I have evaluated a number of different ultrasound devices for therapy, and would like to comment on the differences between "stationary" and "non-stationary" ultrasound, especially with regard to the Hill Laboratories' ultrasound system.

Therapeutic ultrasound systems must satisfy two potentially conflicting requirements: to heat targeted tissue, while at the same time, preventing any unwanted overheating or "hot spots". This is especially difficult for conventional Continuous Wave (CW) ultrasound devices, especially those with relatively small scanheads. CW systems have the possibility of creating a "standing wave". This occurs if the sound is reflected back towards the transducer from some structure within the body, for instance, from bone. In this case, the reflected wave interacts with the transmitted wave to produce regions of high ultrasound energy concentration, again leading to "hot spots". Further, most of these systems have relatively small ERA values (representing beams with a diameter of only several centimeters) and moderate BNR values (indicating some level of concentration). Therefore these conventional ultrasound devices must be continually moved around on the body to avoid the potential for overheating the tissue.

Thus the practice of moving the scanhead around on the skin ("non-stationary" application) is really a compensation for some of these technical limitations of conventional technology.

Unfortunately, moving the probe around in order to assure safety can have some negative consequences for efficacy. Because the probe is continually moved around by the operator, any one volume of tissue is only exposed to ultrasound for some portion of the time, in general as a ratio of the ERA to the total scanning area. Even with a conservative assumption of a scanning range twice as large as the scanhead, this would reduce the effective dose at tissue by 50 percent. Thus the "non-stationary" approach has the potential, in fact, to reduce the effectiveness of the ultrasound therapy treatment.

The Hill Laboratories Hands-Free system has been designed to address the specific concerns with overheating the tissue by specific technical solutions. First, it has a large ERA of 65cm^2, equivalent to a beam diameter of 6.4cm (2.5 inches). Second, it has a BNR of less than 5.0, so that the beam is not particularly concentrated (the practical lower bound is on the order of 3.5 for ultrasound transducers). Finally, the system operates in a Pulsed Wave mode to reduce standing waves. The total power is up to 10 acoustic Watts, which is typical of many therapeutic systems. These features combine to permit the safe operation of the device in a "hands free" condition.

Thus it should be concluded that the Hands-Free approach, as implemented in the HF54/HF27, provides the same level of safety and efficacy as other therapeutic devices. The issue of "stationary" versus "non-stationary" ultrasound should really be viewed as a safety and efficacy concern for the "non-stationary" systems: they have a higher potential for either overheating tissue because of their beam hot spots or standing waves, or a

potential for ineffectual treatment because their beams do not properly encompass the entire tissue to be treated.

Respectfully,

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