

FROM: Engineering

TO: All Daavlin Employees and International Distributors

DATE: 4/10/09

SUBJECT: SmartTouch Safety Features Compared to Straight Dosimetry

DEVICE TYPE/SERIAL NUMBERS AFFECTED: 3 Series Devices only

DESCRIPTION:

The reason for this bulletin is to inform the Daavlin Sales department and distributors of marketing techniques for Daavlin SmartTouch controlled equipment, especially the 3 Series PC and SP machines.

SCOPE:

This pertains to 3 Series devices only.

PURPOSE:

The purpose is to inform Daavlin Sales employees and distributors of the safety advantages of Daavlin dosimetry controllers compared to competing machines with simple dosimetry controllers such as the NBC HOUVA III.

DETAILS:

Recently it has been noticed that competing phototherapy manufacturers have attempted to downplay safety considerations and to merely compare all phototherapy dosimetry controllers as more or less equal, differing only in cost and appearance. Merely adding a touchscreen or a more sophisticated display to a simple dosimetry controller does not increase its safety profile and it is important to distinguish simple dosimetry from more advanced Daavlin controllers.

Since the 1993 introduction of the Daavlin UV2001 controller, Daavlin has taken great pains to produce controllers that, insomuch as possible, eliminate the potential for dosage errors, reduce physician liability, and promote accurate and effective treatment protocols. A comparison between the latest generation of Daavlin's software, SmartTouch 2.01 and a simple dosimetry controller clearly shows the advantages:

**Simple Dosimetry:**

On a simple dosimetry controller, the physician must calculate a treatment plan for each patient, including dose increases, then either personally operate the phototherapy device or delegate the task to a trusted staff member. Whatever dose is entered into the machine will be delivered as soon as the operator presses the start button. There are no safeguards against:

1. Accidentally entering too high or low of a dose, such as 1000mJ instead of 100mJ.
2. Calculating the wrong percentage of increase between treatments.
3. Treating without enough time between treatments.

4. Using the wrong type of lamps in a combination machine (UVB instead of UVA or UVA instead of UVB).
5. Treating with too much time elapsed between treatments.
6. Having a poorly trained employee change a dose.
7. Confusing treatment protocols between patients.
8. Patient concerns about accidentally being over-treated

### **SmartTouch:**

With a Daavlin 3-Series equipped with SmartTouch, after a physician selects a treatment plan based on skin type or MED testing, all treatments are calculated automatically in the SmartTouch software, and a variety of levels of operator access can be setup that restrict an operator's ability to make changes in a treatment protocol. Although successful, literature supported protocols are included in the software, an advanced user is always free to create their own modified protocol. In SmartTouch, the software prevents poor patient outcomes and reduces liability by:

1. Automatically suggesting the correct dose and not allowing an operator to change it without their supervisor's assent.
2. Automatically following scientifically supported protocols to ensure optimum patient outcomes.
3. Preventing any situation where a patient might be treated too soon after the last treatment.
4. Preventing a patient that has missed several treatments from getting treated with too high of a dose.
5. Never allowing a patient to be changed from one lamp type to another without authorization from a high level user and without starting at the beginning of the newly authorized protocol.
6. Automatically reminding even supervisory users with detailed warning messages if an attempt is made to change a dose.
7. Keeping detailed, printable, patient records, including actual treatments given, with dates, times, and protocol information.
8. Using a computer generated voice, in the patient's native language to tell them how much time remains of their treatment, and to remind them to take appropriate eye and skin protective measures.

### **Conclusion:**

It is possible for a very careful physician with well trained, reliable staff to use a simple dosimetry controller quite successfully, but they are always completely dependant on maintaining absolute vigilance with every single button push. When one considers that a busy practice can easily conduct thousands of individual treatments per year, even a very slight chance of error becomes quite significant.

With SmartTouch, the customizable, comprehensive nature of the software safeguards virtually eliminates the dose errors found in simple dosimetry controllers, especially for established patients.

Also in the common event that a patient has an idiosyncratic reaction and burns through no fault of the physician, with a simple dosimetry controller there is no proof available of exactly what treatment was given. With SmartTouch, the patient can be assured, in part by the machine's own audio announcements, that the entire treatment protocol was accurately delivered and the physician is assured that there is an absolutely accurate, electronically secure record of the treatments delivered. With SmartTouch, it will never come down to a liability nightmare of a physician's or a staff member's recollection of what dose was given or whether it was appropriate to give it.