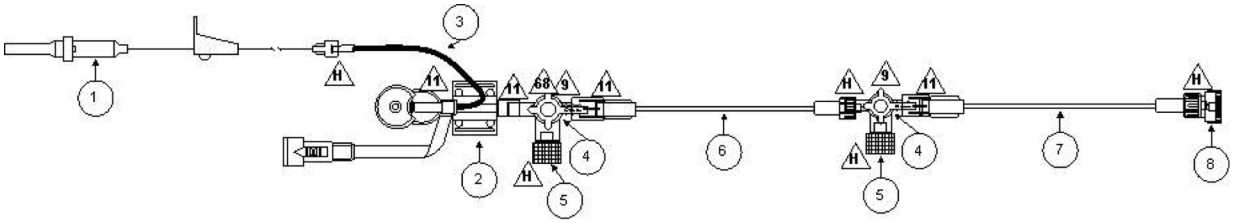
icumedical
human connections

Transpac® with SafeSet® Adherence to Association for the Advancement of Medical Instrumentation (AAMI) Patient Monitoring System Specifications

All ICU Monitoring products are manufactured with no natural rubber latex components and non-DEHP tubing. The products are designed to meet the requirements of AAMI BP22 standards for Resonant Frequency, Natural Frequency, and Dampening Coefficient and are burst pressure rated to 9 psi.

In order to evaluate these characteristics, we developed and tested a reference set design. This product was tested to determine the behavior of the pressure waveform for the Transpac Monitoring Product Line. This reference test includes a series of components in conjunction with 60" of pressure tubing. The reference test set design appears below.



ICU Medical conducted additional testing of the following sets in order to verify their performance and to demonstrate consistency with our components regardless of configuration. Measurements are obtained in accordance with AAMI BP22 and the results shown below.

Product	Resonant Frequency Hz	Natural Frequency Hz	Dampening Coefficient / Ratio	15% Bandwidth Hz
Reference Set	50.9	51.8	0.18	68.0
46103-05	32.6	33.3	0.20	43.4
46103-25	29.0	29.5	0.19	38.6
46103-90	29.2	29.7	0.20	38.8
46103-91	25.0	25.5	0.21	33.1

All of the ICU Medical products employ design standards that will not significantly reduce the frequency response or over-dampen the waveform. These characteristics would be consistent in product designs that are either pole-or-patient mounted. Full product drawings can be provided for review of the exact configurations tested upon request.

If there are further questions or concerns, please visit our website at www.icumed.com or contact the corporate offices at 949-366-2183 or 800-824-7890.

Technical Services
ICU Medical Inc.