Instruction Full Sheet Specification

Part Number	Revision	Description	UOM
NW0766	D	IFU, 6988A-PV-ACP ProAxis® PKIT	EA

Purchasing Information

Manufacturer	Mfg. P/N
ANY	NW0766

Description (critical information, e.g. size, material, tolerance or other parameters; font, margin, paper type, etc.)

- Size = 8.5 x 11
- Standard 20 lb. white copy paper, or equivalent
- Margins (minimum) = Top: .25", Bottom: .25", Left: .5", Right: .5"
- Template must include:

  Top:
  Approved Mizuho OSI logo graphic = .34" x 1.55" or larger
  Device Description = 12 -14 pt. Arial bold, all capitals
  Ref (Part Number) and Quantity = 12 - 20 pt. Arial
  Standard disclaimer e.g. for Single Patient Use Only = 10 -14 pt. Arial, bold

  Bottom:
  Designated area for ISO Symbols (Please refer to graphical symbols and regulations standards)

  Date of Manufacture: Locate above line next to 

  Standard Footer:
  Mizuho OSI Name = 10 - 12 pt. Arial, bold
  Address, telephone number, fax number and web address = 7 pt. Arial, bold
  European Representative name and address = 6 pt. Arial
  Instruction Sheet Part Number, Revision, Title and ECN Date = 6 -10 pt. Arial
- Print Type = (e.g. color vs. black and white)

Special Instructions (special handling requirements, refrigeration, exposure to sunlight, packaging etc.)

Note: Page 1 is instructions only. Not to be included with the final printed instruction sheet shown on page 2.
Packaging Instructions: (e.g. Bulk pack; label)

Inspection Criteria (consult with QA)

- Template shown is representative of actual Instruction Sheet. Layout and placement may differ as content is populated.
- Verify no blurring, ghosting, etc.
- Verify all pages are present.

Revision History

ECN	Rev.	Reason for Change	Effective Date
101506	A	Production Release	04/28/2014
103389	B	Update names and symbols to current format as needed. Update instruction sheet template to current revision.	06/14/2017
105828	C	Added MD medical device symbol and EY/ MDR language around reportability of a serious incident; General format changes, update non-product related wording to provide consistency with similar documents.	05/06/2021
2024	D	Updated EC REP address on page 1, added UKCA symbol and UKRP address to footer of page 1; update to current IFU template.	

ProAxis® SYSTEM

PATIENT CARE KIT INSTRUCTIONS FOR USE

REF 6988A-PV-ACP CONT 6

⚠ ***CAUTION:*** **This Patient Care Kit is for SINGLE PATIENT USE ONLY. Discard after use. Re-use of any component in this Patient Care Kit may result in cross contamination.**

1. Open the Patient Care Kit. When using the ProneView® Cushion Insert, it is recommended to open the cushion at least 60 Minutes prior to use to allow for complete expansion. Follow the instructions on the underside of the ProneView® Mirror for proper Cushion Insert placement and additional warnings.

   ⚠ ***CAUTION:*** The ProneView® Helmet extends above the patient's head. When placing the patient on the ProAxis®, check to ensure the Helmet does not contact the Head-End Support Assembly or the Chest Pad during the anticipated patient range of motions. Monitor patient during table movement to ensure the desired head support is maintained.

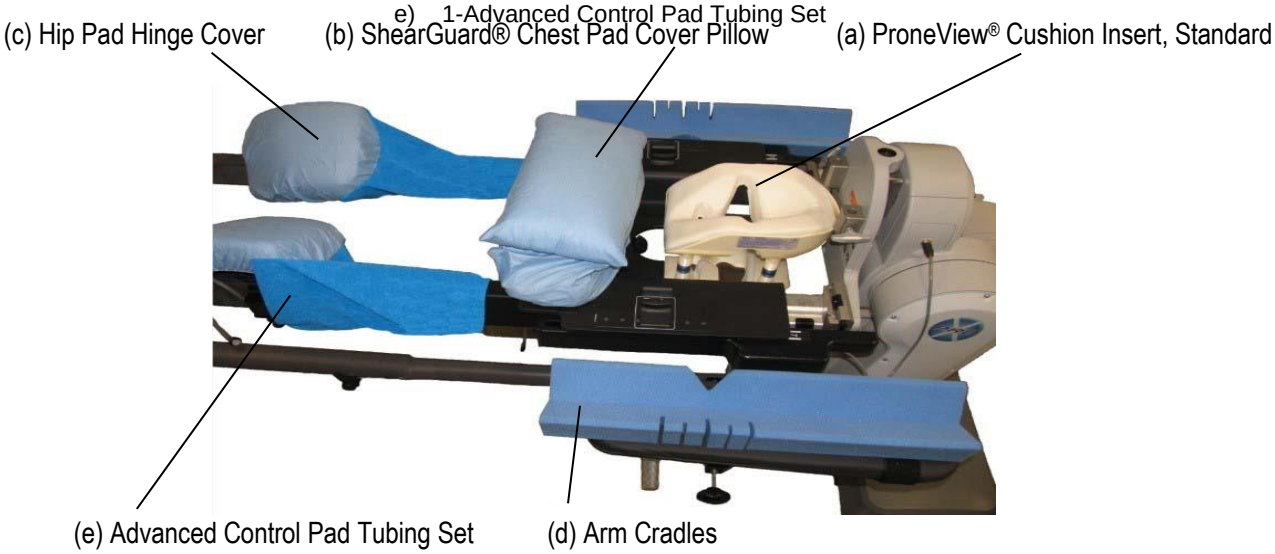
2. Connect the Advanced Control Pad Tubing to the connection port on the Foot-End column of ProAxis® and to the Hip Pads.
3. Apply the Single Chest Pad Cover.
4. Apply the Hip Pad Covers over the Hip Pads by covering the distal end of the pad and pulling toward the Chest Pad. Extend the elastic portion of the Hip Pad Cover over the ProAxis® hinge and secure with the Velcro® strips. Confirm the contact surface of the covers are smooth and without wrinkles or folds. Confirm that the Hinge Cover does not impede the movement of the Torso Trolley®. Re-adjust the portion covering the hinge as needed.
5. Once the patient has been transferred, gently lift the patient at the location of contact for each pad and smooth the contact surface of the cover.

   ⚠ ***CAUTION:*** Confirm that the patient is free of any skin folds and is absent of any pressure on the nipples. Re-check the patient at all contact points throughout the procedure to ensure proper positioning.

6. Place the Arm Cradles between the Arm Boards and the patient.

PKIT 6988A-PV-ACP *includes:*

a) 1-ProneView® Cushion Insert
b) 1-ShearGuard® Chest Pad Cover Pillow
c) 2-Hip Pad Hinge Covers
d) 2- Arm Cradles
e) 1-Advanced Control Pad Tubing Set



NOTE*: (European Union) Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.*

Mizuho OSI ● **30031 Ahern Ave.** ● **Union City, CA 94587-1234 USA** ● **(800) 777-4674** ● **+1 (510) 429-1500** ● **FAX +1 (510) 429-8500**

www.mizuhosi.com ● EC REP Emergo Europe ● Westervoortsedijk 60● 6827 AT Arnhem, The Netherlands

UKRP Emergo Consulting (UK) Limited ● c/o Cr360 - UL International ● Compass House, Vision Park Histon ● Cambridge CB24 9BZ ● United Kingdom