

<u>Revision</u>	<u>ECO #</u>	<u>Date Released</u>
Rev. A	ECO-1771	2-14-07

1.0 PURPOSE

The purpose of this document is to define the mechanical requirements for the Visica II 3.4 mm Probe.

2.0 SCOPE

This document defines the mechanical requirements for the Visica II 3.4mm probe assembled by Sanarus Medical.

3.0 REFERENCES

PS-71-0001, Product Specification Visica II.

4.0 DOCUMENT CONVENTIONS

Requirements are indicated by use of the word "shall". Sentences lacking the word "shall" are not to be construed as requirements.

5.0 MECHANICAL REQUIREMENTS

The probe shaft shall not become separated from the probe handle when subjected to a 5 pound tensile load.

The completed probe tubing assembly shall not leak cryogen when folded back on itself 180 degrees with an inside bend radius of 1 inch.

The completed probe tubing assembly shall not leak cryogen when bent over the edge of a surface at approximately 90 degrees under a one pound suspended load.

The completed probe tubing assembly shall be flexible enough to bend over the edge of a surface such that a one pound load will bend the tubing at approximately 90 degrees.

The probe outer tubing shall remain connected to the probe handle under 5 pounds tension.

The probe outer tubing shall remain connected to its cart connection handle under 5 pounds tension.

The probe pneumatic connection to the cart shall remain functional after a minimum of 10 mate/de-mate cycles.

The probe shall not leak cryogen when pressurized to 60 psi for one minute.

The probe shall not leak cryogen after 20 pressurization cycles under nominal operating pressure.

The completed probe tubing assembly shall not leak cryogen after being stepped on by a minimum 200 pound person wearing street shoes.

The probe shaft shall not leak cryogen after being bent through an angle of 45 degrees.

The probe shall not leak liquid nitrogen in the event of a supply tube breach.

The probe electrical connection to the cart shall remain functional after a minimum of 10 mate/de-mate cycles.

6.0 PHYSICAL REQUIREMENTS

The probe shaft shall extend nominally 5 inches out of the distal end of the probe handle.

The probe outer tube assembly shall extend approximately 8 feet from the probe handle connection to the cart connection.

The probe shaft diameter shall be nominally 0.13 inches (ref. 3.4 mm).

The probe shaft distal end shall be a three faceted 11 degree tip measured from the longitudinal axis of the probe shaft.