



Standard Specification for Cranial Traction Tongs and Halo External Spinal Immobilization Devices¹

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1. Scope

1.1 This specification covers standards a manufacturer shall meet in the designing, manufacturing, testing, labeling, and documenting of halo and tong external spinal immobilization devices, but it is not to be construed as production methods, quality control techniques, manufacturer's lot criteria, or clinical recommendations.

1.2 This specification represents the best currently available test procedures at this time and is a minimum safety and performance standard.

1.3 This specification covers only those halo and tong devices intended for use on humans for therapeutic purposes. This specification assumes the user is well-trained in the procedures and maintenance of halo and tong application and has the ability to determine if an abnormality is treatable by these procedures.

1.4 This specification describes those devices commonly known as halo external fixation devices and what is known as cranial traction tongs.

1.5 Cranial traction tongs and halo devices are used to achieve and maintain optimal spinal alignment, in order to enhance fusion and decrease neurological deficit.

1.6 Monitoring the progress of treatment after application of these devices is important, this should be done in accordance with the manufacturer's recommendation and guidelines pertaining to the specific device.

1.7 The values stated in both inch-pound and SI units are to be regarded separately as the standard. The values given in parentheses are for information only.

1.8 The following precautionary statement pertains only to the test method portions Sections 10-15 of this specification: *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 IEC Standard:

IEC 601-1 ²

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *cranial traction tong*—a device providing weighted cervical traction to a patient through invasive attachment to the skull. This traction instrument is indicated for closed reduction of a cervical spine injury (that is, fracture or dislocation).

3.1.1.1 *adjustable tong*—a cranial traction tong that adjusts for size, pin positioning, or pin pressure.

3.1.1.2 *one-piece tong*—a rigid, single-piece, semicircular cranial traction tong designed to accommodate a minimum of two skull pins for mounting the device to the patients head below the equator.

3.1.2 *halo device*—an external fixator for cervical stabilization that fastens by invasive means to a patient's skull, and maintains the position of the skull in relation to the thoracic area of the patient.

3.1.3 *halo ring*—the portion of the halo device that fastens by invasive means to a patient's skull below the head equator.

3.1.3.1 *closed loop halo ring*—a halo ring incorporating a closed loop anywhere in the design for purposes of structural integrity when the ring is in use. This type of ring has multiple positioning options for the selection of pin sites and is mounted to the head with multiple skull pins.

3.1.3.2 *head equator*—the greatest circumference of the head in the coronal aspect

3.1.3.3 *open loop halo ring*—a halo ring with a posterior opening, such that the part does not incorporate a closed loop anywhere in the design for structural integrity. This ring has multiple position options for the selection of pin sites and is mounted to the head with multiple skull pins.

3.1.4 *halo superstructure*—a rigid external framework used to maintain positioning of the skull and cervical spine in relation to the thoracic and lumbar spine. Connects the halo ring to halo vest.

3.1.4.1 *halo superstructure adjustment mechanisms*—components that allow adjustment of angles and distances between ring and uprights or vest and uprights.

3.1.4.2 *transverse bar*—a rigid horizontal component of the halo superstructure.

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