

STORAGE

Once you have completed a patient's test session, place 3 new **ComforTen™** devices in the extract filled tray, cover and store at 2°-8° C until the next test session.

READING SKIN TEST REACTIONS

Measure wheal and erythema responses for histamine positive control at 10 minutes and allergens at 15 minutes. To improve accuracy, precision and uniformity of diagnostic testing and eliminate confusion as to the quantitation of the allergic response, we recommend recording wheal and erythema measurements. Reactions from the **ComforTen™** device may be graded as follows:

European Prick Test Grading System

Grade	Wheal (mm)	Erythema
Negative	<3	Not Measured
Positive	>3	Not Measured

Graduated System

Grade	Wheal (mm)	Erythema (mm)
0+	<3	<15
2+	<6	<15
3+	7-9	16-30
4+	>9	>30

A positive skin reaction to any allergenic extract must be interpreted in light of the patient's history of symptoms, time of the year, and known allergen exposures.

The skin tests are in no way a substitute for a careful allergic history. Rather, they serve as additional information to aid in identifying causative allergens in patients with allergic disorders.

DISPOSAL

ComforTen™ devices are designed to be used once and discarded (in accordance with all local, state and federal regulations). These devices cannot be cleaned sufficiently to prevent cross contamination from repeated use or to protect subsequent patients from possible transfer of serum hepatitis or other bloodborne pathogens.

The reservoirs in the **ComforTen™** tray should be replaced periodically. For best results, discard and replace the reservoirs as they are emptied and fill with fresh extract. If a used **ComforTen™** device is inadvertently placed in the reservoirs, the affected reservoirs should be discarded and new reservoirs prepared prior to the next test session.

HOW SUPPLIED

- Item # Description**
- 8408ZA **ComforTen™** Multiple Skin Test Device (sterile), Case of 63 blister packs (189 devices). Manufactured in England.
- 8406ZA **ComforTen™** Covered 30-Hole Tray (Includes Spacers and Labels). Manufactured in the U.S.A.
- 8924ZA **QUINTIP®** Reservoirs (sterile), 30 per pouch. Manufactured in the U.S.A.

Distributed in the U.S.A. by:
Hollister-Stier Laboratories LLC
Spokane, WA 99220-3145
1.800.992.1120

www.allergy.hollister-stier.com



Multiple Skin Test System FOR PUNCTURE SKIN TESTING

ComforTen™ is a ten-test skin test device designed to apply allergenic extract using the puncture technique.

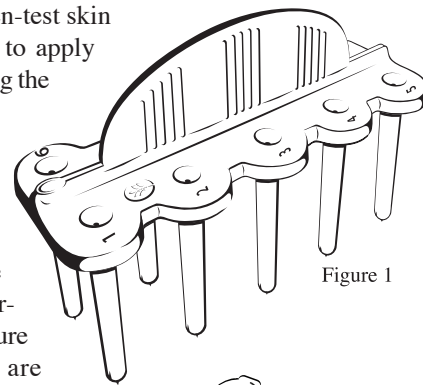


Figure 1

ComforTen™ is designed for use by allergy practitioners who are trained in the application and interpretation of the puncture technique and who are trained in the recognition and treatment of adverse allergic reactions should they occur.

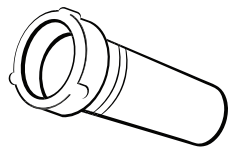


Figure 2

ComforTen™ Multiple Skin Test System consists of three components:

The **ComforTen™** skin test device (Figure 1), the **QUINTIP®** reservoirs (Figure 2) that contain the extracts, and the **ComforTen™** covered tray (Figure 3) that holds the reservoirs. The test devices are packaged three per sterilized blister pack container, 63 blister packs (189 devices) per case. The **ComforTen™** covered, stackable tray (Figure 3) is provided as a single unit that holds 30 **QUINTIP®** reservoirs and accommodates 3 **ComforTen™** skin test devices (Figure 1). Each tray includes 3 optional-use spacers for increasing the number of tests between filling the reservoirs.

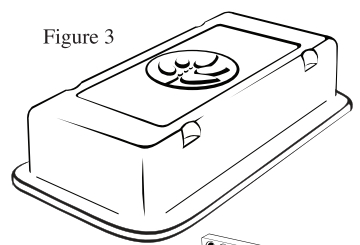


Figure 3

PRODUCT DESCRIPTION

The **ComforTen™** device has a molded plastic handle with ten testing probes (Figure 1). Inserted into each testing probe is a stainless steel lancet tip (Figure 4) that protrudes from the probe enough to give the proper testing depth. The **ComforTen™** device is to be used once and discarded.

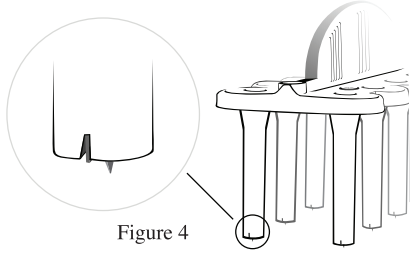


Figure 4

SET-UP INSTRUCTIONS

Remove the **ComforTen™** covered tray from the box. Each **ComforTen™** covered tray is supplied with blank self-adhesive labels and spacers (Figure 5). Each label strip has five designated areas corresponding to the reservoirs. Write the name of each antigen in the area provided, remove the label backing and place on the tray to correspond with the antigen.

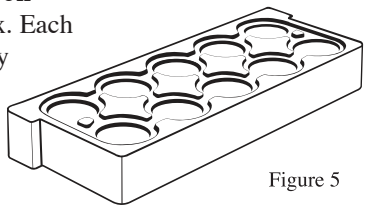


Figure 5

The reservoirs are provided in a sterile pouch of 30. Peel back the paper label as indicated on the pouch of the reservoirs. Firmly place a reservoir into each hole in the 30-hole **ComforTen™**. If using the optional spacers, fill the appropriate reservoir with approximately 20 drops (not more than 0.8 mL) using the dropper from the Hollister-Stier 5mL scratch test extract vial (Figure 6b). Place the spacers on top of the reservoirs as noted in Figure 6a. If the spacers are not used, fill the appropriate reservoir

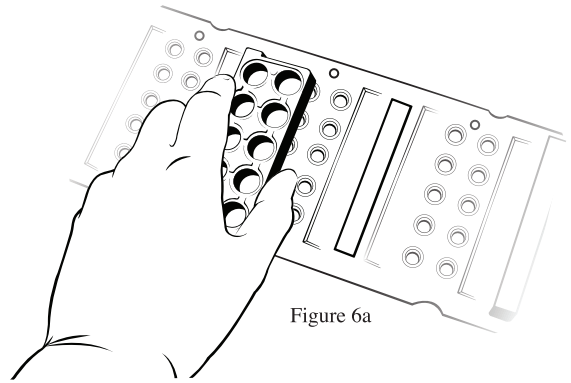


Figure 6a

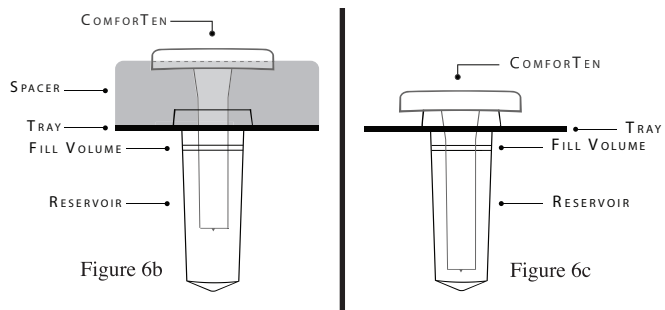


Figure 6b

Figure 6c

with approximately 12 drops (not more than 0.5 mL) using the dropper from the Hollister-Stier 5mL scratch test extract vial (Figure 6c). Store the unused spacers in the slots provided on the tray.

Once the tray is prepared, remove a **ComforTen™** device from the blister pack by peeling off the label as indicated on the package. Pick up the device by the handle using caution not to touch any part of the legs or the lancet tips. Place the tips in the prefilled reservoirs. To assure that test extracts are applied to the proper test sites, always place the test device handle with the leaf and HS logos plus the numbers 1 and 6 facing upward and toward the patient's head. Both the device and the tray contain a small indented circle to be used as directional indicators (Figure 7).

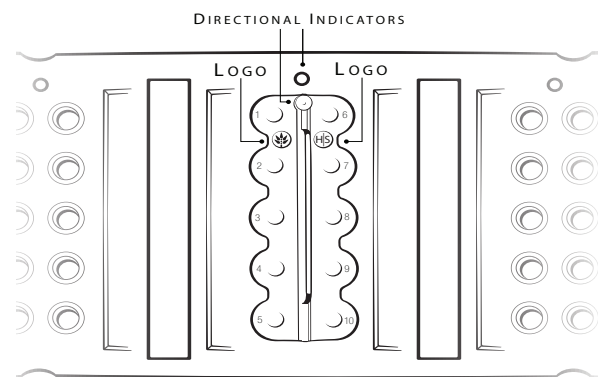


Figure 7

The 30-hole tray holds 3 **ComforTen™** devices. With the **ComforTen™** device on the tray, the reservoirs are covered to prevent foreign matter from entering the extract. Once the tray is loaded, it can be used immediately or covered and stored in the refrigerator until needed.

SKIN TEST PROCEDURE

Prior to skin testing, clean the test area with alcohol and allow to dry. (Refer to Hollister-Stier Laboratories' "Allergenic Extracts for Scratch and Prick/Puncture Testing" or other manufacturer's

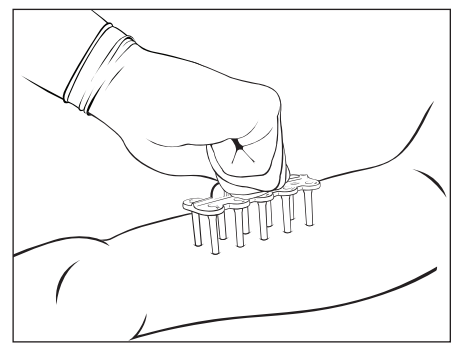


Figure 8

package insert for more detailed testing instructions.) Remove a **ComforTen™** skin test device slowly from a prepared tray by lifting it vertically, being careful not to touch the tips on the reservoirs or spacer. With the **ComforTen™** perpendicular to the skin, press down on the skin with medium pressure (Figure 8). While maintaining this pressure, slightly tilt the device once to the right, and then to the left while ensuring that all 10 lancets remain in contact with the skin. Remove by lifting vertically and discard the **ComforTen™**. Faint circles about 4mm in diameter created by the device's depth control guards should remain at the test site indicating the correct amount of pressure was applied (Figure 9). The actual duration and visibility of the circles will vary between patients according to the thickness, fragility, or pigmentation of their skin. The amount of pressure needed to produce a satisfactory test site requires that all of the ten depth control guards (Figure 9) come in full contact with the skin.

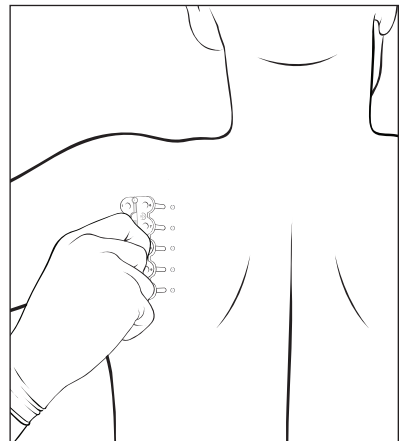


Figure 9

When used as described above, the **ComforTen™** device will produce ten uniform skin tests all at the proper depth without inducing bleeding.

The spacers are used to increase the number of tests between refilling the reservoirs. Once the extract volume in the reservoirs has dropped to approximately half with a device in place, remove the spacer and continue using the extracts until reservoirs are nearly empty and need to be refilled. The spacers can be washed with soap and warm water as needed.