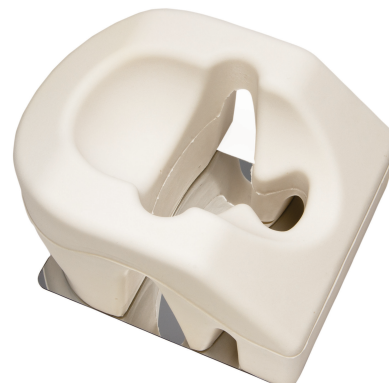


VITAL SIGNS® HEAD POSITIONER

LATEX FREE | DISPOSABLE | SINGLE USE | NON-STERILE | DEHP FREE | PVC FREE | BPA FREE

DEVICE MANUFACTURING SPECIFICATIONS

Reference Number	8000HDP
Manufacturer	AirLife
Manufacturer Address	2710 Northridge Dr. NW, Suite A, Grand Rapids, MI USA
Country of Origin/Made In	USA
Classification - US/510k #	Class I
FDA Product Code	CCX- Support Patient Position
Classification - Canada	Class I
Classification - Japan	Class I
Classification - UK	Non-Medical Device
Classification - EU	Class I
CE Mark/Notification Body	CE
EU Authorized Representative	MT Promedt Consulting GmbH
EMDN Code	V089302 - Patient Positioning Medical Cushions
GMDN Code	58080 - Freestanding Headrest
UMDNS Code	16223 - Positioning Aids
UNSPSC Code	42295111 - Operating Room Patient Positioning Devices or Accessories
Usage	Disposable, Single Patient Use
Patient Population	Adult, Pediatric
Area of Use	Hospital or Surgical Centers
Sterility	Non-Sterile. Packaging for non-sterile devices is intended to protect the product from dust and does not provide a sterile barrier.
Packaging	Individually Packaged, 6/Case
Shelf Life	2 Years
Storage Conditions	There are no special storage conditions or handling requirements.
Disposal Instruction	Dispose in accordance with national and local authority regulations.



DEVICE MATERIAL

COMPONENT	MATERIAL
Headrest (One Piece)	Flexible Polyurethane Foam
Mirror	Acrylic
Packaging Material	Polyethylene Bag/Cardboard Box

Biocompatibility: All materials are biocompatible, meeting skin irritation and sensitization requirements. The head positioner does not contain DEHP, natural rubber latex or BPA. This device does not incorporate medicinal products. This device does not contain blood derivatives or materials derived from animals or human tissue.

PART	UOM	GTIN
8000HDP	Each	10889483589786
	Case	30889483589780

Description: Free-standing head positioner with a mirror for prone procedures. The head positioner is made from soft foam. The contoured cradle comforts and supports the patient's head and neck while in the prone position, allowing a clear view of the mouth, nose, eyes, and tracheal tube through the slotted design and mirror. The side opening of the head positioner near the patient's mouth provides access to the endotracheal tube. The larger side opening is to view the patient's face and monitor the endotracheal tube.

Intended Purpose: Intended to maintain the position of an anesthetized patient during prone position surgery.

Contraindications: None known.

TECHNICAL SPECIFICATIONS

DESCRIPTION	SPECIFICATION
Weight	9.5 lb
Height	5.84" (14.83 cm)
Width	9.50" (24.13 cm)
Length	12.05" (30.61 cm)