

kVue™ Pronumbra™

Proton Head & Neck System

TECHNICAL DATA SHEET



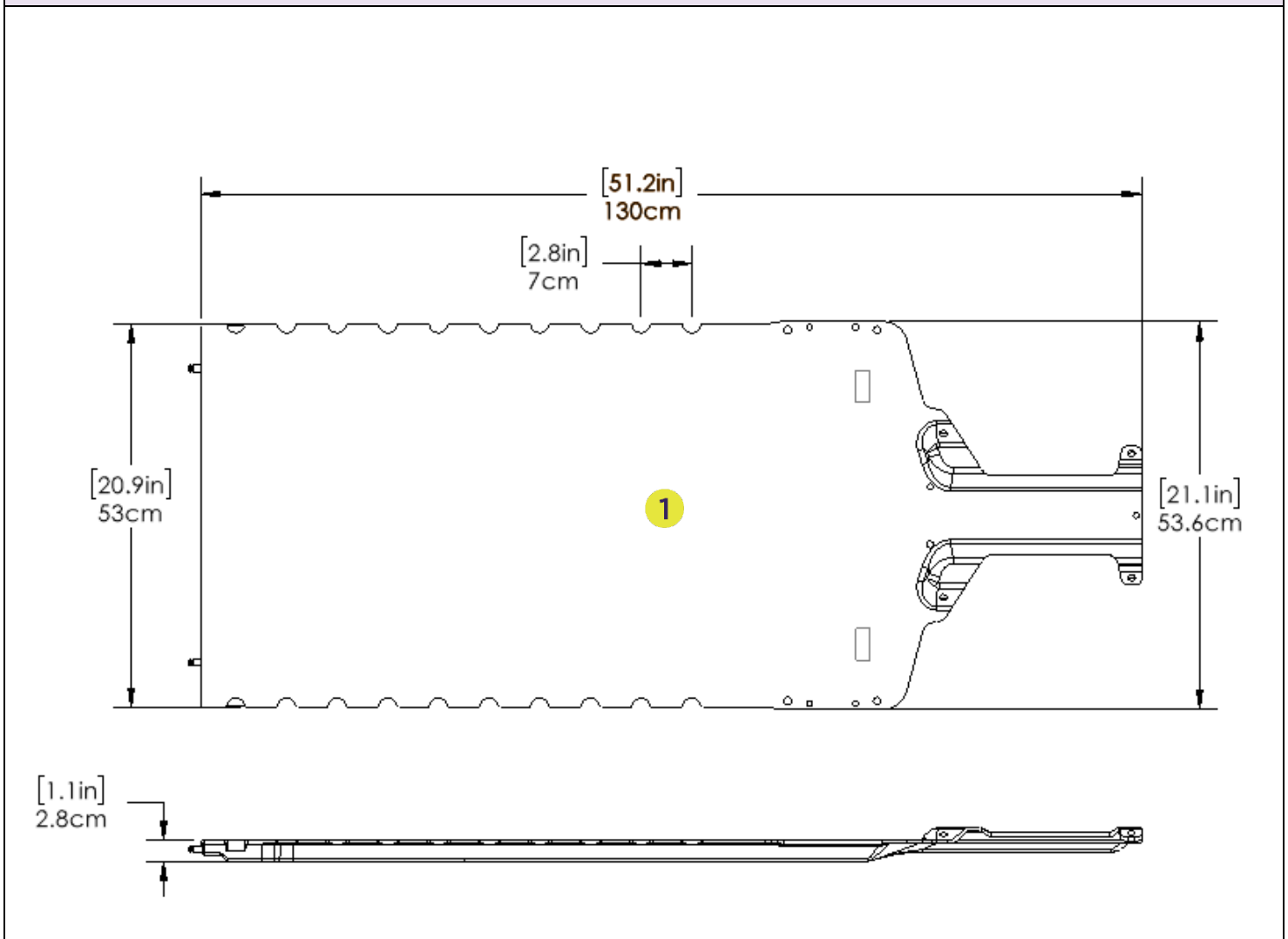
KVUE PRONUMBRA SYSTEM	RT-4536KV-100 kVue Pronumbra Insert, 130 cm Package. Includes insert, neck supports (3 sizes), Helping Hands™ cushion manager, shoulder adapters, InfinityLock™ hand grips, and locking locating bar.
GENERAL DESCRIPTION	The Pronumbra system aids in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery, and electron, photon and proton treatments. The device is also used during image acquisition to support treatment planning.
NECK SUPPORTS	RT-4536-NS40 Pronumbra Neck Support, 40 mm RT-4536-NS50 Pronumbra Neck Support, 50 mm RT-4536-NS65 Pronumbra Neck Support, 65 mm
HELPING HANDS™ CUSHION MANAGER	RT-4536-HH01R Pronumbra Helping Hands Cushion Manager, Right RT-4536-HH01L Pronumbra Helping Hands Cushion Manager, Left
SHOULDER ADAPTERS	RT-4536-SA01 Pronumbra Shoulder Adapters
LOCATING BARS	RT-4551BAR-05 Locking Locating Bar
HAND GRIPS	RT-4800-04 InfinityLock™ Hand Grips
THERMOPLASTIC MASKS	RT-C876K Pronumbra, Head Only with Integrated Shim™, Fibreplast®, Microperf, 3.2 mm RT-C878K Pronumbra, Head, Neck & Shoulders with Integrated Shim, Fibreplast, Microperf, 3.2 mm RT-C889K Pronumbra, Head Only with Integrated Shim, Fibreplast, Standard Perf, 3.2 mm RT-C892K Pronumbra, Head, Neck & Shoulders with Integrated Shim, Fibreplast, Standard Perf, 3.2 mm
INDICATIONS FOR USE	RT-4536KV-01, RT-C876K, RT-C878K, RT-C889K, RT-C892K, RT-4536-SA01, RT-4551BAR-05, RT-4800-04 These devices are indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery, and electron, photon and proton treatments. The device is also used during image acquisition to support treatment planning. RT-4536-HH01R, RT-4536-HH01L, RT-4536-NS40, RT-4536-NS50, RT-4536-NS65 These devices are indicated to aid in supporting and positioning adult and pediatric patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.

FDA CLEARANCE	Yes
CE MARKED (EU DOC)	Yes
OTHER COUNTRY REGISTRATIONS	Available upon request
COUNTRY OF MANUFACTURE	USA

TECHNICAL DETAILS

COMPONENT	RT-4536KV-01 kVue Pronumbra Insert, 130 cm	
PRIMARY MATERIALS	Carbon Fiber Composite with Foam Core	
WEIGHT (APPROX)	4.5 kg / 10 lbs	
MAX SAFE WORKING LOAD	250 kg / 550 lbs	
DIMENSIONS (CM)	130 L x 53 W x 4.6 H	
DOSIMETRIC PROPERTIES	LOCATION	PROTON WATER EQUIVALENCY (R80) 10 X 10 FIELD SIZE (CM³)
	1 - Body area	Estimated at 5.9 mm
	Performance Specifications are for reference only, values may vary based on setup and equipment.	

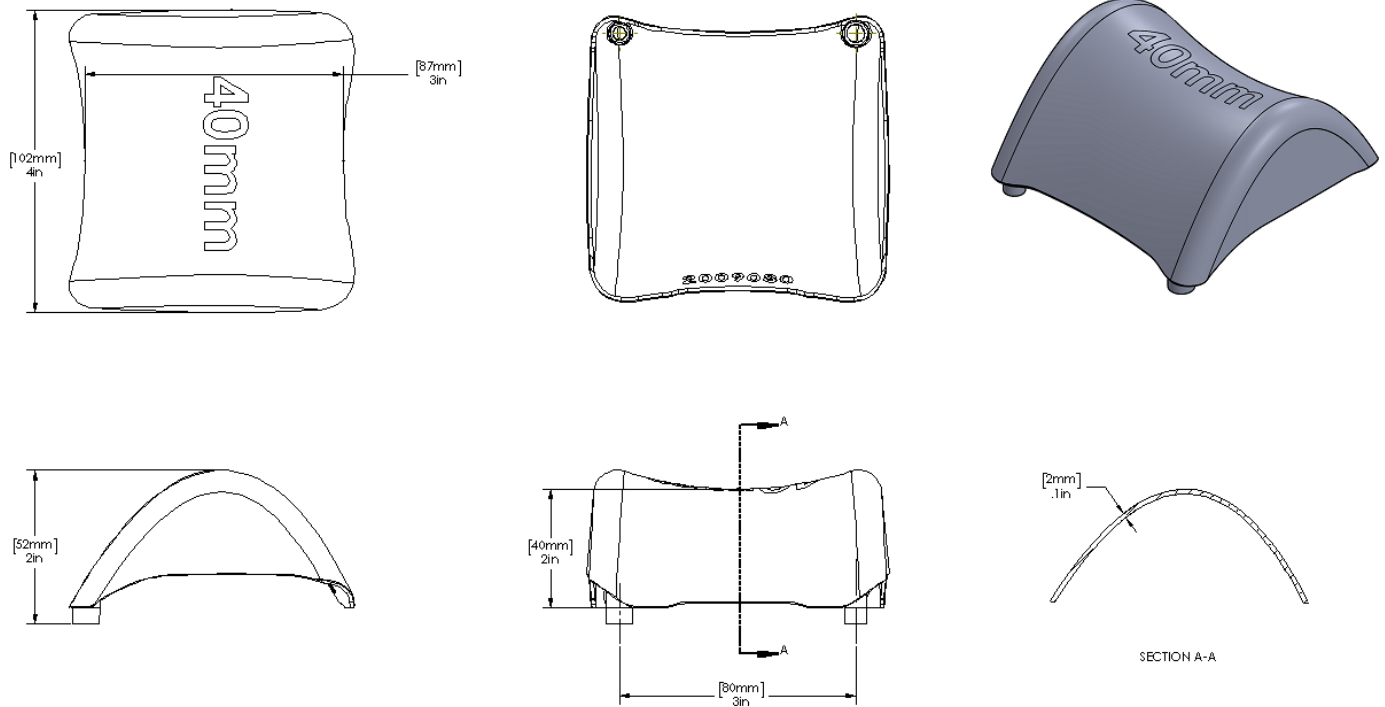
TECHNICAL DRAWING



TECHNICAL DETAILS

COMPONENT	RT-4536-NS40 Pronumbra Neck Support, 40 mm
PRIMARY MATERIALS	Nylon
WEIGHT (APPROX)	Less than 0.1 kg
DIMENSIONS (MM)	102 L x 88 W x 52 H

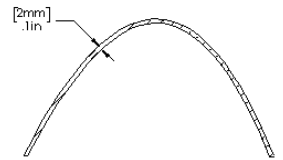
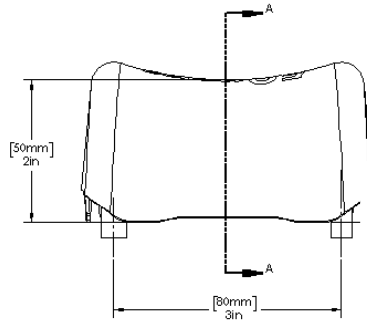
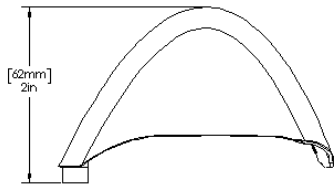
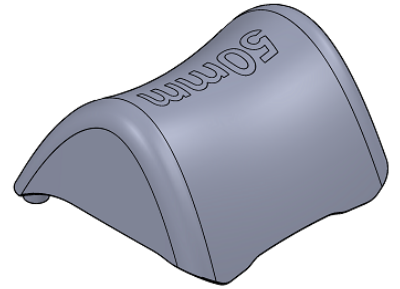
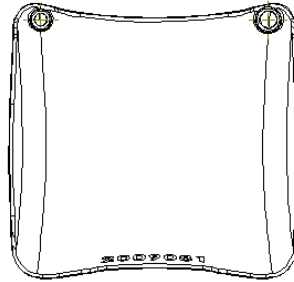
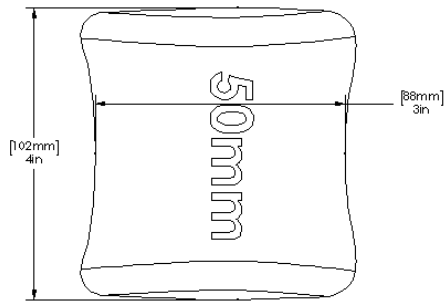
TECHNICAL DRAWING



TECHNICAL DETAILS

COMPONENT	RT-4536-NS50 Pronumbra Neck Support, 50 mm
PRIMARY MATERIALS	Nylon
WEIGHT (APPROX)	Less than 0.1 kg
DIMENSIONS (MM)	102 L x 88 W x 62 H

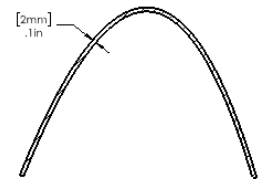
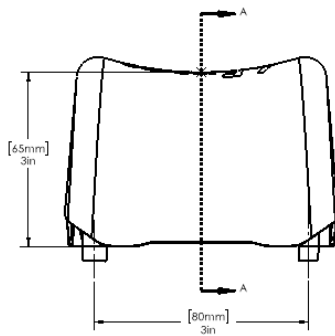
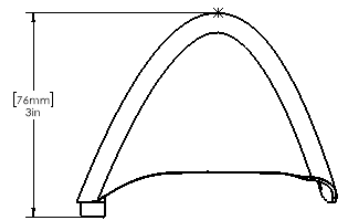
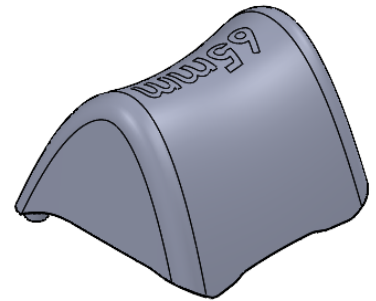
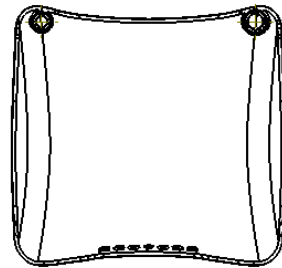
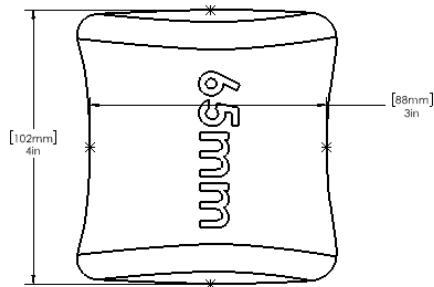
TECHNICAL DRAWING



TECHNICAL DETAILS

COMPONENT	RT-4536-NS65 Pronumbra Neck Support, 65 mm
PRIMARY MATERIALS	Nylon
WEIGHT (APPROX)	Less than 0.1 kg
DIMENSIONS (MM)	102 L x 88 W x 76 H

TECHNICAL DRAWING

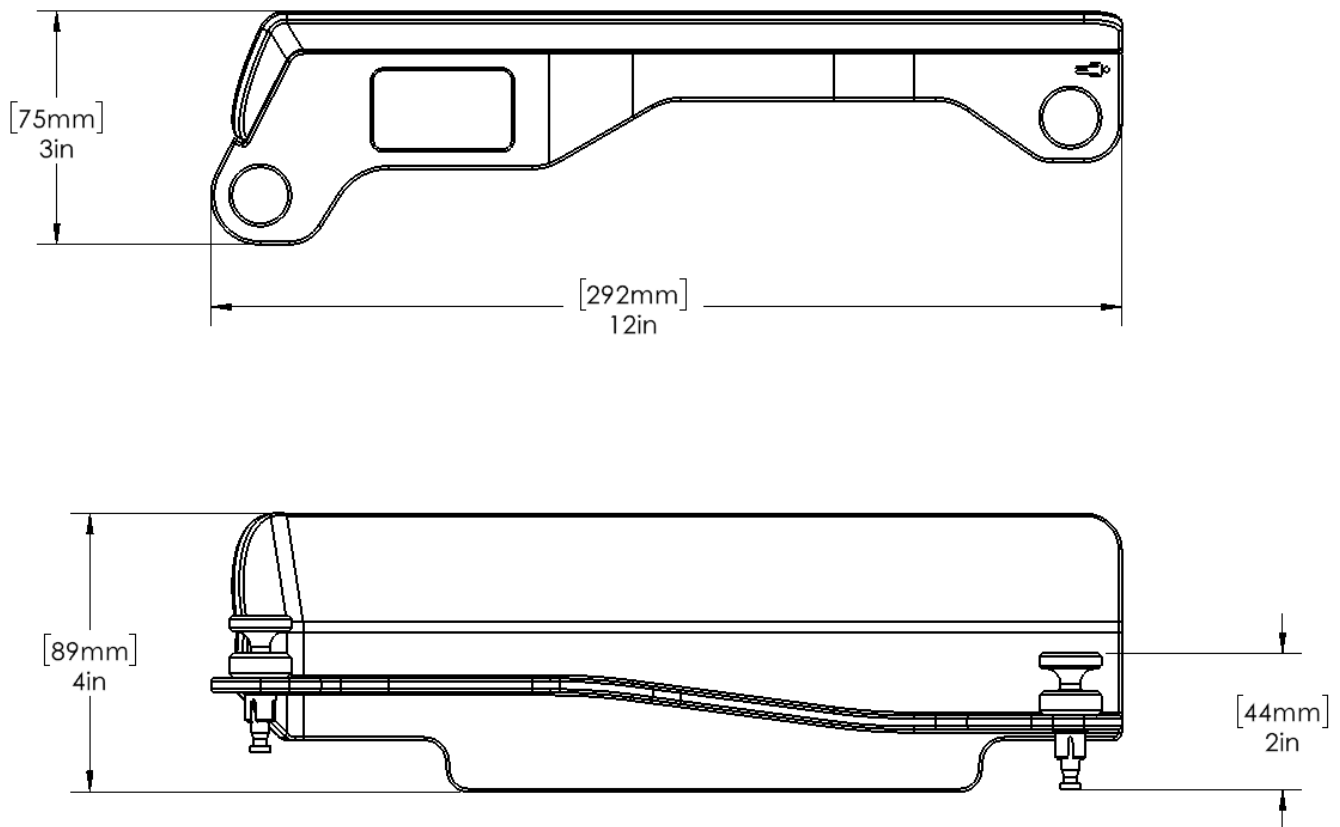


SECTION A-A

TECHNICAL DETAILS

COMPONENT	RT-4536-HH01R Pronumbra Helping Hands, Right RT-4536-HH01L Pronumbra Helping Hands, Left
PRIMARY MATERIALS	Nylon
WEIGHT (APPROX)	0.1 kg / 0.3 kg each
DIMENSIONS (MM)	292 L x 75 W x 89 H

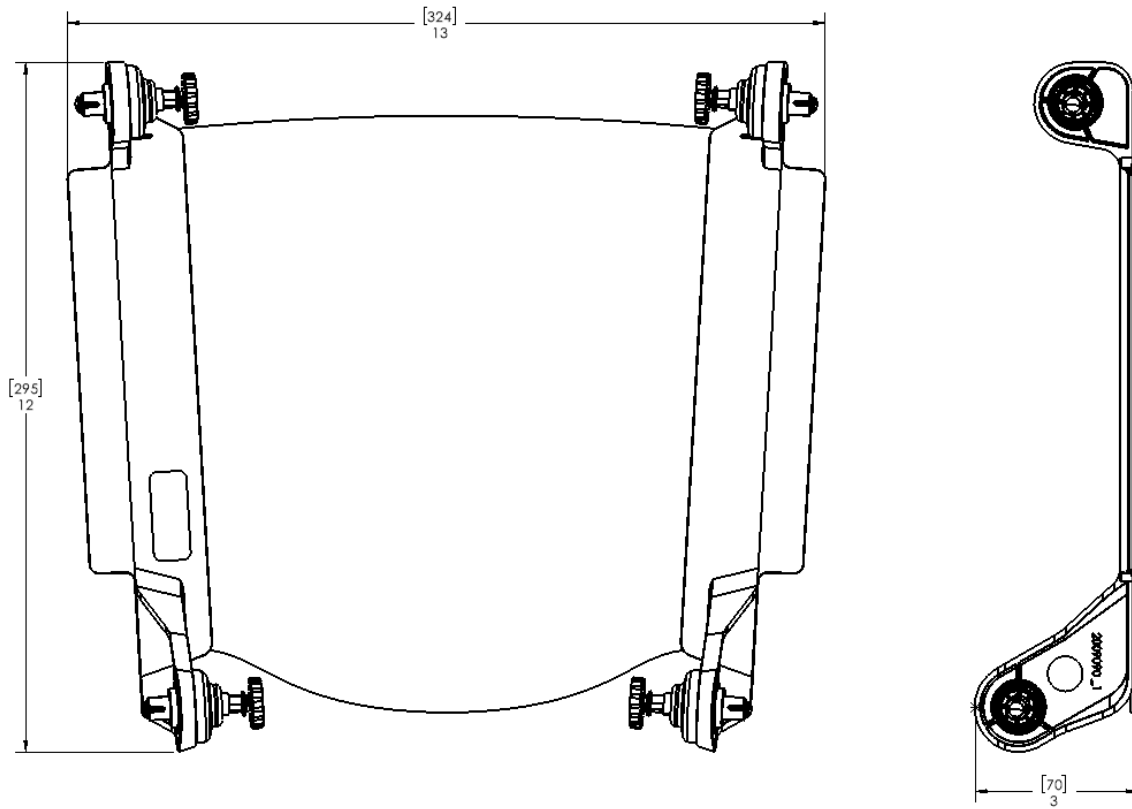
TECHNICAL DRAWING



TECHNICAL DETAILS

COMPONENT	RT-C876K Pronumbra, Head Only with Integrated Shim, Fibreplast, Microperf, 3.2 mm RT-C889K Pronumbra, Head Only with Integrated Shim, Fibreplast, Standard Perf, 3.2 mm
PRIMARY MATERIALS	PC / Thermoplastic
WEIGHT (APPROX)	0.4 kg / 0.8 lbs
DIMENSIONS (MM)	295 L x 324 W x 70 H

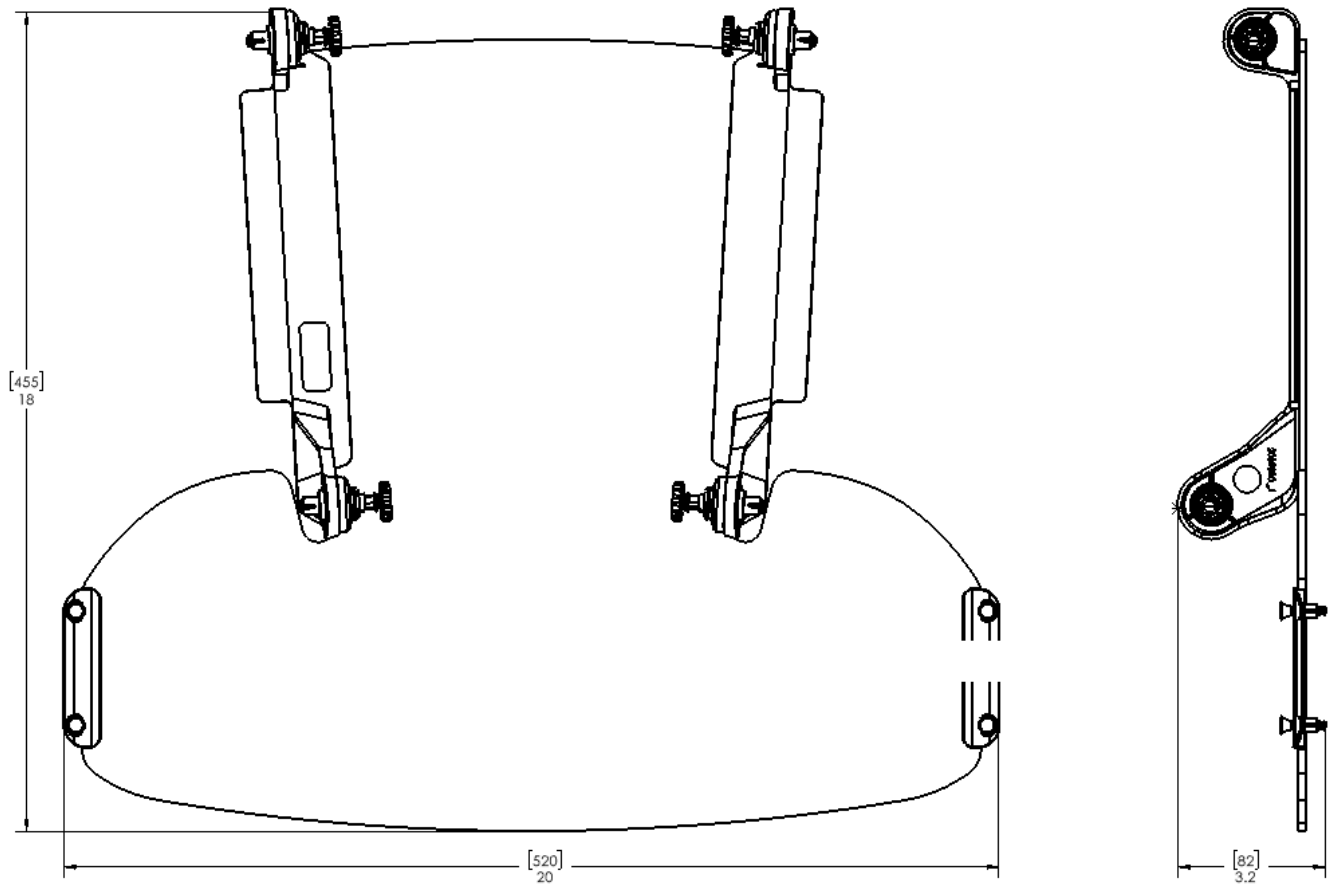
TECHNICAL DRAWING



TECHNICAL DETAILS

COMPONENT	RT-C878K Pronumbra, Head, Neck & Shoulders with Integrated Shim, Fibreplast, Microperf, 3.2 mm RT-C892K Pronumbra, Head, Neck & Shoulder with Integrated Shim, Fibreplast, Standard Perf, 3.2 mm
PRIMARY MATERIALS	PC / Thermoplastic
WEIGHT (APPROX)	0.7 kg / 1.5 lbs
DIMENSIONS (MM)	455 L x 520 W x 82 H

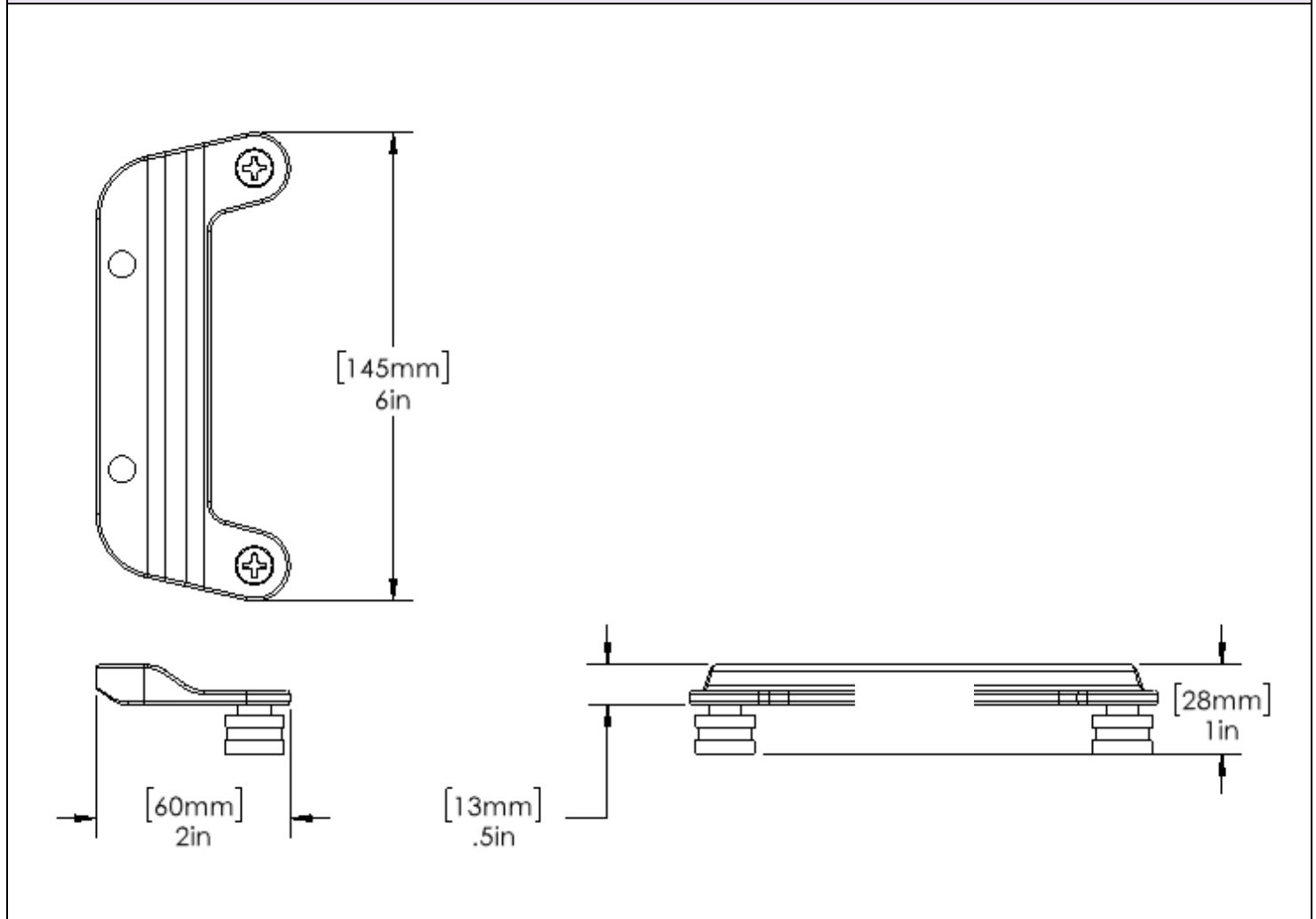
TECHNICAL DRAWING



TECHNICAL DETAILS

COMPONENT	RT-4536-SA01 Shoulder Adapters
PRIMARY MATERIALS	Nylon
WEIGHT (APPROX)	Less than 0.1 kg / 0.4 lbs
DIMENSIONS (MM)	145 L x 60 W x 28 H

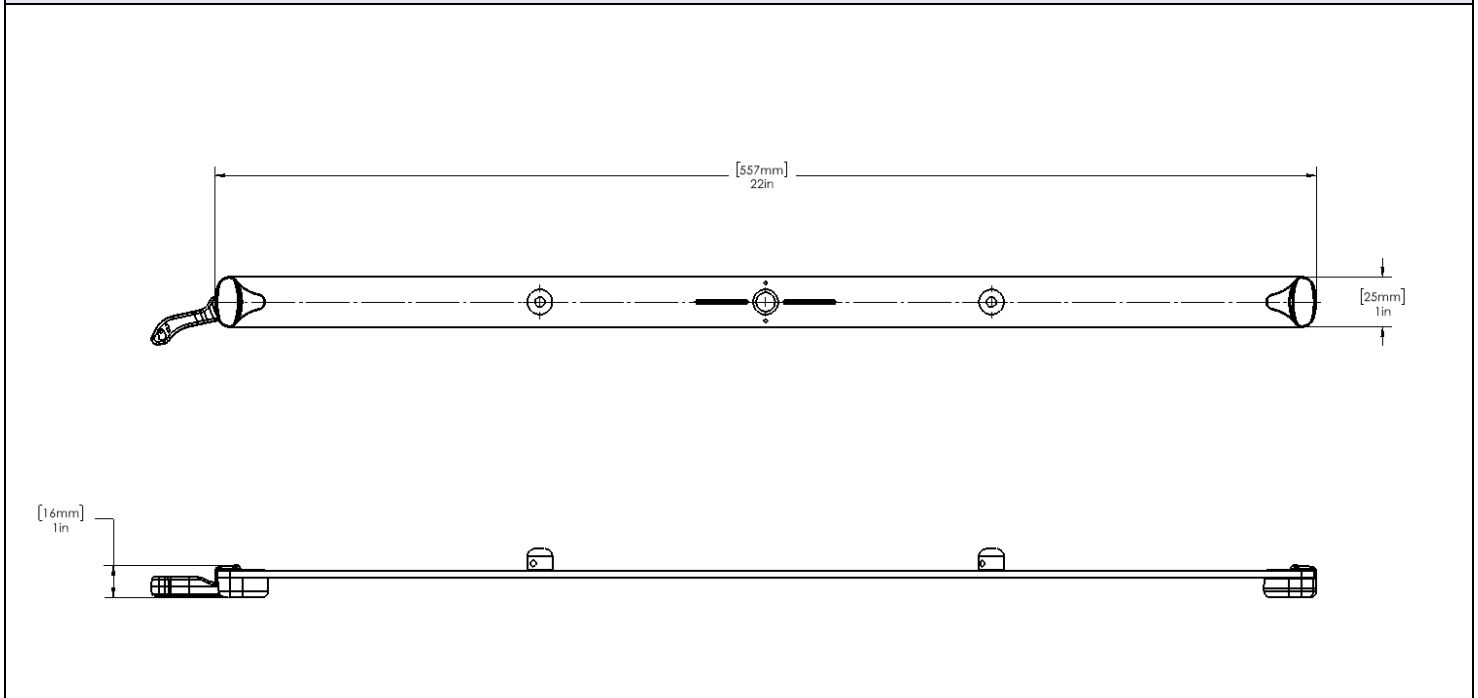
TECHNICAL DRAWING



TECHNICAL DETAILS

COMPONENT	RT-4551BAR-05 Locking Locating Bar
PRIMARY MATERIALS	Aluminum, Plastic
WEIGHT (APPROX)	0.1 kg / 0.4 lbs
DIMENSIONS (MM)	557 L x 25 W x 16 H

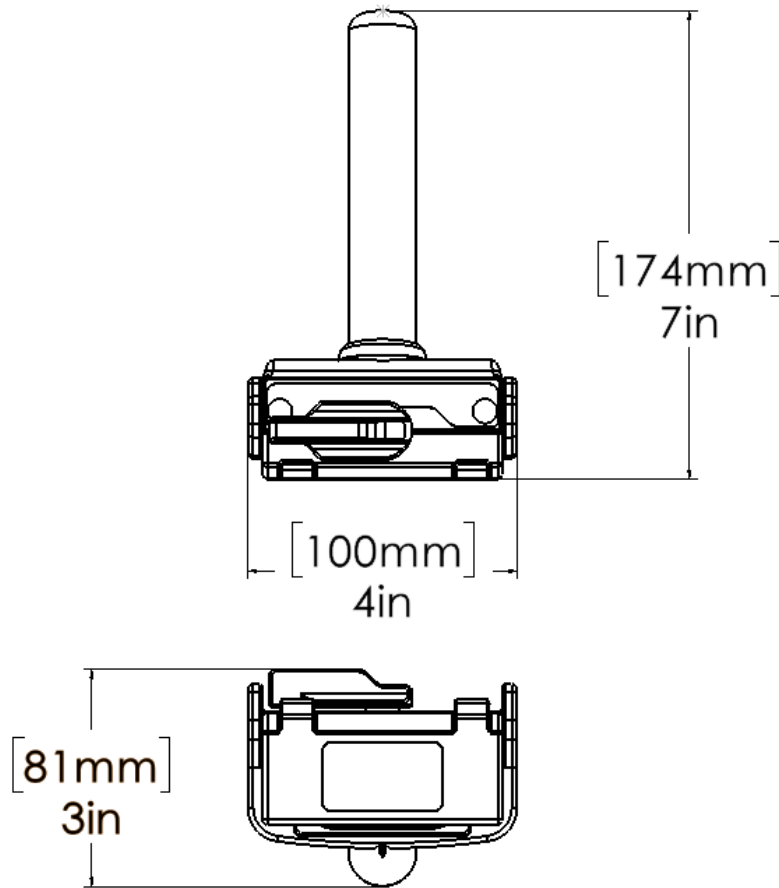
TECHNICAL DRAWING



TECHNICAL DETAILS

COMPONENT	RT-4800-04 InfinityLock Hand Grips
PRIMARY MATERIALS	PC, Nylon
WEIGHT (APPROX)	0.3 kg / 0.7 lbs
DIMENSIONS (MM)	81 L x 100 W x 174 H

TECHNICAL DRAWING



PACKAGING

UNIT PACK	Each
UNITS / BOX	kVue Pronumbra Insert: One device – may have several component parts in box Head Only Thermoplastic: Qty 5 Head, Neck & Shoulders Thermoplastic: Qty 4
SHELF LIFE	n/a
WARRANTY	See CQ Medical website for Product Warranty Statement
STERILIZATION	Non-Sterile
LAUNCH DATE	August 2024