Instruction Full Sheet Specification

Part Number	Revision	Description	UOM
NW0778	E	IFU, 6988A-PCS ProAxis® Patient Care Kit	EA

Purchasing Information

Manufacturer	Mfg. P/N
ANY	NW0778

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 = black and white

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

Note: Pages 1-2 are instructions and revision history only. Not to be included with the final printed instruction sheet shown on the following page(s).

Packaging Instructions: Bulk pack; label contents (not applicable when printed in house)

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
101715	A	INITIAL RELEASE	09/29/2014
101826	B	CHANGE CONTENTS FROM 1 TO 6. ADD PHONE & FAX TO EC REP INFO.	10/27/2014
103389	C	Update names and symbols to current format as needed. Update instruction sheet template to current revision.	06/14/2017
105829	D	Added MD medical device symbol and EU/ MDR language around reportability of a serious incident; General format changes, update non-product related wording to provide consistency with similar documents.	05/21/2021

200006	E	Updated EC REP address on page 1, added UKCA symbol and UKRP address to footer of page 1; update to current IFU template.	

ProAxis® PATIENT CARE KIT

INSTRUCTIONS FOR USE

REF 6988A-PCS CONT 6 PKITS

⚠ The Patient Care Kit is SINGLE PATIENT USE ONLY. Discard after use.
Re-use of any part of this kit may result in cross contamination.

1. Open the Patient Care Kit.

   NOTE: *This Patient Care Kit does not include Advance Control Pad (ACP) Tubing or a ProneView® Positioning Pillow. Mizuho OSI recommends the ProneView® System and ACP Tubing be used in conjunction with the ProAxis® System and its ACP System.* ***For a complete Patient Care Kit with the Prone Positioning Pillow, Arm Cradles and the ACP Tubing order REF 6988A-PV-ACP or 6988A-GT-ACP.***

   ⚠ **CAUTION:** When placing the patient on the ProAxis®, check to ensure the ProneView® Positioning Pillow 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. Select and apply the ShearGuard® Chest Pad Pillow Cover to the Chest Pad.

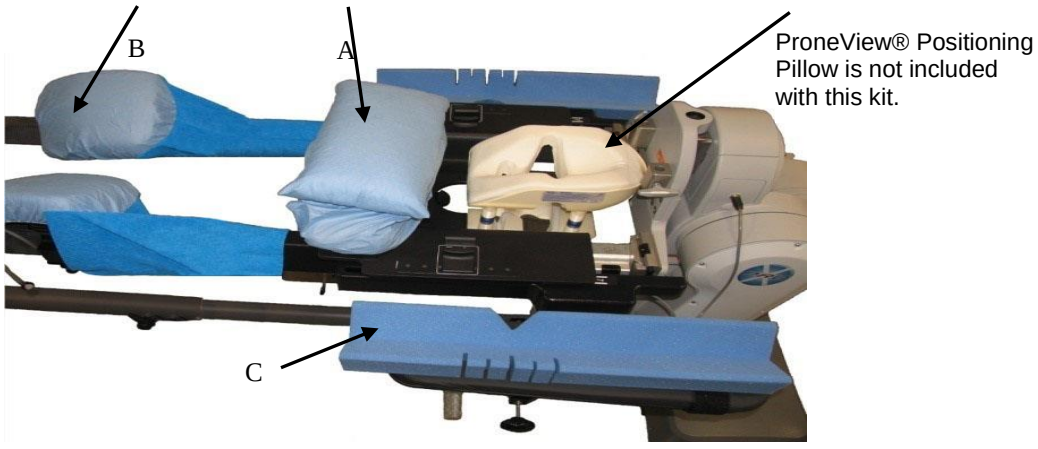
3. Apply the Hip Pad Covers over the Hip Pads by covering the distal end of the pad and pulling toward the Chest Pad. Extend the elastic portion of the Hip Pad Cover over the ProAxis® hinge and secure with the Velcro® strips. Confirm the contact surface of the covers are smooth and without wrinkles or folds. Confirm that the cover does not impede the movement of the Torso Trolley®. Re-adjust the portion covering the hinge as needed.

4. 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.

Each PKIT includes:

A) ShearGuard® Chest Pad Pillow Cover, 1 each
B) Hip Pad Covers, 1 pair
C) Foam Arm Cradles, 1 pair



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

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