

Operations / Service Technical Manual

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

Applicable Product Families:

Dabir Surgical[™] System (Facility Use Only)

Applicable Model Numbers:

Controllers & Accessories (CA-XXXX) Surfaces (DA-XXXXX-XX-XX) Visit: <u>www.dabir-surfaces.com/models</u> for a complete list of model numbers

Controller

Hose Assembly







Content

1.1	Important Before You Start	3
1.2	Safety Warnings	3
1.3	Labels and Descriptions	4-7
1.4	About this Manual	7
1.5	Indications for Use	7
1.6	Contraindications	7
1.7	About the Dabir System	8
1.8	How it Works	8
2.0	Controller, Hose Assembly and Accessories	9
3.1	Controller Pre-Assembly	10
3.2	System Installation - Controller	11
3.3	System Installation - Surfaces	12
3.4	System Installation - Connections	13
4	Operations and Settings	14
5	Interrupting, Rapid Deflate and Resuming Operation	15
6	Information Center: Alert Codes	16-17
7	Cleaning Procedures	18
8	Preventative Maintenance / Service	19-24
9	Troubleshooting	24
10	Specification Sheets	25-30
11	Limited Warranty	31-32
12	Contact Information	33



1.1 Important Before You Start

Please read the "Instructions-for-Use" device manual carefully and completely before using Dabir products. Failure to do so may result in decreased performance or product failure.

1.2 Safety Warnings

- **WARNING:** To avoid patient injury, do not place the controller on surface with patient.
- **WARNING:** Always place the surface on top of your mattress pad and cover it with a bed sheet.
- **WARNING:** Surfaces are not to be used in direct contact with patient's skin.
- **WARNING:** Therapy is not provided unless controller is powered "ON" and the surface is "ACTIVATED".
- **WARNING:** It is the responsibility of the caregiver to secure and protect against patient movement and falls.
- **WARNING:** Surfaces are intended to be used above an underlying mattress or pad with good pressure redistribution properties over full patient contact area.
- **WARNING:** Always remove patient from surface prior to cleaning and allow for the surface to fully dry before patient placement.
- It is the responsibility of the caregiver to ensure that the user can operate this product safely.
- It is the responsibility of the caregiver to properly dispose of surface when damaged or soiled.
- Only use Dabir certified Controllers, Surfaces and Accessories when operating this Device.
- Unless otherwise specified, use of this device is not recommended around medical equipment that intentionally radiates electromagnetic energy.
- MRI compatible Surfaces are designed to be used with the Controller placed outside of patient imaging room.
- Do not operate the Device in the presence of flammable liquids or gases.
- Prior to use, allow one hour for Device to acclimate to room temperature.
- Maintain accessibility to Power Cord such that it can be easily unplugged from the wall power source prior to cleaning and inspecting. Do not service while in use.
- To avoid irreparable damage, closely follow the recommended cleaning guidelines. (See Section 7)
- It is the responsibility of the caregiver to properly clean the device prior to patient use.
- Do not place the Controller in direct sunlight.
- Do not over tighten screws during assembly.
- Do not use petroleum based lubricants on seals as it may cause swelling and/or leakage.
- Turn Device "OFF" during patient transfer, cleaning and before patient positioning.
- Do not transport the Controller with Surface attached.
- For best performance, always place patient upon the

installed Surface before powering the Controller "ON".

- Power "OFF" or "STOP" the Controller for cardiac arrest events. This unit is not intended for use during CPR. (See Section 5)
- Only use specified operating wall currents. Alternative power sources and currents may result in irreparable damage to the Device and possible hazardous event.
- To avoid electric shock, Device must be connected to a supply mains with protective earth ground.
- To ensure proper electrical grounding, do not use an extension cord with this Device.
- Do not allow liquid to enter any part of the Controller.
- Keep Controller air intake and exhaust vents free of liquids, contamination or loose particle debris which may restrict air flow.
- Keep Surface exhaust vents free of any liquids, contamination or loose particle debris which may restrict air flow.
- Sharp objects from any source may damage the surface and compromise function.
- Properly route and secure all Cords and Hoses to avoid trip hazard or damage.
- To avoid damage, do not drop Hose Assembly to floor after connecting.
- To avoid de-pressurization noise, do not unplug Surface connector while system is activated.
- Once surface life expires, power interrupt or pausing therapy may force surface replacement depending on the model.
- Small parts present a choking hazard.
- Shipping Damage: Please contact the manufacturer for appropriate action.
- Usage Damage: Please remove unit from service and contact manufacturer for appropriate action.
- Modification of the Device voids warranty and may compromise intended function. Service should be performed exclusively by the manufacturer.
- Do not autoclave.
- No Latex is used in the manufacturing of this device.
- Place cover sheet and incontinence pad ABOVE Dabir Surface.
- Notice: 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.

1.3 Labels and Descriptions

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

Label	Description	Application
CERTIFIED SAFTINGS E465956	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	Controller label
CERTIFIED	UL Badge Indicates UL compliance on marketing, advertising, and packaging materials	Controller label, Box labels, Surface labels, Hose Assembly label
NON STERILE	Non-Sterile Indicates a medical device that has not been subjected to a sterilization process.	Surface labels & Overlay Box labels
Ĺ	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.	Instructions For Use
	Manufacturer Indicates the medical device manufacturer.	Box labels & Controller label
YYYY-MM-DD	Date of Manufacture Indicates the date when the medical device was manufactured.	Box labels, Controller label, Hose Assembly label, Surface labels
	Separate Collection Separate collection for electronic waste required.	Box labels, Surface Box labels, Surface labels, Controller label, Hose Assembly label

1.3 Labels and Descriptions - Continued

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

Label	Description	Application
C	Follow instructions for use	Controller label, Surface labels, Hose Assembly label
	Defibrillation-proof Type BF Applied Part Indicates a defibrillation-proof type BF applied part complying with IEC 60601-1.	Controller label
YYYY-MM-DD	Use-by Date Indicates the date after which the medical device is not to be used.	Surface Box labels & Overlay labels
IP20	Protected Against Solid Foreign Objects Of 12.5mm Ø and greater. Not protected against liquid ingress.	Controller label
<u>11</u>	This Way Up Indicates a medical device that can be broken or damaged if not handled in a specific orientation.	Controller Starter Kit Box label
Ĵ	Keep Dry Indicates a medical device that needs to be protected from moisture.	Box labels
I	Fragile, Handle With Care Indicates a medical device that can be broken or damaged if not handled carefully.	Controller Starter Kit Box label
"" "	Humidity Limitation Indicates the range of humidity to which the medical device can be safely exposed.	Box labels
kPA-kPA	Atmospheric Pressure Limitation Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	Controller label & Controller Starter Kit Box label
xx° c	Temperature Limit Indicates the temperature limits to which the medical device can be safely exposed.	Box labels & Controller label

1.3 Labels and Descriptions - Continued

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

Label	Description	Application
SN	Serial Number Indicates the manufacturer's serial number so that a specific medical device can be identified.	Box labels, Surface label, Se- rial ID labels, Surface labels
#	Model Number Indicates the manufacturer's model number so that the medical device can be identified.	Box labels, Controller label, Hose Assembly label, Surface labels
LOT	Batch Number Indicates the manufacturer's batch code.	Power Cord Box label
\sim	Alternating Current Indicates that the equipment is suitable for alternating current only.	Controller label, Controller Starter Kit label
	Direct Current Indicates that the equipment is suitable for direct current only.	Hose Assembly label
	"ON" (power) Indicates connection to the mains.	Controller
0	"OFF" (power) Indicates disconnection to the mains.	Controller
	Universal Serial Bus	Controller
F©	FCC Declaration of Conformity Certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.	Controller label
$(((\bullet)))$	Non-ionizing Electromagnetic Radiation Indicates equipment in the medical electrical area that includes RF transmitters.	Instructions For Use label

1.3 Labels and Descriptions - Continued

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

Label	Description	Application
CE	CE Mark for European Conformity The CE marking is the manufacturer's declaration that the product meets the requirements of the applicable EC directives.	Box labels, Controller label, Hose Assembly label, Surface labels, & Instruction For Use.
EC REP	European Authorized Representative Legal entity for non-EU manufacturers that represents them in the EU to ensure their compliance with the European directives.	Box labels & Instruction For Use
MD	Medical Device Indicates that the device is a medical device.	Labels & Instructions For Use

NOTE: All labels are to be read from 0.5m.

1.4 About this Manual

This manual is your introduction to the Dabir Surfaces Patient Support System. Use it to assure proper installation of the Controller, Hose Assembly and Surface. Also keep it as a reference for day-to-day operation, annual service and maintenance.

1.5 Indications for Use

The Dabir Surface Patient Support System is indicated for:

- Pressure ulcer (injury) reduction when combined with a comprehensive plan which addresses the industry accepted causes of pressure related injuries.
- **SURGICAL TABLES:** Use with patients weighing 15 to 400 lbs above a surgical mattress or pad with good pressure redistribution properties and patient contact area. Adequate patient positioning measures must be taken to secure patients against movement and/or falls, especially during extreme positioning.
- **BEDS & STRETCHERS**: Use with patients weighing 15 to 600 lbs above a mattress or pad with good pressure redistribution properties and patient contact area. (Applicable to discontinued models only. See Dabir **Patient Care** *Plus* family of products for bed and stretcher applications.)

1.6 Contraindications

• Dabir is not intended for use on patients with unstable spinal fractures or burns.

1.7 About the Dabir System

Dabir Surfaces are low-profile, semi-disposable, alternating pressure relief surfaces. The Dabir Patient Support System as a whole consists of:

Control Unit

- Easy Power Activation
- Smart Interconnect System
- START/STOP Touch Activation
- Multiple Cycle Speed Settings
- Multiple Firmness Settings
- 00000

- Surfaces
 - Multi-Patient Use / Semi-Disposable
 - Alternating Nodal Support
 - Reduced Skin Shear
 - Easy Wipe-down Cleaning
 - Covers with Standard Sheets and Incontinence Pads

NOTE: Surfaces are the applied part.

1.8 How it Works

Dabir Technology was developed on the principle of supporting a person on small, closely spaced contact areas (Comfort Nodes) that dynamically alternate to relieve at-risk tissue against pressure related injury. The aim is to promote and preserve the healthy circulatory components of arterial, venous and lymphatic blood flow and to release any stretched tissue resulting from external shear forces.

Skin Shear

By shortening the distance in between areas of contact, skeletal structure movement and skin stretch during alternating support cycles and immersion is reduced, thus decreasing the risk of shear related injury. Skin stretch from external shear forces is also released during each alternating Dabir cycle.

Alternating Pressure / Duration

Dabir Surfaces achieve alternating support and "tissue relief" using independent rows of small comfort nodes that are intended to promote interstitial blood flow between 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.

2.0 Controller, Hose Assembly, Surfaces and Accessories

Controller

User Interface Panel

Hose Assembly

Accessories

See individual component packaging for Accessory related instructions.

3.1 Controller Pre-Assembly

- 1. Place Controller on a flat, stable surface away from any edges to prevent fall damage.
- 2. Insert Hose Assembly Connector (Male) into the female end of the Controller until fully seated.
- 3. Insert the four (4) provided screws and tighten as shown below. (#1 Philips screwdriver included)
- 4. Insert Power Cord into the receptacle shown below.

Power Cord Disconnect Procedure

- **Standard Power Cords (Non-Latching):** Unplug Power Cord from wall receptacle, then pull cord from Controller to disconnect.
- Latching Power Cords: Unplug Power Cord from wall receptacle, press the cord release button at the controller end, then pull cord from controller to disconnect.

NOTE: See Power Cord Installation Guide for more detail (R01-0006-00244).

Finished Assembly

3.2 System Installation - Controller

Controller and Hose Assembly Installation

- 1. Place Controller in a safe, stable location near a wall power outlet and approximately 3 feet away from the patient support surface . Please refer to Dabir Accessories for alternative mounting options.
- 2. Route Power Cord and Hose Assembly such that it does not present a trip hazard.
- 3. Secure Hose Assembly to fixed or stable structure as needed using supplied Tie-Straps.
- 4. Plug the Power Cord into a wall receptacle or other power source with specified currents and protective earth ground.

NOTE: IV Pole Stand and Accessory mounting kit sold separately.

Example: IV Pole Mount Accessory Application

CAUTION: Unless otherwise specified, use of this Device is not recommended around medical equipment that intentionally radiates electromagnetic energy.

CAUTION: To ensure proper electrical grounding, do not use an extension cord with this Device.

CAUTION: Properly route and secure all Cords and Hoses to avoid trip hazard or damage.

CAUTION: Only use specified operating wall currents. Alternative power sources and currents may result in irreparable damage to the Device and possible hazardous event.

CAUTION: To avoid electric shock, Device must be connected to a supply mains with protective earth ground.

3.3 System Installation - Surfaces

- 1. Place Dabir Surface flat onto pad or mattress with "THIS SIDE UP" facing up (gray side down) and secure optional corner straps when applicable. (Surface should lay flat.) Hose routing is preferred at the foot end.
- 2. Place facility supplied cover sheet and incontinence pad(s) over the top of the Surface and tuck edges underneath the pad or mattress. Avoid wrinkles whenever possible to optimize performance and patient comfort.

NOTE: Use up to 2 standard incontinence pads above the bed sheet for increased patient comfort.

WARNING: Never place Surfaces directly on bed frame. Surfaces are intended to be used above an support mattress or pads with good redistribution properties and maximum patient contact area.

WARNING: It is the responsibility of the caregiver to secure and protect against patient movement and falls.

CAUTION: Surfaces are not to be used in direct contact with patient's skin. Always use a sheet or other protective covering between the patient and Surface.

CAUTION: Place cover sheet and incontinence pad ABOVE Dabir Surface. (Not shown)

CAUTION: Sharp objects from any source may damage the Surface and compromise function.

CAUTION: It is the responsibility of the caregiver that the device is properly cleaned and disinfected prior to patient use.

1. Connect Hose and Surface with Controller "PAUSED" or powered "OFF".

Connection Procedure

Insert the Surface Connector into the Hose Connector. An audible "click" can be heard once the connectors are fully seated. Confirm connector seating with a slight pull.

Disconnection Procedure

Depress the orange button and pull Surface connector to release.

CAUTION: To avoid de-pressurization noise, do not unplug Surface connector while system is activated.

CAUTION: Do not transfer the Controller with the Surface attached.

CAUTION: Do not use petroleum based lubricants on seals as it may cause swelling and/or leakage.

4 Operation and Settings

To operate the Dabir Device:

RECOMMENDED: For optimal performance, always place patient upon the installed Surface before powering the Controller "ON".

Step 1: Power Controller "ON" by depressing the main toggle switch located on the side of the Device:

CAUTION: Power "ON" does not immediately activate the Surface. (See Step 2 below.)

Step 2: Touch "START/STOP" (■▶) Key to activate Surface cycle.

Note: The Dabir Auto-start feature will activate the system within 30 seconds of main power "ON" or within 10 minutes of being stopped during normal operation. The "START/STOP" key is still functional at any time while the Device is powered "ON".

Customizing Cycle Speed and Firmness settings:

Step 3: Touch the desired "CYCLE SPEED" Key to select a setting:

LOW	10.0 minutes - RECOMMENDED (Default Setting)
MEDIUM	7.5 minutes
HIGH	5.0 minutes

Step 4: Touch the desired "FIRMNESS" Key to select a setting:

LOW	RECOMMENDED (Default Setting
MEDIUM	Optional (Comfort Preference)
HIGH	Optional (Comfort Preference)

NOTE:

Cycle speed will vary depending on the surface model. (Approximate times shown)

NOTE:

All settings will provide effective Dabir therapy. System default settings are recommended for most applications.

5 Interrupting, Rapid Deflate, and Resuming Operation

Interrupting or Rapid Deflate Options:

1. Main Power "OFF"

Toggle the main power switch to the "OFF" position.

NOTE:

Turning power "OFF" will automatically deflate the Surface and reset Cycle Speed and Firmness to default settings.

CAUTION: Power "OFF" or "STOP" the Controller for cardiac arrest events. This unit is not intended for use during CPR.

2. System "PAUSE" or "STOP"

Touch the "START / STOP" (Key to pause or resume operation. NOTE: Autostart feature will engage after 10 minutes time has passed.

KEY NOT BACKLIT = SYSTEM <u>PAUSED</u> SOLID GREEN BACKLIT KEY = SYSTEM <u>ACTIVATED</u>

WARNING: Always confirm Device is powered "ON" and that the Surface is activated during intended use.

CAUTION: It is the responsibility of the caregiver to ensure that the user can operate this product safely.

The Controller utilizes soft tones, illuminated graphics and informational displays for communication feedback. The "INFORMATION CENTER" display provides critical instruction for proper Device operation.

If the system requires user action, one or more of the following alerts will appear:

SERVICE UNIT

Contact manufacturer's Technical and Warranty Support (See Section 12 - Contact Information)

CHECK CONNECTIONS

Look for hose connection problems or air leaks. As a first step, simply stop the controller, re-connect the Surface and start the unit again. (See next page for further diagnosis codes.)

REPLACE OVERLAY

All Dabir Surfaces include smart electronics which instruct the Controller when its preprogrammed usage life has expired. Simply replace the overlay when prompted.

CAUTION: Prior to use, allow one hour for Device to acclimate to room temperature.

CAUTION: Keep Controller air intake and exhaust vents free of liquids, contamination or loose particle debris which may restrict air flow.

CAUTION: Keep Surface exhaust vents free of any liquids, contamination or loose particle debris which may restrict air flow.

NOTE: See diagnostics table on the following page for specific alert code messages and required actions. Alert codes will automatically clear once the problem is resolved. Please contact the manufacturer in the event that proper operation does not resume.

Information Center Indicator	Alert Buzzer	Meaning
Check Connections Continuous	Frequency: 2 kHz 2 sec "ON" after touching START/STOP key, then "OFF" continuous	Controller improperly communicating with the Surface. Check Hose to Surface connection. The light will clear when proper connection is made, returning function to normal operation. If light does not clear, replace the Surface. If problem persists, contact the manufacturer.
Check Connections Flashing 2 sec "ON" 2 sec "OFF"	Frequency: 2 kHz 2 sec "ON" after touching START/STOP key, then "OFF" continuous	Controller improperly communicating with the Hose Assembly. Check the Hose connection to the Controller. Power the unit "OFF" and wait 5 seconds using the Main Toggle Switch. Power the unit "ON" again. If alert code does not clear, please contact the manufacturer.
Replace Overlay Flashing 1 sec "ON" 3 sec "OFF"	Frequency: 2 kHz 3x - 1 sec "ON", 5 sec "OFF" every 30 min after expiration OR (model dependent) 2 sec "ON" - 24 hr before expiration	The Surface will remain active beyond its usable life until power is interrupted. Depending on the model, pausing therapy or disconnecting the surface may also force surface replacement. Please contact manufacturer for specific details.
Replace Overlay <i>Continuous</i>	Frequency: 2 kHz 1 sec "ON", 5 sec "OFF"	The Surface has exceeded its usable life and must be replaced. System will not function with an expired Surface. Certain models may alert every 30 sec when this condition occurs. Please contact manufacturer for specific details.
Service Unit Flashing 2 sec "ON" 2 sec "OFF"	Frequency: 2 kHz 3x - 0.5 sec "ON", 0.5 sec "OFF", then "OFF" continuous	Controller failed to reach the pressure set point upon startup. Power "OFF" using the Main Toggle Switch. Check the Surface and Hose Assembly for leaks and power "ON" again. If problem persists, contact the manufacturer.
Service Unit Continuous	Frequency: 2 kHz 3x - 0.5 sec "ON", 0.5 sec "OFF", then "OFF" continuous	The Controller has encountered a physical error. Power "OFF' using the Main Toggle Switch. Wait 5 seconds and power "ON" again. If problem persists, contact the manufacturer.

7 Cleaning Procedures

Cleaning procedures listed below are recommended by the manufacturer and should be adjusted according to specific healthcare facility policy. Aggressive cleaning measures may cause damage. NOTE: It is the responsibility of the caregiver to replace Surfaces when needed.

CAUTION: Maintain accessibility to Power Cord such that it can be easily unplugged from the wall power source prior to cleaning and inspecting. Do not service while in use.

CAUTION: Turn Device "OFF" during patient transfer, cleaning and before patient positioning.

CAUTION: It is the responsibility of the caregiver to properly dispose of the Surface when damage or soiled. Do not autoclave.

CAUTION: Do not allow liquid to enter any part of the Controller.

CAUTION: Sharp objects from any source may damage the Surface and compromise function.

Cleaning the Controller and Hose Assembly

Power "OFF" the Controller and disconnect the Power Cord from the wall outlet prior to cleaning. Remove visible soiling then disinfect by wiping down all areas with a hospital grade disinfectant cleaner. Always allow proper dwell / contact drying time per the disinfectant manufacturers instructions.

NOTE: Do not saturate cloth or apply cleaning fluids/liquids directly to the Controller or Hose Assembly to prevent fluid ingress of this electronic device. Inspect air intake and exhaust ports located on the bottom of the Controller and Handle End-plate respectively to ensure they are not obstructed.

Cleaning the Surface

With the Surface and Hose Assembly connected, remove visible soiling then disinfect by wiping down all areas with a hospital grade disinfectant cleaner. Always allow proper dwell / contact drying time per the disinfectant manufacturers instructions. If excessive disinfectant residue diminishes slip resistance, wipe down the Surface with a water moistened cloth and disinfect again.

Approved & Unapproved Cleaners

Please visit: www.dabir-surfaces.com/cleaners.

NOTE: Test results have shown that the above "unapproved cleaners" will reduce Dabir product life with repeated use.

Surface Disposal

Please follow Section 7 Cleaning Procedures prior to disposal or recycling per hospital standard procedure.

The Dabir Surfaces Patient Support System

Routinely check all electrical connections, Power Cord and Hose Assembly for signs of wear or damage and replace if necessary with certified parts. For any non-serviceable damage, please contact the manufacturer. (Do not dispose.)

Serial Number Labels

All serial numbers are in the following format: LSYYDDDXXXXT Please provide component serial numbers when requesting service.

- The Controller serial number is located on the underside label. •
- The Hose Assembly serial number is located on the Hose Assembly label.
- The Surface serial number is located on the Surface label. •

Preventative Maintenance Checklist: (Suggested)

At minimum, check all items listed below during annual preventative maintenance. You may need to perform checks more frequently based on your specific level of use. Always remove product from service, clean and disinfect (while unplugged) before performing preventative maintenance or servicing.

PREVENTATIVE MAINTENANCE CHECKLIST:

Product Serial Number: _____

Completed By: _____ Inspection Date: _____

Visual Inspection Checklist (POWER DISCONNECTED)

REQUIRED: ASSEMBLED CONTROLLER: (Surfaces are semi-disposable and not considered serviceable.)

Inspect the following components and assemblies for signs of visible damage or wear. Replace if applicable or contact manufacturer for service.

- □ Case Cover (top & bottom: cracks, loose or missing parts, structural damage)
- □ User Interface Panel (cracks, legibility, gasket integrity)
- Rubber Mounting Feet (four: located underside of controller, loose or missing parts)
- □ End Plate Assemblies (left & right cracks, loose parts, gasket integrity)
- □ Hose Connector (controller end: cracks, missing screws, tubing disconnect, loose parts)
- □ Hose Connector (surface end: cracks, missing button, tubing disconnect, obstructions)
- □ Hose (pinched, tears, cuts, other damage)
- Power Cord (loose or missing terminals, cracking, exposed wires, poor retention)
- □ Labels (pealing, legibility, torn or missing)
- □ Air Inlet (underside of controller: remove any debris)
- Air Exhaust (handle side end plate: remove any debris)

NOTES:

8 Preventative Maintenance / Service - Continued

System Performance Check (POWER CONNECTED)

REQUIRED: ASSEMBLED CONTROLLER and a DABIR SURFACE (Any model listed: dabir-surfaces.com/models)

Set-up Instructions: Follow the procedure defined in Section 3. (Surface does **NOT** require surgical table, stretcher or bed installation for performance check. No tools required.)

Perform the following system checks to confirm basic function:

1. MANUAL START FEATURE:

- Place the controller assembly on a safe, stable work location and connect a surface.
- Confirm that the unit is plugged in and powered "OFF".
- Power the unit "ON". (Reference Section 4, Step 1) System start-up mode should begin with flashing lights and audible tones. Default "LOW" settings will apply for cycle speed and firmness.
- **MANUAL START:** Within 15 seconds of powering the controller "ON", touch the "START/STOP" (Key for 1 second and remove finger. (Reference Section 4, Step 2) The key should illuminate green accompanied by a single audible tone and the system should begin to activate. The surface should begin to inflate its first zone. Monitor function for 1 full cycle. (Approximately 10-12 minutes at the default setting.)
- Confirm that the INFORMATION CENTER display has no alert codes. (Record if any appear and follow the steps defined in Section 6 to clear.) If alert codes do not clear, the check is considered a "FAIL".
- Power unit "OFF" (Reference Section 5, Step 1)

(PASS	/	FAIL)

NOTES: ____

□ Document results:

System Performance Check (continued)

2. AUTOSTART FEATURE:

- Place the controller on a safe, stable work location and connect the surface. •
- Confirm that the unit is plugged in and powered "OFF".
- Power the unit "ON". (Reference Section 4, Step 1) System start-up mode should begin with flashing lights and audible tones. Default "LOW" settings will apply for cycle speed and firmness.
- AUTOSTART OPTION: The autostart feature should automatically activate the surface within 30 seconds of powering the controller "ON". (Reference Section 4, Step 1) The "START/STOP" (•) Key should automatically illuminate green accompanied by a single audible tone. The surface should begin to inflate its first zone. Monitor function for 1 full alternating cycle. (Approximately 10-12 minutes at the default setting.)
- Confirm that the INFORMATION CENTER display has no alert codes. (Record if any appear and follow the steps defined in Section 6 to clear.) If alert codes do not clear, the check is considered a "FAIL".
- Manually pause the system by touching the "START/STOP" (**•**) Key for 1 second and remove finger. (Reference Section 5, Step 2) The green indicator light should turn off along with a single audible tone.
- The system should remain paused for approximately 10 minutes before restarting automatically. If system restart does not automatically occur with in 15 minutes, it should be considered a "FAIL".
- Confirm that the INFORMATION CENTER display has no alert codes. (Record if any appear and follow the steps defined in Section 6 to clear.) If alert codes do not clear, the check is considered a "FAIL".
- Power unit "OFF" (Reference Section 5, Step 1) ۲

Document results:

NOTES:

3. SETTINGS FUNCTION:

- Complete normal system start up steps defined in Section 4 and with the system activated in default "LOW" Cycle Speed and "LOW" Firmness settings, perform the following checks:
- **CHANGE THE CYCLE SPEED SETTING** by touching the "Medium" key. The indicator light should change to the new setting accompanied by a single audible tone. Upon its next transition cycle, the surface should alternate inflation zones every 3.5 - 4.0 minutes, half of the full 7.5 minute cycle period. Once confirmed, switch to the "High" setting and repeat measurements to confirm alternating inflation cycles every 2.3 - 2.7 minutes, half of the full 5.0 minute cycle period. Record any anomalies.
- CHANGE THE FIRMNESS SETTING by touching the "Medium" key. The indicator light should change to the new setting accompanied by a single audible tone. The surface should now change its inflation pressure at the next inflation cycle. After monitoring for 1 full alternating cycle, change to the "High" setting and monitor for 1 full alternating cycle. Record any anomalies or alerts that cannot be cleared per Section 6. If alert codes do not clear, the check is considered a "FAIL".
- Power unit "OFF" (Reference Section 5, Step 1) •
- Document results:

NOTES:

(PASS / FAIL)

(PASS / FAIL)

System Mechanical Diagram (Controller Only)

Primary Components List:

- 1. Top Case Cover Assembly (1)
- 2. Pump Mounting Screw (4)
- 3. Air Inlet Screen (1)
- 4. Pump Assembly (1)
- 5. Pump Isolators (2)
- 6. Cage Mounting Screws (4)
- 7. Medical Grade Power Supply (1)
- 8. Cage Assembly (1)
- 9. Base Plate Screws (4)
- 10. Solenoid Block Screws (3)
- 11. Base Plate (1)
- 12. Solenoid Module (1)
- 13. Bottom Case Cover (1)
- 14. Mother Board (1)
- 15. Left End Plate Assembly (1)
- 16. Right End Plate Assembly (1)
- 17. Rubber Isolators (4)
- 18. Rubber Isolator Screws (4)

NOTES / COMMENTS:

Accessory component detail not shown.

Modification of this device voids warranty and may compromise intended function. Service should be performed exclusively by the manufacturer unless otherwise specified.

Technical and Warranty Support support@dabir-surfaces.com Tel: +1 (888) 559-3642

System Electrical Schematic (Controller Only)

Quick Reference Replacement Parts (Controller & Accessories)

Please reference Section 3 for service part replacement instructions.

Model #	Description	
CA-1001	Controller	
CA-9001-01	1' Hose Assembly	
CA-9001-02	2' Hose Assembly	
CA-9001-04	4' Hose Assembly	
CA-9001-09	9' Hose Assembly	
CA-9003	IV Pole Mount	
CL-90B2-10	10' Power Cord - Latching (Non-COO*)	
GA-90B2-10	10' Power Cord (COO*)	
GA-90B2-15	15' Power Cord (COO*)	
*Country of Origin Compliant		

Replacement parts are available for purchase at:

Dabir Surfaces, Inc. 7447 West Wilson Ave. Harwood Heights, IL 60706 USA Tel: +1(888)559-3641

9 Troubleshooting

Repairs and Technical Support

See Section 6: Information Center: Alert Codes for specific alert codes. For non-alert codes troubleshooting, see the table below.

Problem	Potential Cause	Remedy
Controller does not power "ON".	No electric supply	Confirm Power Cord is plugged into the Controller and appropriate wall outlet
	Blown fuse	Contact manufacturer
	Internal malfunction	Contact manufacturer
Controller powers "ON" but does not operate when "START/ STOP" Key is pressed.	Surface life expired, connection issue or other malfunction.	Replace Surface See Section 6, Page 16-17
Abnormal noises and/or vibration coming from the Controller.	Internal malfunction	Power "OFF" the Controller. Contact manufacturer.
Air leakage sounds	Hose connection issue or other leakage source	See Section 6, Page 16-17
Abnormal odors coming from the Controller.	Internal malfunction	Power "OFF" the Controller. Contact manufacturer.

NOTE: If fuse is blown - contact Dabir technical support for service. (DO NOT REPLACE)

How to reach us:

Dabir Surfaces maintains regular business hours from 9:00 a.m. to 5:00 p.m. Eastern time.

Technical and Warranty Support support@dabir-surfaces.com Tel: +1 (888) 559-3642 STERIS Corporation Customer Service Tel: +1(800)548-4873 Fax: +1(440)639-4450 Service Support Tel: +1(800)333-8828

Distributor (North America) - Healthcare Customers

Controller Specifications

Model:		CA-1001 (Controller Only), CA-1000 (Starter Kit)	
Supply V	/oltage:	100-240 VAC	
Supply F	requency:	50-60 Hz	
Power Ir	nput:	170 VA Max	
Size:		356 x 178 x 127 mm (14 x 7 x 5 in.)	
Weight:		3.95 kg (8.7 lb)	
Case Ma	terial:	Plastic	
Fuse Ratings:		2A, 5 x 20mm, Time Delay	
Type of protection against electric shock:		Class I	
Degree of protection from electrical shock:		Type BF	
Degree o	of protection from liquid ingress:	IP20	
Mode of Operation:		Continuous	
Environment Conditions:			
	Operation: (Controller) Operation: (Overlay)	10°C to 35°C (50°F to 95°F) 30-80% RH 10°C to 45°C (50°F to 113°F) 30-80% RH	
	Storage and Transport:	-40°C to 60°C (-40°F to 140°F) 10%-95% RH (non-condensing)	
	Maximum Operating Altitude:	3,000 m (9,842 ft.)	

No Latex is used in the manufacture of this product. Data subject to change.

10 Specification Sheets - Continued

Accessory Specifications

Replacement Hose Assembly

•	-	
Model:	CA-9001 Family	
Weight:	0.73kg (1.6lb)	
Input:	5VDC 250mA	
$\left(\left(\left(\bullet\right)\right)\right)$	RF Transmitter	
	Separate collection for electronic waste	

Replacement Power Cord			
Model:	CA-90B2 Family		
Weight:	0.34 kg (0.75 lb.)		
Length:	10'		
Wall Plug:	NEMA 5-15P 3P Hospital Grade Green Dot		
Controller Plug:	IEC 60320-C13		

Model CA-1001 & CA-1000 Manufacturer's Declaration- Electromagnetic Immunity

The **Model CA-1001** or **CA-1000** system is intended for use in the electromagnetic environment specified below. The customer or the user of the **Model CA-1001 & CA-1000** system should assure that it is used in such an environment.

Immunity Test	IEC 60601-1, 3rd Edition Test Level	Compliance Level	Electromagnetic Environment/Guidance
Electrostatic discharge (ESD)	± 6 kV contact	± 6 kV contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with curthotic material, the relative
IEC 61000-4-2: 2008	± 8 kV air	± 8 kV air	humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4: 2012	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5: 2005	± 1 kV line(s) to line(s) ± 2 kV air line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11: 2004	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model CA-1001 or CA-1000 requires continued opera- tion during power mains interrup- tions, it is recommended that the Model CA-1001 or CA-1000 be pow- ered from an uninterruptible power supply or a battery.
NOTE: UT is the AC mains voltage prior to application of the test level.			

Model CA-1001 & CA-1000 Manufacturer's Declaration- Electromagnetic Immunity

The **Model CA-1001** or **CA-1000** system is intended for use in the electromagnetic environment specified below. The customer or the user of the **Model CA-1001** or **CA-1000** system should assure that it is used in such an environment.

Immunity Test	IEC 60601-1, 3rd Edition Test Level	Compliance Level	Electromagnetic Environment/Guidance
Conducted RF IEC 61000-4-6: 2013	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Model CA-1001 or CA-1000 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2VP d=1.2VP 80 MHz to 800 MHz
			d=2.3VP 800 MHz to 2.3 GHz
			Where <i>P</i> is the maximum output power rating for the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF	3 V/m	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , a should be less than the compliance level in each frequency range.
IEC 61000-4-3: 2006	80 MHz to 2.6 GHz	80 MHz to 2.6 GHz	Interference may occur in the vicinity of equipment marked with the following symbol:
A1: 2007 A2: 2010			$\left(\left(\left(\bullet \right) \right) \right)$

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the **Model CA-1001 or CA-1000** is used exceeds the applicable RF compliance level above, the **Model CA-1001 or CA-1000** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary such as re-orienting or relocating the **Model CA-1001 or CA-1000**.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Model CA-1001 & CA-1000 Manufacturer's Declaration-Electromagnetic Emissions

The **Model CA-1001 or CA-1000** system is intended for use in the electromagnetic environment specified below. The customer or the user of the **Model CA-1001** or **CA-1000** system should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment/Guidance	
RF emissions CISPR 11: 2009 A1: 2010	Group 1	The Model CA-1001 or CA-1000 uses RF ener- gy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A	The Model CA-1001 or CA-1000 is suitable for	
Harmonic emissions IEC 61000-3-2	Not applicable	use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that sup-	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	plies buildings used for domestic purposes.	

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and Model CA-1001 or CA-1000

The **Model CA-1001 or CA-1000** system is intended for use in the electromagnetic environment specified below. The customer or the user of the **Model CA-1001** or **CA-1000** system should assure that it is used in such an environment.

Rated Maximum Out-	Separation Distance According to Frequency of Transmitter(m)			
mitter (W)	150 kHz to 80 MHz d=1.2√P	80 MHz to 800 MHz d=1.2√P	800 MHz to 2.5 GHz d=2.3√P	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters radiated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Changes or modifications not expressly approved by Dabir Surfaces, Inc. could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules and with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le present appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisee aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioelectrique subi, meme si le brouillage est susceptible d'en compromettre le fonctionnement.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Conformement ir la reglementation d'Industrie Canada, le present emetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inferieur) approuve pour l'emetteur par Industrie Canada. Dans le but de reduire les risques de brouillage radioelectrique a l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnee equivalente (p.i.r.e.) ne depasse pas l'intensite necessaire a l'etablissement d'une communication satisfaisante.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a hospital installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

11 Limited Warranty

Dabir Surfaces, Inc. warrants that the product ("Dabir Product") accompanied by this Limited Warranty, shall be free from defects in material and workmanship under normal use for a period of one (1) year. Except where prohibited by applicable law this warranty is valid, beginning from date of original purchase, for the specific period associated with the Dabir Product purchased, and is nontransferable and is limited to the original, end user purchaser. This warranty gives you specific legal rights, and you may also have other rights which vary under local laws.

Remedies

Dabir Surfaces, Inc. entire liability and your exclusive remedy for any breach of warranty shall be, at Dabir Surfaces, Inc. option, (1) to replace the Dabir Product, or (2) to refund the price paid, provided that the Dabir Product is returned to a location as specified by Dabir Surfaces, Inc. with a copy of the sales receipt, or dated itemized receipt, from an authorized reseller, and with a return authorization number provided by Dabir Surfaces, Inc. Shipping and handling charges may apply except where prohibited by applicable law. Dabir Surfaces, Inc. may, at its option, use new or refurbished or used parts in good working condition to replace any hardware product. Any replacement Dabir Product will be warranted for the remainder of the original warranty period or thirty (30) days, whichever is longer or for any additional period of time that may be required in the end user's jurisdiction.

This warranty does not cover problems or damage resulting from (a) accident, abuse, misapplication, or any unauthorized repair, modification or disassembly; (b) improper operation or maintenance, usage not in accordance with product instructions or connection to improper voltage supply; or (c) use of consumables, such as replacement batteries, not supplied by Dabir Surfaces, Inc. except where such restriction is prohibited by applicable law.

How to Obtain Warranty Support

Before submitting a warranty claim, you must contact Dabir technical support at: support@dabir-surfaces. com or by calling (888) 559-3642 to verify the product failure and to receive a Return Material Authorization (RMA) number. **RETURNS WILL NOT BE ACCEPTED WITHOUT AN RMA NUMBER.** The addresses and customer service contact information for the Dabir Product can be found in the documentation accompanying your Dabir Product and on the web at <u>www.dabir-surfaces.com</u>. You must include a copy of the sales receipt, or dated itemized receipt, from an authorized reseller, along with a return authorization number provided by Dabir Surfaces, Inc. with your return. You must report any defect to Dabir Surfaces Inc. within the one (1) year period of the warranty.

The following information must be marked on the outside of each carton and/or pallet:

- 1. Shipper's name and address
- 2. Dabir Surfaces' Ship to address as listed below:

Dabir Surfaces, Inc. Attention: Repair Dept. / RMA #_____ 7447 W. Wilson Ave. Harwood Heights, IL 60706 USA

Limitation of Liability

DABIR SURFACES, INC. SHALL NOT BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS, REVENUE OR DATA (WHETHER DIRECT OR INDIRECT) OR COMMERCIAL LOSS FOR BREACH OF ANY EXPRESS OR IMPLIED WARRANTY ON YOUR DABIR PRODUCT OR FOR ANY OTHER CLAIM, EVEN IF DABIR SURFACES, INC. HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN ADDITION, TO THE EXTENT PERMITTED BY LAW, THE MAXIMUM LIABILITY OF DABIR SURFACES, INC. WITH RESPECT TO ANY DABIR PRODUCT FOR ANY CLAUSE WHATSOEVER (WHETHER BREACH OF CONTRACT OR WARRANTY, TORT OR OTHERWISE), IS LIMITED TO THE AMOUNT ACTUALLY PAID OR PAYABLE BY YOU FOR THE DABIR PRODUCT THAT GAVE RISE TO SUCH LIABILITY. THE FOREGOING LIMITATIONS SHALL APPLY EVEN IF THE PROVISIONS OF THIS AGREEMENT FAIL OF THEIR ESSENTIAL PURPOSE.

Some jurisdictions do not allow the exclusion or limitation of special, indirect, incidental or consequential damages, so the above limitation or exclusion may not apply to you.

THE WARRANTIES SET FORTH HEREIN ARE IN LIEU OF AND TO THE EXCLUSION OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY AS TO THE MERCHANTABILITY OR FITNESS OF THE PRODUCT FOR A PARTICULAR PURPOSE OR AS TO ITS PERFORMANCE.

Any statement, description or specification in Company's literature is for the sole purpose of identification of products sold by the Company and imparts no guarantee, warranty or undertaking by Company of any kind. Components and accessories not manufactured by Company are not included in this warranty and may be warranted separately by their respective manufacturers. Some jurisdictions may not permit this disclaimer so the above disclaimer may not apply to you.

National Statutory Rights

Consumers have legal rights under applicable national legislation governing the sale of consumer goods. Such rights are not affected by the warranties in this Limited Warranty.

No Other Warranties

No Dabir dealer, agent, or employee is authorized to make any modification, extension, or addition to this warranty.

Registration

You do not need to register the product for the Limited Warranty to be effective.

Miscellaneous

This limited warranty shall be governed by and construed in accordance with the laws of State of Illinois, United States of America, as if performed wholly within the state and without giving effect to the principles of conflict of law. If any portion hereof is found to be void or unenforceable, the remaining provisions of this limited warranty shall remain in full force and effect. This Limited Warranty constitutes the entire limited warranty extended by Dabir Surfaces, Inc. with respect to Dabir Surface Patient Support System.

12 Contact Information

Electronic copies available at: Instructions-for-Use: Model Number List: Dabir Approved & Unapproved Cleaners:

www.dabir-surfaces.com/IFU www.dabir-surfaces.com/models www.dabir-surfaces.com/cleaners

Corporate Headquarters and Sales

Dabir Surfaces, Inc. 7447 West Wilson Ave. Harwood Heights, IL 60706 USA Tel: +1(888)559-3641 sales@dabir-surfaces.com

Manufacturer

Dabir Surfaces, Inc. 7447 West Wilson Ave. Harwood Heights, IL 60706 USA Tel: +1(888)559-3641

Distributor (North America) - Healthcare Customers

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support@dabir-surfaces.com Tel: +1(888)559-3642

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EMERGO EUROPE Westervoortsedijk 60 6827 AT Arnhem The Netherlands

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