Operation / Service Technical Manual

NOTE: Electronic copies available at www.dabir-surfaces.com/IFU

PROFESSIONAL (FACILITY USE ONLY)

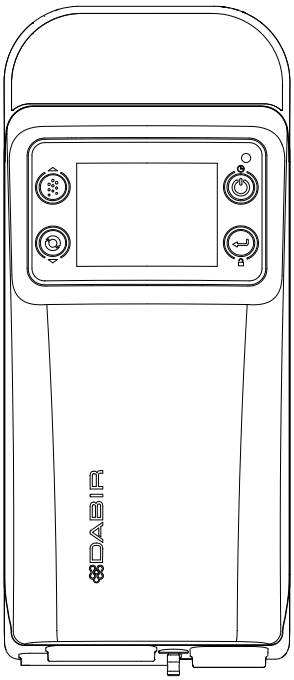
CONTROLLER & ACCESSORIES: MN

C2-1001	Controller Starter Kit w/ 15' Power Cord (Facility Use)
C2-90B2-15	15’ Power Cord (Latching, non-COO*)
C2-9001	Mount - IV Pole Kit
C2-9002	Filter Service Kit

**Non-USA Government "Country of Origin" compliant.*

MICROPRESSURE SURFACES (MP): MN

D2-3S3384-05-1L	MP Surface - ICU/Med-Surg Bed (33"W x 84"L, 5' Hose)
D2-3S3384-10-1L	MP Surface - ICU/Med-Surg Bed (33"W x 84"L, 10' Hose)
D2-3S3384-16-1L	MP Surface - ICU/Med-Surg Bed (33"W x 84"L, 16' Hose)

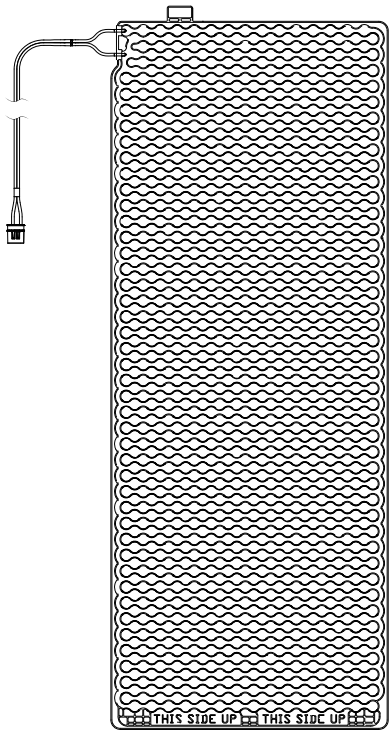


Controller

SURFACE MODEL NUMBER KEY:

D2 - 3 S 33 84 - 05 - 1 L

- FRICTION IDENTIFIER
  - H = HIGH
  - L = LOW
- HOSE EXIT LOCATION
  - 0 = BOTTOM & TOP
  - 1 = LOWER RIGHT / UPPER LEFT
  - 2 = LOWER LEFT / UPPER RIGHT
  - 3 = MIDDLE
- HOSE LENGTH (FEET)
- SURFACE LENGTH (INCHES)
- SURFACE WIDTH (INCHES)
- FEATURE DESIGNATOR
  - 0 = NO STRAP
  - S = RETENTION STRAP
- MARKET SEGMENT
  - 3 = ICU / MED-SURG BED
- FUNCTION CODE (2 = C2 CONTROLLER FAMILY)
  - D2 = MICROPRESSURE
  - M2 = MICROCLIMATE



Surface

DOC# R02-0006-00061-BA

1.0 Table of Contents

1.1 Important Before You Start

Please read this manual carefully and completely before using Dabir products. Failure to do so may result in decreased performance or product failure. The "System" or "Device" is defined as the Controller & Surface.

1.2 System Warnings

- Do NOT place the Controller on the Surface with patient.
- Surfaces are intended to be used ABOVE an underlying bed mattress with good pressure redistribution properties over the full patient contact area.
- Always place the Surface ABOVE the mattress and cover it with a bed linen. (Surfaces are NOT intended to be used in direct contact with the patient's skin.)
- Therapy is NOT provided unless the Controller is powered "ON" and the Surface is actively cycling.
- It is the responsibility of the user to secure and protect against patient movement and/or falls.
- Always remove patient from Surface prior to cleaning.
- After cleaning / disinfecting, allow Surface adequate time to fully dry before patient use.

1.3 System Cautions

- It is the responsibility of the user to properly clean and disinfect the System prior to patient use.
- To avoid irreparable damage, closely follow recommended cleaning guidelines outlined in Section 7.
- It is the responsibility of the user with medical knowledge to operate this product safely in accordance with these instructions.
- Only use Dabir certified Controllers, Surfaces and Accessories when operating this System.
- Surfaces are imaging compatible and designed to be used with the Controller placed outside of the imaging room.
- Do NOT operate the System in the presence of flammable liquids or gases.
- Small parts present a choking hazard.
- Prior to use, allow one hour for the System to acclimate to room temperature.
- Do NOT use product if damaged.
- Do NOT transport the Controller with Surface attached.
- Power "OFF" Controller before replacing Surface.
- Do NOT autoclave.
- To avoid depressurization noise, do NOT unplug Surface connector while the System is activated.
- Powering "OFF" or "PAUSING" the Controller after the preprogrammed Surface life has expired will automatically force Surface replacement.
- Properly route and secure all Cords and Hoses to avoid trip hazard or damage.
- Modification of the Device voids warranty and may compromise intended function.
- Reference specific accessory instruction manuals when applicable.
- Do NOT use petroleum based lubricants on seals as it may cause swelling and/or leakage.
- Stop use and notify user if patient experiences discomfort related to the use of this Device.
- SHOCK hazard: Always ensure power cord is fully inserted into grounded wall outlet.
- SHOCK hazard: Do NOT submerge. If submerged, unplug the Power Cord from wall outlet immediately.

1.4 Other Cautions

Controller Cautions:

- Use of Controller is NOT recommended around medical equipment that intentionally radiates energy.
- Maintain accessibility to Power Cord such that it can be easily unplugged prior to cleaning and/or servicing.
- Always turn the Controller "OFF" during patient transfer, cleaning and before patient positioning.
- Power "OFF" or "PAUSE" the Controller for cardiac arrest events. (NOT intended for use during CPR. See Section 5)
- Do NOT place the Controller in direct sunlight.
- Only use specified operating wall currents. Alternative power sources and wall currents may result in irreparable damage to the Controller and a possible hazardous event.
- Do NOT use with extension cords.
- Do NOT allow liquids or loose particle debris to enter or block any part of the Controller. (See Section 7)
- It is the responsibility of the user to adequately secure the Controller to prevent fall damage.

Surface Cautions:

- Always install cover linen and incontinence pads ABOVE the Dabir Surface.
- Keep Micropressure Surface vents free of any liquids or loose particle debris which may restrict air flow.
- Sharp objects from any source may damage the Surface and compromise function.
- It is the responsibility of the user to properly dispose of the Surface when damaged or soiled.

1.5 Labels & Descriptions

The Symbols below appear on the Controller, Surfaces, Accessories and/or packaging.

Label	Description
	**UL Mark** ANSI/AAMI ES60601-1 AMD (2012), "Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, Amendment 1" CAN/CSA-C22.2 No. 60601-1 (2014), "Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
	**UL Badge** Indicates UL compliance on marketing, advertising, and packaging materials
	**Non-Sterile** Indicates a medical device that has NOT been subjected to a sterilization process.
	**Caution** Alerts the reader of a potentially hazardous situation which, if NOT avoided, may result in minor or moderate injury to the user or patient or damage to the product or other property. This includes special care necessary for the safe and effective use of the device and the care necessary to avoid damage to the device that may occur as a result of use or misuse.
	**Manufacturer** Indicates the medical device manufacturer.
 YYYY-MM-DD	**Date of Manufacture** Indicates the date when the medical device was manufactured.
	**Separate Collection** Separate collection for electronic waste required.
	**Follow instructions for use**
	**Defibrillation-proof Type BF Applied Part** Indicates a defibrillation-proof type BF applied part complying with IEC 60601-1.
 YYYY-MM-DD	**Use-by Date** Indicates the date after which the medical device is NOT to be used.

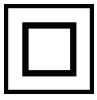
1.5 Labels & Descriptions - Continued

The Symbols below appear on the Controller, Surfaces, Accessories and/or packaging.

Label	Description
IP33	**Level of Ingress Protection Against Solid Foreign Objects and Liquids**
	**This Way Up** Indicates a medical device that can be broken or damaged if NOT handled in a specific orientation.
	**Keep Dry** Indicates a medical device that needs to be protected from moisture.
	**Fragile, Handle With Care** Indicates a medical device that can be broken or damaged if NOT handled carefully.
	**Humidity Limitation** Indicates the range of humidity to which the medical device can be safely exposed.
	**Atmospheric Pressure Limitation** Indicates the range of atmospheric pressure to which the medical device can be safely exposed or operated in.
	**Temperature Limit** Indicates the temperature limits to which the medical device can be safely exposed or operated in.
SN	**Serial Number** Indicates the manufacturer's serial number so that a specific medical device can be identified.
MN	**Model Number** Indicates the manufacturer's model number so that the medical device can be identified
LOT	**Batch Number** Indicates the manufacturer's batch code.
	**Alternating Current** Indicates that the equipment is suitable for alternating current only.
	**Power "ON" & "OFF"** Indicates where to Power the Controller "ON" and "OFF".

1.5 Labels & Descriptions - Continued

The Symbols below appear on the Controller, Surfaces, Accessories and/or packaging.

Label	Description
	**FCC Declaration of Conformity** Certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.
	**Non-ionizing Electromagnetic Radiation** Indicates equipment in the medical electrical area that includes RF transmitters.
	**CE Mark for European Conformity** The CE marking is the manufacturer's declaration that the product meets the requirements of the applicable CE directives.
	**European Authorized Representative** Legal entity for non-EU manufacturers that represents them in the EU to ensure their compliance with the European directives.
	**Double Insulated** Indicates the device is Class II Double Insulated

1.6 About this Manual

This manual is your introduction to the Dabir Patient Support System. Please read and follow these recommended installation / operation guidelines closely. (Accessory instructions are supplied separately.)

1.7 Indications for Use

The Dabir Patient Support System is indicated for:

- Pressure ulcer (injury) prevention when combined with a comprehensive wound prevention plan.
- **BEDS & STRETCHERS**: Use with patients weighing 15 to 600 lbs. ABOVE a bed mattress with good pressure redistribution properties and full patient support contact area.

NOTE: Adequate positioning measures MUST be taken to secure patients against movements and/or falls, especially during extreme positioning.

1.8 Contraindications

- Do NOT use the Dabir Patient Support Systems for patients with unstable spinal fractures or burns.

2.0 About the Dabir System

Dabir is a low-profile, semi-disposable, alternating pressure relief surface that is controlled by a System Controller.

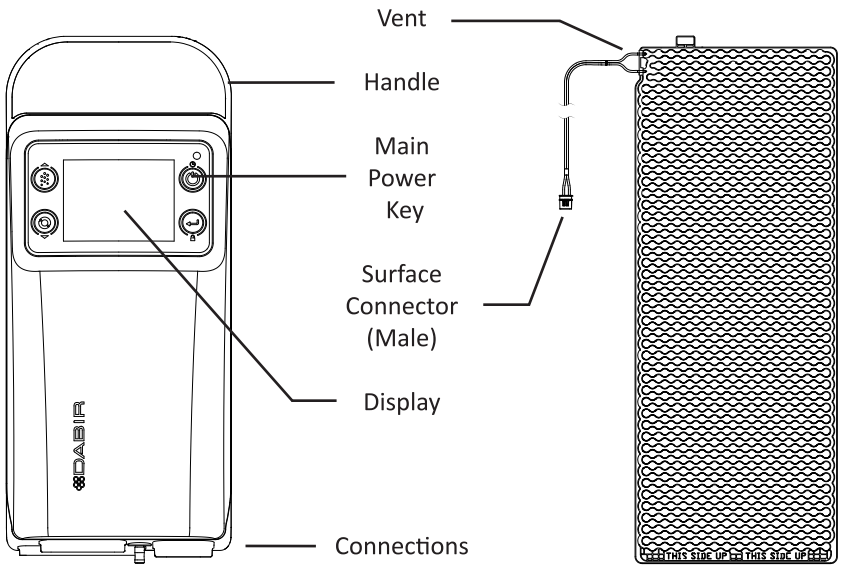
Controller Features:

- Easy Power Activation
- Auto-Start with System "PAUSE"
- Smart Connection System
- Intuitive Display
- Variable Cycle Speed Settings

Micropressure Surfaces:

- **Multi-Patient Use / Semi-Disposable**
- Alternating Nodal Tissue Relief with Reduced Skin Shear
- Easy Wipe-down Cleaning
- 1" (25mm) fully inflated
- Installs ABOVE Standard Bed Mattress
- Covers with Standard Linens & Incontinence Pads

NOTE: Surfaces are the applied part.



Controller **Surface**

Accessories

- Unless noted in this manual, individual Accessory instructions are provided in component packaging.
- Only use Dabir certified Controllers, Surfaces and Accessories when operating this System.

2.1 How it Works

Dabir Technology was developed on the principle of supporting a patient on small, closely spaced areas of contact (nodes) that dynamically alternate in height to relieve at-risk tissue against pressure injury/ulcer formation. The aim is to preserve the circulatory components of arterial, venous and lymphatic blood flow in between these areas of contact.

Skin Shear

By shortening the distance between areas of contact, vertical skeletal structure (patient) movement and skin stretch during alternating support cycles and bed mattress immersion is reduced, thus decreasing the negative impact of skin shear. The result of the alternating cycles without lifting the body in effect, releases any stretched skin which allows previously compressed tissue to naturally reposition and reperfuse. (Perfusion is Prevention!)

Alternating Pressure / Duration

Dabir Micropressure Surfaces achieve alternating support and tissue relief using independent rows of small, inflatable nodes which cycle up and down to promote healthy interstitial blood flow (perfusion) between individual areas of contact.

Low Profile & Self Contouring

Dabir Micropressure Surfaces are designed to be thin and flexible so that they do NOT impact the overall height of the bed mattress. They also contour to the shape of the individual patient as they immerse into a mattress, which provides the broad pressure redistribution support needed beneath Dabir. The end result is improved ergonomics for users during manual patient turning and transfer processes, and easier patient bed exit given the unchanged relative bed height from Dabir.

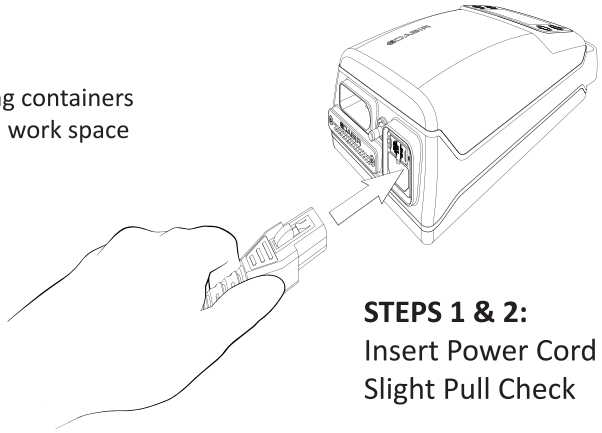
3.0 Controller Pre-Assembly

Simple 2-Step Pre-Assembly:

BEFORE YOU START: Remove components from their individual packaging containers and place on a flat, stable surface (table or bench) with adequate cleared work space and away from any edges to prevent drop damage. (No tools required.)

1. Insert latching Power Cord as shown.
2. Confirm proper insertion with a slight pull.

NOTE: Optional Accessory attachment instructions provided separately.



STEPS 1 & 2:
Insert Power Cord
Slight Pull Check

3.1 System Installation - Controller

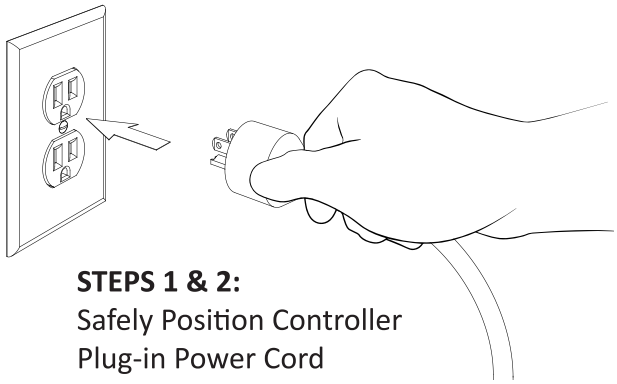
Controller Mounting: Horizontal "Table Top" Installation

BEFORE YOU START: Place Controller in a safe, stable location near a wall power outlet and at an appropriate distance from the patient care area. (See cover page for available hose lengths by model number.)

NOTE: The Controller includes four (4) rubber feet to provide increased "grip" to most horizontal (Table Top) surfaces.

Please refer to Dabir Accessories Guide for alternative Controller mounting options.

1. Route the Power Cord such that it does NOT present a trip hazard.
2. Plug the Power Cord into a AC wall receptacle or other power source with appropriate currents and protective earth ground.



STEPS 1 & 2:
Safely Position Controller
Plug-in Power Cord

⚠ IMPORTANT INSTALLATION RELATED NOTES:

WARNINGS:

- Do NOT place the Controller on the Surface with the patient.

CAUTIONS:

- Prior to use, allow one hour for Controller to acclimate to room temperature.
- Use of Controller is NOT recommended around medical equipment that intentionally radiates energy.
- Only use specified operating wall currents. Alternative power sources and wall currents may result in irreparable damage to the Controller and a possible hazardous event.
- Do NOT use with extension cords.
- SHOCK hazard: Always ensure power cord is fully inserted into grounded wall outlet.