

# Patient Information

## SAMPLE IMAGES

Your TempStat<sup>®</sup> images will be in vibrant colors – usually bright greens and lighter and darker shades of blue. These images are examples of how pinkish orange or yellow “hot spots” may look. Pinkish orange or yellow “hot spots” indicate active inflammation that may be present under the skin of your feet. Your images will be in color, and color differences could appear anywhere on the footprint, not just the locations shown in the samples.

## FREQUENTLY ASKED QUESTIONS

### Why should I use TempStat?

The American Diabetes Association (ADA) recommends that people with diabetes have an annual Diabetic Foot Exam (DFE) to identify any potential risk factors for the development of diabetic foot complications. You have been provided with a TempStat device by your healthcare professional to help you monitor your feet on a daily basis for areas of increased temperature that signals possible irritation, injury, or infection. There may also be redness and swelling. By looking for these early signs, you can be alerted to areas of possible injury or damage. Breaks in the skin on your feet can trap bacteria and lead to infection. Equipped with a magnification mirror and temperature sensitive pads, TempStat allows you to **SEE** the areas of focal inflammation that are indicators of a possible diabetic foot ulcer.

### How do the TempStat pads work?

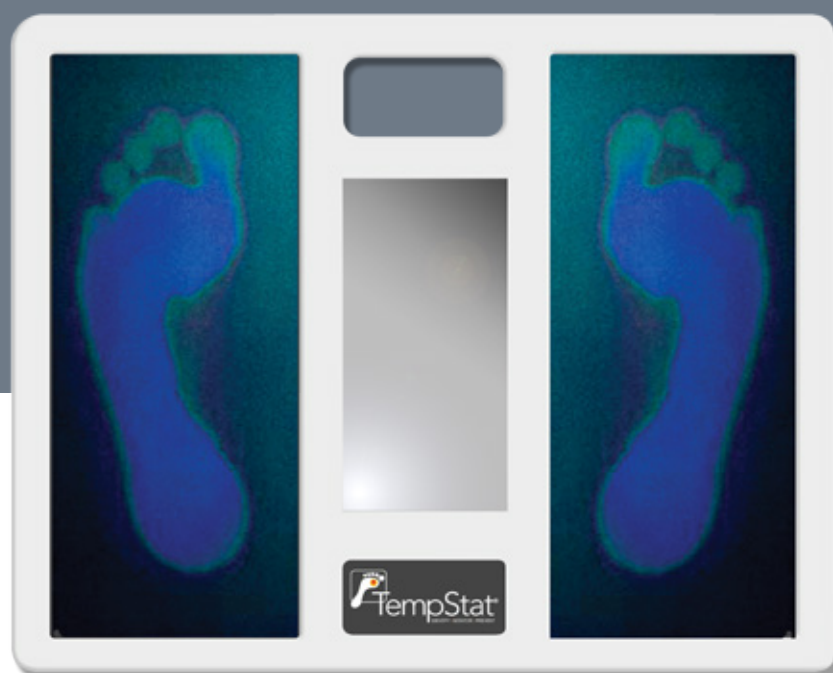
TempStat is designed to allow you to **SEE** the temperatures of the bottoms of your feet. Using Liquid Crystal technology, TempStat captures a thermal image of the bottom of your feet, with different colors representing different temperatures. Your thermal images may be one color or a collection of many colors. It doesn't matter. The specific colors or exact temperatures are not important. The purpose of Tempstat is to highlight focal areas of increased temperature identified by pinkish orange or yellow “hot spots”.

### What should I be looking for?

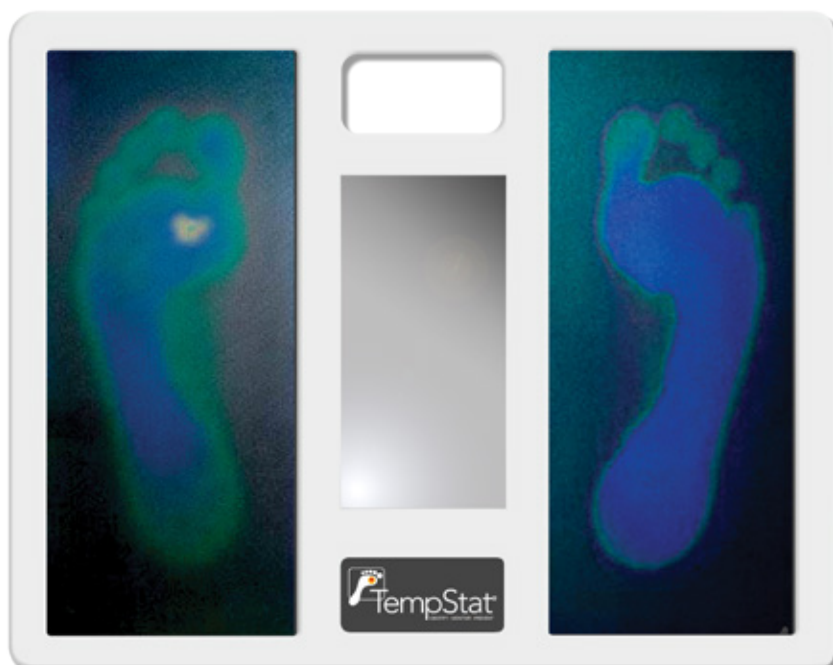
Look for any pinkish-orange or yellow “hot spots”. Since the soles of your left and right foot are generally about the same temperature, the two thermal images should look similar. However, if one or more pinkish orange or yellow “hot spots” appear it means these areas are potential sites for a diabetic foot ulcer. Your footprints should fade at approximately the same time. If a spot is still visible on one pad after the footprint has faded, that is another indication that you may have a “hot spot”.

### What do I do if I see a pinkish orange or yellow “hot spot”?

Don't panic. The purpose of the sensitive liquid crystal temperature pads is to alert you that something is different and there may be a problem. You should use the magnification mirror, or get a family member or friend, to **INSPECT** the soles of your feet for irritation, abrasions, cuts and bruises, paying particular attention to any differences or pinkish orange or yellow “hot spots”. In the event that you notice a “hot spot,” stay off your feet, wait 15 minutes and test again. If you notice the “hot spot” again after retesting 15 minutes later, contact your healthcare professional for further instructions. Also check your shoes to make sure that no foreign objects, like a small pebble, have fallen into your shoes. Always follow your health care professional's instructions about what to do if you discover a “hot spot,” irritation, abrasion, cut or bruise.



Normal prints



Pinkish orange or yellow “hot spot” on the left foot

## DIRECTIONS FOR USE:

1. Use TempStat in a **WELL-LIT** area.
2. TempStat should be used at the beginning of your day, after walking for long periods of time or after exercise.
3. Make sure your feet are warm and dry. Cold feet may not change the color on the device.
4. **Sit down in a chair and place your bare feet on the pads for 60 seconds. DO NOT STAND ON THE DEVICE.** Lean slightly forward with hands on knees to make sure both feet are touching the pads. Use the 60 seconds to inspect the tops of each of your feet for signs of irritation, cuts, bruises or other damage. Remove feet from pads.
5. **A pinkish orange or yellow “hot spot”** will appear at the highest temperature ranges, which indicates active inflammation may be present under the skin of your feet. Contact your physician if you see a pinkish orange or yellow “hot spot”. Your footprints should fade at approximately the same time. If a spot is still visible on one pad after the footprint has faded, that is another indication that you may have a “hot spot”.
6. **If you think you notice a pinkish orange or yellow “hot spot” wait 15 minutes and repeat the measurement, just to be sure.** If you see this again, contact your physician.
7. **Use the magnification mirror to INSPECT the bottom of your feet for irritation, abrasions, cuts, and bruises.** Pay particular attention to areas that register as a pinkish orange or yellow “hot spot” on the pads. If possible, have a family member or friend visually inspect your feet for any signs of injury.
8. TempStat is intended to help you determine when you should contact your healthcare provider if you notice any “hot spots” or irritations abrasions, cuts or bruises on your feet.

IDENTIFY • MONITOR • PREVENT

## STORAGE AND HANDLING INSTRUCTIONS

TempStat should be returned to its storage case following use and kept out of direct sunlight, dampness, or heat. Ideally, TempStat should be stored between 20-30°C (68-86°F). Do not freeze, immerse in liquid, expose to outdoor elements, or have pads come in contact with temperatures above 100°F. The TempStat pads are not sterile and should be cleaned periodically by wiping with a mild, non-abrasive soap, dish-washing liquid, or alcohol pads.

If you consistently fail to get a reading on the pads with your feet, try placing your warm hands on the pads. If you still fail to get a clear image, the pads may be damaged and need to be replaced.

One Year Limited Warranty: When used and handled in accordance with the Storage and Handling Instructions, Arche Healthcare warrants this product against defects in materials and workmanship for a period of one (1) year from the date of original purchase. If a defect exists, at its option, Arche Healthcare will (i) repair the product at no charge or (ii) replace the product.

## FOR PRESCRIPTION USE ONLY

TEMPSTAT IS INTENDED TO BE USED ONLY IN CONNECTION WITH A PROGRAM OF CARE RECOMMENDED BY YOUR HEALTH CARE PROFESSIONAL. DO NOT USE TEMPSTAT UNLESS YOU HAVE BEEN PROPERLY TRAINED IN ITS USE. DO NOT USE TEMPSTAT AS A SUBSTITUTE FOR ROUTINE CARE AND TREATMENT BY YOUR HEALTH CARE PROFESSIONAL.

TEMPSTAT IS NOT INTENDED TO BE USED TO ACCURATELY MEASURE SPECIFIC FOOT TEMPERATURE, TO FORECAST THE LIKELIHOOD OF DEFORMITY, FORECAST THE LIKELIHOOD OF AMPUTATION, OR OTHERWISE DIAGNOSE THE PRESENCE OR ABSENCE OF ANY SPECIFIC DISEASE STATE.

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