

# HEAD POSITIONER

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

## DEVICE MANUFACTURING SPECIFICATIONS

Reference Number	8000HDP, 8000HDP-CE
Manufacturer	AirLife (8000HDP) SunMed LLC (8000HDP-CE)
Manufacturer Address	2710 Northridge Dr NW Ste A Grand Rapids, MI 49544 USA
Country of Origin /Made In	United States
Classification - US / 510k #	Class I
FDA Product Code	CCX - Support Patient Position
Classification- Australia	Class I
AUS Authorized Representative	AirLife Australia Holdings Pty Ltd
Classification - Canada	Class I
Classification- Japan	Non-Medical Device
Classification - EU	Class I
CE Mark	CE (8000HDP-CE)
EU Authorized Representative	MT Promedt Consulting GmbH
EMDN Code	V089302 - Patient Positioning Medical Cushions
GMDN Code	64413 - Freestanding Headrest, Single-Use
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, 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
Packaging Material	Polyethylene Bag/Cardboard Box
Shelf Life	2 Years
Storage Conditions	There are no special storage conditions or handling requirements.
Disposal Instruction	Dispose of in accordance with national and local authority regulations.



## DEVICE MATERIAL

Component	Material
Headrest (One Piece)	Flexible Polyurethane Foam
Mirror	Acrylic

**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 Number	UOM	GTIN
8000HDP-CE	Each	10889483642351
	Case	30889483642355
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 endotracheal tube through the slotted design and mirror. The side opening of the head positioner near the patient's mouth provides access to the ET tube. The larger side opening is to view the patient's face and monitor the ET tube.

**Intended Purpose:** A head positioner is a device intended to maintain the position of an anesthetized patient during prone position surgery.

**Contraindications:** None known.

## DEVICE SPECIFICATIONS

Description	Specification
Weight	9.50 lbs
Height	5.84" / 14.83 cm
Width	9.50" / 24.13 cm
Length	12.05" / 30.61 cm