

August 10, 2001

## Urgent Notice

### For All Users of Multidata Treatment Planning Systems

Dear Customer of Multidata Systems:

The attached *Notice for All Users of Multidata's Treatment Planning Systems* is a follow up to the recently distributed *Medical Device Safety Alert*. It explains an improper entry of block shapes and its effect on dose calculation results. In short, as long as the block outline does not cross itself, the dose calculations should correlate with the results obtained by an appropriate method of independent validation. For the Multidata Treatment Planning System, such methods include hand calculations or calculations using the central axis dose calculation program (CHT) or the irregular fields utility (IRF).

Multidata shares the concern that an improper data entry sequence was permitted as input. Therefore, through its Project Safeguard, Multidata has identified a data entry sequence that creates a self-intersecting shape outline (See Fig. 1 on the attached sheet) as what is not acceptable. Digitizing direction and exceeding the limitations on the number of blocks, numbers of points per block or the block shape have no unexpected effect on the dose calculation. For information about specific limitations as to the number of blocks or points used in a particular plan, please refer to the user manual provided with your version of the software.

A filter program which automatically rejects an improper data entry sequence as an unacceptable outline, on the basis that it is not a true polygon, has been developed and is currently being tested. Once the project is complete, Multidata will make this program available to all customers in the form of an easy to install update. It is expected that this safeguard program will be compatible with any software version in use.

#### Your Response

We ask that you confirm receipt of this letter by August 24, 2001. Notify Multidata Helpdesk by telephone at (800) 225-1130, by facsimile (FAX) at (314) 968-6443, or by E-mail at [helpdesk@multidata-systems.com](mailto:helpdesk@multidata-systems.com). If you no longer use the treatment planning system, let us know so that you can be removed from the user list. If you have any questions, concerns, or doubt about the proper operation of the treatment planning system, please contact us.

Multidata Systems International Corp.



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