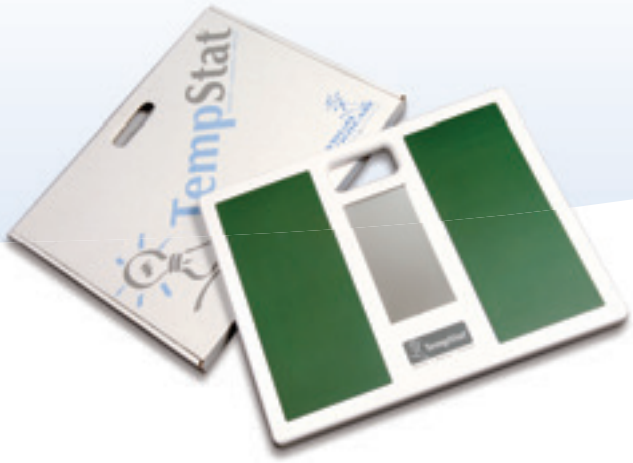
With TempStat®, patients with diabetes can observe what they often can't feel and monitor what they can't see.

Visually compelling and easy-to-use, TempStat is the only at-home temperature monitoring device approved by the FDA to detect signs of inflammation on the soles of the feet.[1] TempStat monitors temperature change – one of the earliest indications of tissue injury and ulceration. Yellows, for example, mean the hottest temperatures, possibly indicating the onset of complications below the skin's surface. Additionally, the device's magnification mirror helps patients monitor parts of their feet that may be difficult to see directly.

Inflammation is often the invisible precursor sign of infection and pending ulceration. All major diabetes organizations and clinical practice guidelines agree and state that people with diabetes – especially those who have lost sensory feelings – have a significant risk of developing a foot ulcer and must be encouraged to monitor their feet daily for signs of inflammation or variations in skin surface: color, sores, swelling, peeling cracking or other signs of change.

The patient with diabetic neuropathy has lost the "gift of pain". Neuropathy is the harbinger of inflammation leaving patients unaware of a developing sore. An example of dilatory effects to be associated with neuropathy can be ill–fitting shoes. The patient's neuropathy makes them insensitive to the pain resulting from an improper fit leaving them without warning to developing inflammation. The unnoticed inflammation can be the precursor of a diabetic foot ulcer requiring treatment. If left unattended, this condition can lead to the amputation of a toe or foot.

TempStat®
Thermal Imaging Device



Patient Study

A patient study by Frykberg, et al. (2009) was conducted to obtain an estimate of the ability of TempStat to assist in self-examinations of the feet[1]. Results show that the instrument clearly visualizes hot spots and that once a patient has lost SWM (monofilament) sensation, (daily) self-measurement of sole temperature with TempStat is **currently the only scientifically supported device for the prediction of diabetic foot ulcers in the insensate foot.**[7]

Studies demonstrate that an increased temperature may be detected at a stage where a potential diabetic foot complication is still reversible.[2, 3] Note that yellow "hot spots" indicate active inflammation or infection, the cause of an increase of focal temperature, may be present under the patient's skin.

Self-monitoring has proven to be an effective measure in preventing foot complications in patients with diabetes. Studies of at-home monitoring of foot temperature show that the incidence of foot ulcers in risk group may be reduced by more than 60%.[4, 5, 6]

TempStat's LCT technology offers rapid temperature imaging, but the thermograph images must be interpreted with consideration to the findings from a Comprehensive Diabetic Foot Exam (CDFE). However, an advantage with the TempStat technology is that it clearly visualizes problem areas for the patient, and it has been suggested that it could lead to a higher patient compliance when combined with therapeutic advice in diabetic foot care.[6]

Summary overview:

- Increased temperature, when detected, may be an early warning for foot complications in people with diabetes.
- At-home monitoring of foot temperature may reduce the incidence of foot ulcers by more than 60%.
- The TempStat can be used for at-home care and for medical office or scheduled diabetes screening and care at hospitals.
- Early diagnosis and treatment is critical to the healing of diabetic lesions.
- Self-monitoring with TempStat in combination with therapeutic advice in diabetic foot care by a health care professional can lead to an increase in patient compliance.

References

1 Frykberg RG, et al. Diabetic foot self-examination with the TempStat® as an integral component of a comprehensive prevention program. J. Diabet. Foot Complications 1(1), 13-18 (2009). **2** Sun PC, et al. Relationship of skin temperature to sympathetic dysfunction in diabetic at-risk feet. Diabetes Res. Clin. Pract. 73(1), 41-46 (2006). **3** Armstrong DG, et al. Skin temperature monitoring reduces the risk for diabetic foot ulceration in high-risk patients. Am. J. Med. 120(12), 1042-1046 (2007). **4** Lavery LA, et al. Preventing diabetic foot ulcer recurrence in high-risk patients: use of temperature monitoring as a self-assessment tool. Diabetes Care 30(1), 14-20 (2007). **5** Lavery LA, et al. Home monitoring of foot skin temperatures to prevent ulceration. Diabetes Care 27(11), 2642-2647 (2004). **6** Roback K, et al. Feasibility of a thermographic method for early detection of foot disorders in diabetes. Diabetes Technol. Ther. 11(10), 663-667 (2009). **7** Arad Y, et al. Beyond the monofilament for the insensate diabetic foot: A systematic review of randomized trials to prevent the occurrence of plantar foot ulcers in patients with diabetes. Diabetes Care 34(4), 1041 (2011).

VISUAL FOOTCARE™ TECHNOLOGIES LLC
IDENTIFY • MONITOR • PREVENT