FLOW
AIR

MADE IN ITALY

TECHNICAL DATA SHEET

ServiceMed
HUMAN WIDE CARE

TECHNICAL DATA SHEET

1. GENERAL INFORMATION

1.1 INTENDED USE OF THE PRODUCT

The medical device described in this document is a true air-loss anti-decubitus system, designed to dynamically relieve pressure at the contact points between the patient's body and the hospital bed, thereby preventing the development or worsening of pressure ulcers and avoiding skin maceration.

1.2 INDICATIONS FOR USE

The medical device described in this document is a true air loss anti decubitus system. Thanks to its specific features, it can dynamically manage the off loading of the patient's weight on the support surface, minimizing contact pressure. To preserve the skin integrity of patients at risk of developing pressure injuries, proper microclimate management is essential. This involves minimizing the skin's exposure to moisture caused by incontinence, perspiration, or exudate from existing wounds. The innovative technology of the true air loss anti decubitus system can prevent skin maceration, the onset of pressure injuries, and support the treatment of those already present.

2. DEVICE DESCRIPTION

True air-loss anti-decubitus system that completely replace hospital standard mattresses.

The device includes the following components:
• Inflation unit
• Power supply cable
• Support surface with corresponding air connection tube
• High breathability cover
• Carrying bag

2.1 TREATMENT MODES

The medical device described in this document is a true air-loss anti-decubitus system, designed to dynamically relieve pressure at the contact points between the patient's body and the hospital bed, thereby preventing the development or worsening of pressure ulcers and avoiding skin maceration.

Treatment Modes:

- **STATIC:** a continuous low-pressure mode. The set pressure remains constant, adjusting (inflating or deflating) the cells according to the patient's position to ensure adequate immersion and improve weight distribution. This mode reduces interface pressure below the capillary closing pressure (POC, 32 mmHg), creating a "floating" effect while ensuring excellent patient comfort.
- **IMMERSION:** a continuous low-pressure mode with deep immersion. This advanced therapeutic function is designed to maximize interface pressure redistribution by increasing the contact area between the body and the surface, thereby achieving full immersion.
- **ALTERNATE:** a dynamic one-to-one alternating pressure mode. This mode simulates the natural spontaneous movements of the patient to ensure optimal tissue perfusion. Surface cells inflate and deflate alternately in a defined cycle, maintaining the average interface pressure below the POC (32 mmHg) 100% of the time.

  Zero Pressure feature: when activated, the "unloading" line is set to zero pressure, fully deflating the cells to accommodate specific body conformations or bony prominences. When not activated, the deflated cells still maintain a minimal operating pressure.
- **WAVE:** a high frequency dynamic one-to-one alternating pressure mode. This high-frequency alternation of loading/unloading pressure points simulates a continuous, gentle massage that promotes tissue perfusion.

2.2 SURFACE

The system's support surface features:

- **8" polyurethane cells**
- **Individually excludable cells**
- **Single-action head section exclusion**
- **Four distinct zones:** heels, trunk, head, and air-filled lateral containment support
- **Silent Flow™ system:** an innovative air release design with holes directing airflow optimally toward patient contact zones. Positioned on both sides of each cell, this ensures continuous, consistent air discharge that cannot be blocked regardless of patient position. It also prevents cell overheating and reduces noise compared to traditional systems.
- **CPR valve** with emergency deflation time < 10 seconds

2.2.1 SURFACE STRUCTURE

The anti decubitus surface consists of 20 individually excludable air cells, divided into 3 different and independent areas to effectively relieve interface pressure and prevent pressure transfer between zones. Each cell can be disconnected and replaced individually via designated fasteners on the side of the surface. The head section is fully excludable with a single maneuver to facilitate endotracheal intubation.

Head Zone: Composed of 3 static cells to prevent unwanted head movement.

Trunk/Leg Zone: Made up of 12 "8"-shaped cells engineered to support all patients in any position, consistently delivering therapeutic effects and avoiding cell collapse under patient's weight and bottom out.

Heel Zone: Consists of 5 cells with a unique shape that provides greater compliance, ensuring maximum immersion - even with minimal weight - which optimizes contact pressures under all conditions.

Lateral Containment Support: An independent section consisting of 2 perforated lateral panels. These provide continuous air release while offering enhanced support for patients and caregivers during bed transfers. They also reduce the risk of lateral cell compression, which could lead to patient falls, sliding, or entrapment between the bed rails and surface base.

2.3 COVER

The cover, thanks to its exclusive composition, adapts to the body's shape, reducing shear and friction forces.

The technical fabric is **bi-stretch, antistatic, biocompatible, liquid-resistant**, and highly breathable (moisture-vapor permeable). These characteristics ensure optimal breathability and maintain the skin's natural thermoregulation in contact areas, effectively managing the risk of maceration and preserving an ideal microclimate.

The cover is securely attached to the surface base via strategically placed anchors along the entire perimeter, protected by a dedicated flap to prevent accidental detachment. The use of elasticized anchor points, combined with the inherent bi-stretch properties of the material, allows the cover to conform seamlessly to the surface, eliminating the so-called "hammock effect" and ensuring consistent pressure distribution.

2.4 INFLATION UNIT

The Flow Air system's inflation unit, equipped with an automatic and feedback-controlled system, continuously monitors and adjusts the delivered pressure multiple times per second. This ensures stable treatment even during patient movements or position changes.

BUILT-IN ANTIBACTERIAL PRODUCT PROTECTION
MICROBAN PROTECTED

The system integrates **Dual-Drive™ technology**, which separately manages the two inflation lines via high-efficiency miniaturized turbines. These turbines respond rapidly to surface load variations, maintaining consistent pressures throughout the treatment duration. The system's rapid response times and independent line control enable unique and highly precise treatment profiles. Additionally, it operates with extremely low noise levels, thanks to advanced noise and vibration reduction technologies.

DUAL DRIVE TECHNOLOGY

The entire inflation unit and its user interface are made of a**ntimicrobial and antibacterial materials**, providing protection against various bacteria such as MRSA, Escherichia coli, and Salmonella during use in high-risk infection areas like hospitals and medical offices. The antibacterial function has been tested according to **ISO 22196** and is guaranteed by **Microban®** and **MacDermid® (Autotex AM)** for the product's entire life.

The user interface features a large 3.5-inch color display and a membrane keyboard with simple and intuitive controls, aided by on-screen instructions.

The unit is placed on the bed's foot section using two large, robust anchoring brackets located on the back side of the inflation unit, ensuring maximum stability and compatibility.

2.5 CLOUD TELEMETRY FUNCTIONALITY (AVAILABLE ONLY FOR SFAIRCL MODELS)

The Flow Air system is equipped with an internal Cloud module featuring 2G/4G technology and an integrate multi-operator SIM card for real-time telemetry data transmission, enabling remote system monitoring. This system ensures periodic transmission of alarms, events, and diagnostic data, allowing the service center to continuously monitor the system's proper functioning and intervene proactively, minimizing potential service disruptions for the patient.

2.6 CPR FUNCTION (CARDIO PULMONARY RESUSCITATION)

The CPR is the rapid deflation function of the anti-decubitus surface, essential for effectively performing cardiopulmonary resuscitation (CPR). To activate, turn the valve clockwise or counterclockwise (either direction); the device will click outward, releasing air from the system and causing the surface to deflate quickly. The valve can be activated with one hand and is protected against accidental activation, without interfering with nursing management of the bed.

This feature allows the anti-decubitus surface to deflate in less than 10 seconds, facilitating CPR maneuvers even in the absence of electrical power.

3. TECHNICAL SPECIFICATIONS

3.1 TECHNICAL SPECIFICATIONS - SURFACE

Max weight	350 kg (MAX)
Cells	20
Air Loss Type	Bilateral holes corresponding to each cell except the head zone
Cell height	20.3 cm (8”)
Dedicated Zones	3 + Lateral support system
Support base foam	Sealed 1 cm thick expanded polyurethane
CPR	< 10 s
Bed fixation	Straps
Cable management system	Yes
Radiotrasparente	Yes
Latex Free	Yes
Transport mode	Up to 24h
Dimensions and weight (max)	Size M - 205x85x22 - 14Kg Size L - 205x90x22 - 15Kg

3.2 TECHNICAL SPECIFICATIONS - INFLATION UNIT

Specification	Unit measure	Value
Working temperature	°C	+10/+45
Storage Temperature	°C	-20/+65
Working Humidity	RH%	30% / 85%
Storage Humidity	RH%	30% / 85%
Supply Voltage	VCA	220-240 VCA
Supply frequency	Hz	50

Specification	Unit measure	Value
Peak supply current	A	1,6
Peak power consumption	W	275
Fuses		1x 250 V - 2A (inlet) 2x 24V - 10A (blowers)
Fuses Type		Slow
Dual-Drive Technology maximum flow	LPM	1750
IP		21
Dimensions	mm	355x270x125 (LxHxP)
Weight	Kg	3
Noise (1 meter)	dB(A)	< 35

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