Stage IV 2000

Operating Instructions

SenTech™ Medical Systems, Inc.

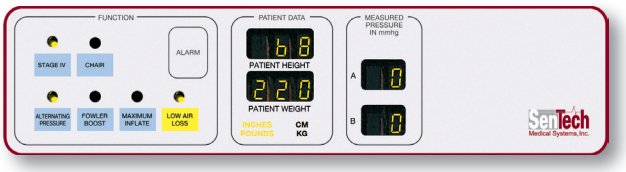
Pressure Relief System with Controlled Low Air Loss

Important Notice

Before operating this medical equipment, it is important to read this manual and to understand the operating instructions and safety precautions. Failure to do this could result in patient injury and/or damage to the products.

If you have any questions, please contact Novis Healthcare on 1300 738 885.

Table of Contents



1.0 Safety Precautions

The purpose of safety precautions are to attract your attention to possible dangers. The safety symbols and the explanations with them, require your careful attention and understanding.

The safety warnings by themselves do not eliminate any danger. The instructions or warnings they give are not substitutes for proper accident prevention measures.

The following symbols may appear in this manual, on the Control Unit, or on its accessories. Some of the symbols represent standards and compliances associated with its use.

SAFETY ALERT SYMBOL
Indicates caution or warning.

WARNING
Failure to obey a safety warning can result in serious injury to yourself or to others. Always follow the safety precautions to reduce the risk of fire, electric shock and personal injury.

CAUTION
Failure to obey a safety warning may result in property damage or personal injury to yourself or others. Always follow the safety precautions to reduce the risk of fire, electric shock and personal injury.

ELECTRICAL HAZARD
Indicates risk of electric shock.

IMPORTANT INFORMATION

IMPORTANT: The STAGE IV 2000 system should only be used by order of a physician. Always consult with the patient's physician before placing a patient on the STAGE IV 2000 system.

CAUTION: Certain medical conditions and treatments are contraindicated for use of the STAGE IV 2000 system. Always consult with the patient's physician before placing a patient on the STAGE IV 2000 system.

CAUTION: Bed frames used with the STAGE IV 2000 system can vary greatly depending on the specific health care setting, e.g. hospitals, nursing homes, home care, etc. Therefore, it is the responsibility of the caregiver to take the necessary precautions to ensure the safety of the patient. This includes, but is not limited to, the appropriate use of side rails to prevent falls and/or patient entrapment.

OPERATING INSTRUCTIONS

WARNING: Do not attempt to operate this product until you have read and understood the safety rules contained in this manual. Failure to comply can result in accidents involving fire, electric shock or serious personal injury. Save owner's manual and review frequently for continual safe operation and for instructing others who may use this product.

1.0 Safety Precautions (continued)

WARNING: This device is not suitable for use in the presence of a flammable anaesthetic mixture with air, or in the presence of a flammable anaesthetic mixture with oxygen or nitrous oxide.

Only plug into a grounded power receptacle and use the power cord supplied with the STAGE IV 2000 system.

Exposure of the electronic controller to any liquid while it is plugged in could result in a severe electrical hazard.

Electronic Controller

CAUTION: The STAGE IV 2000 electronic controller is a precision instrument. Use care when handling or transporting. Dropping, or other sudden impacts, may result in damage to the microprocessor and/or the controller.

ELECTRICAL HAZARD: Exposure of the electronic controller to any liquid while it is plugged in could result in a severe electrical hazard.

CAUTION: Only use fuses that have the same specified rating (See Section 7.0). Using fuses with higher ratings could result in damage and/or injury.

CAUTION: Do not place any objects/items, such as blankets, on, or over, the electronic controller. Excessive weight on the STAGE IV 2000 controller could result in damage to the electronic controller.

After exposure to extreme high or low temperatures, allow electronic controller to equilibrate to room temperature before operating.

WARNING: The STAGE IV 2000 controller circulates room air during operation. Exposure to smoke may cause the system to fail. Therefore, smoking by patients or visitors while using the STAGE IV 2000 system is strongly discouraged.

Only use the power cord supplied with the STAGE IV 2000 system.

WARNING: The power cord to the electronic controller should be positioned to avoid a tripping hazard and/or damage to the cord. SenTech Medical Systems recommends placing the cord under the bed frame and attaching it to an electrical outlet by the head of the bed.

ELECTRICAL HAZARD: Do not attempt to repair or service the electronic controller. Repairs and service should only be done by a SenTech Medical Systems nominated Service Centre. If the unit is not functioning properly, or has been damaged, unplug the unit and take it out of service immediately.

Contact Novis Healthcare on 1300 738 885 for repair and service information.

NOTE: No special skills, training or knowledge are required to operate the control unit.

2.0 Product Overview

The STAGE IV 2000 system is a microprocessor controlled Alternating Pressure Relief and Low Air Loss therapeutic mattress system. The needs of individual patients can be optimised by combining these therapies or operating them independently from each other.

The Alternating Pressure feature of the STAGE IV 2000 system provide pressure relief by deflating and inflating every other air cell on a timed interval. It is widely recognised that constant pressure to a bony prominence is a leading cause of skin breakdown. The systems provide continuous movement of air cells that alleviates constant pressure and enhances circulation. The deflated air cells provide pressure relief, while the inflated air cells support the patient's weight.

The STAGE IV 2000 electronic controller provides a real-time display of air pressure for both the inflated and deflated air cells. The amount of pressure to support a patient can be set automatically based on the patient's height and weight or can be manually set for custom configurations. All settings are stored in non-volatile memory. If power is interrupted, the electronic controller automatically returns to the previous settings when the power returns.

The Controlled Low Air Loss (LAL) feature of the system provide an optimum temperature environment to assist in patient healing and comfort. LAL therapy is delivered through a patented SenTech Coverlet that provides a flow of diffused air directly to the patients skin through thousands of microscopic micro-vents. In addition, the mattress has been designed to provide an anti-shear/ anti-friction surface for patients.

A visible and audible alarm function has a number of indications depending on the cause of failure.

The system includes a rapid release CPR handle for emergency deflation.

3.0 Installation

NOTE: It is recommended that all shipping and packing material be saved in the event that the product has to be sent back to a SenTech Medical Service Centre.

3.1 Unpacking and Inspection

Carefully remove the controller, mattress and all accessories from the shipping cartons. Inspect all items for any damage that may have occurred during shipping. Any damages, or missing components, should be reported to a SenTech Medical Service Centre as soon as possible.

Mattress Replacement: The box contains a completely assembled mattress replacement system.

This system consists of:

- 5 cm/2 inch Foam Mattress
- Air Cell Assembly with CPR Pull Handle
- Top Coverlet with Low Air Loss Hose
- CPR Hose Assembly

Electronic Controller: The electronic controller is in a separate box containing:

- Electronic controller
- Power cord
- Operating Instructions
- Quick Setup Guide

3.2 Installation

The STAGE IV 2000 system is designed to operate in a controlled environment, which is free from extreme temperatures, high humidity and/or excessive amounts of airborne particulates, such as dust and smoke. The controller can be plugged into any standard wall outlet and hung on the upper outside edge of the footboard on most hospital and home care beds.

3.3 Mattress Replacement

Remove the current mattress from the bed frame and replace with the STAGE IV 2000 Mattress assembly. The hose connections should be positioned at the bottom left of the bed.

There are two (2) sets of straps with D-rings on each side and one (1) at the head of the mattress. Use these straps to secure the mattress replacement to the bed frame.

IMPORTANT: Make sure that the attachment of the mattress does not interfere with bed movement/operation.

3.4 Installation of CPR Pull Handle

Attach the CPR assembly to the mattress by inserting the black round hose assembly into the CPR socket **located at the foot of the mattress** and turning it counter clockwise ¼ of a turn.

3.5 Installation of Electronic Controller

3.5.1. Control Unit

Position the STAGE IV 2000 controller to hang from the footboard of the bed frame.

3.5.2 Coverlet Hose

Connect the single Low Air Loss hose from the centre of the coverlet to the connector on the right side of the controller labelled “Low Air Loss”.

3.0 **Installation** (continued)

3.5.3 Mattress Hoses

Connect the hoses from the left side of the mattress shell to the connectors on the left side of the electronic controller: Two (2) hoses connected in any order.

NOTE: Each connector should tightly "click" into place.

3.5.4

Plug into electrical outlet. Turn the POWER on with the power switch located next to the electrical cord, on the right side panel of the controller.

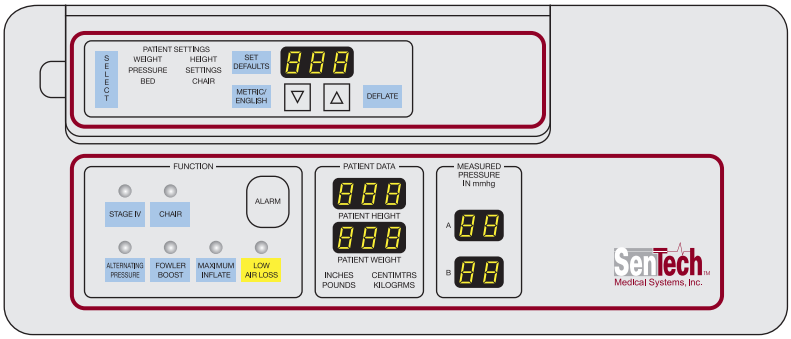
3.5.5.

Inflate the mattress by pressing the blue MAX INFLATE key on the touch panel. In this mode all mattress cells are inflated to 40 mmHg to provide a firm, flat surface. The MAX INFLATE mode will last for 20 minutes, unless it is interrupted by pressing any other function key. The system will then automatically revert back to the previous operating mode.

4.0 Operation

The control panels for the STAGE IV 2000 electronic controller is shown in the diagram below. Refer to these diagram as you read the OPERATION section.

Diagram 1 – Stage IV 2000 Control Panel



4.1 Functions and Settings

Power	The ON/OFF switch is located next to the electrical cord on the right side of the controller. The switch will illuminate in the “ON” position.
FUNCTIONS	The following controls are located on the front display panel:
STAGE IV 2000	Sets the system to the “BED” operating mode with a 5 minute cycle time when in Alternating Pressure.
Chair	Sets the system to the “CHAIR” operating mode with a 2.5 minute cycle when in Alternating Pressure.
Alternating Pressure/Air Flotation	Activates/Deactivates Alternating Pressure Relief mode. When activated, the system operates in alternating pressure mode. When deactivated, the system operates in Air Floatation mode.
Fowler Boost	Activates/Deactivates the Fowler Boost feature. When activated, the set pressure in the mattress is automatically increased by 20%. This feature is used for patients in bed that are put in an inclined or “Fowler” position*. It is not available when the system is in the MAX INFLATE or CHAIR modes.

*Sitting or semi-prone positions.

Maximum Inflate	Activates/Deactivates the MAX INFLATE mode. In this mode, all mattress cells are inflated to a pressure of 40 mmHg to provide a firm, flat surface. This mode will last for 20 minutes, unless interrupted by the pressing of any function key. The system will then revert back to the pre-set operating mode. When the system is in the chair mode, the Maximum Inflate switch is inactive.
Low Air Loss	Activates/Deactivates the Low Air Loss (LAL) feature. When activated, a gentle diffused flow of air is delivered through the LAL coverlet. This feature is not available when the system is in CHAIR mode.
SETTINGS	The following settings are located under the black cover on the top portion of the control panel:
Select	Scrolls through the various setting fields. The active field is displayed in the update window and the appropriate indicator is illuminated. The selection options available are: **PATIENT** **PRESSURE** WEIGHT BED HEIGHT CHAIR
UP/DOWN Arrow Keys	Used to increase or decrease the patient data or pressure settings.
Auto Set	Automatically adjusts the pressure settings based on the patient weight and height entered. Selecting "Auto Set" will override custom set pressures. **NOTE: Changing the patient data does not automatically update the pressure settings. Auto Set must be pressed to incorporate the change.**
Metric/English	Toggles the units of measurement used for the patient weight and height between Metric (centimetres and kilograms) and English (inches & pounds).
Deflate	Allows air to be pumped out of the mattress automatically. After ten (10) minutes, the pump automatically shuts off. During deflation, all displays and indicators, except the deflate indicator, will be shut off. If this key is pressed in error, press the key again to deactivate and the system will revert to it's previously programmed state.

4.2 Indicators

Alarm	Located on the display panel and will illuminate and audibly sound when the mattress fails to reach the set pressure for three consecutive cycles, approximately 30 minutes.
Inches/Pounds	Illuminates when the patient data is displayed in English units of measurement.
CM/KG	Iluminates when the patient data is displayed in Metric units of measurement.
Patient Data	Displays patient height and weight as entered in the “Patient Data”. This data is used by the microprocessor to calculate pressure settings, when AUTO SET is selected.
Measured Pressure	Continuously displays the actual air pressure in mmHg that is delivered to the air cells in the mattress. The STAGE IV 2000 shows measured pressure delivered to the whole mattress. The “A” and “B” on the display panel show the pressure in alternate air cells.

4.3 Programming Electronic Controller

Top Portion of Controller:

1. Open the black cover located on top of the controller. Select the preferred units of measurement for patient data by pressing the METRIC/ENGLISH key. You will see your selection lit in the bottom portion of the display under “Patient Data”.
2. Toggle the SELECT key until PATIENT WEIGHT is lit. Using the UP and DOWN arrow keys select the appropriate patient weight. Weight is adjusted in 1 kg increments.
3. Toggle the SELECT key until PATIENT HEIGHT is lit. Using the UP and DOWN arrow keys select the appropriate patient height.
4. Press AUTO SET. The pressure setting is now automatically set for that patient.

NOTE: The AUTO SET setting is not appropriate for all patients.

Some patients may require custom settings for optimal therapy. To select a custom setting, toggle the SELECT key until BED is displayed and adjust the pressure by using the UP and DOWN arrow keys.

After readjusting the pressure setting, DO NOT hit AUTO SET.

Bottom Portion of Controller:

1. From the bottom left area of the display select which therapy and features you wish to operate. Be sure that STAGE IV 2000 is selected and lit while the patient is in bed. If using a SenTech Air Chair Cushion, select CHAIR.
2. Select the therapy desired. The STAGE IV 2000 has the ability to provide ALTERNATING PRESSURE (AP) or AIR FLOATATION (FLOAT), and LOW AIR LOSS (LAL) therapies:
   - For AP, press the blue ALTERNATING PRESSURE key until it is lit.
   - For FLOAT, turn the Alternating Pressure off by pressing the blue AP key. The alternating pressure light will not appear lit. LAL may be operated simultaneously with AP or FLOAT, or not at all.
   - For Low Air Loss (LAL), press the yellow LOW AIR LOSS key until lit.
3. For patients that are in a Fowler position, i.e. an inclined or sitting position, it is recommended that the FOWLER BOOST be activated by pressing the blue FOWLER BOOST key until lit.
4. Select the MAX INFLATE for a firm surface throughout the entire bed by pressing MAX INFLATE key on the control panel. When MAX INFLATE is selected, it disables all other functions and only LAL will operate.

4.4 CPR Operation

For emergency situations that require rapid evacuation of the air in the mattress, the STAGE IV 2000 system is equipped with a CPR Pull Handle.

The CPR Pull Handle is located at foot of the mattress on the patient's right side.

1. To activate, rotate ¼ turn clockwise and pull.
2. All air cells will begin to deflate and air will be rapidly evacuated. Rate of evacuation is dependent on the weight of the patient.
3. To resume normal operation of the mattress, close the CPR device by fully inserting the "CPR" assembly and rotating ¼ turn counter clockwise.

5.0 Maintenance and Cleaning

IMPORTANT: All disinfection should be done with a "hospital-grade" disinfectant in accordance with the manufacturer's specified instructions. Check manufacturer's instructions before use.

5.1 STAGE IV 2000 Electrical Controller

The STAGE IV 2000 electrical controller is easy to maintain:

Exterior: The exterior of the controller should be periodically wiped down with an approved disinfectant and the electrical cord checked for electrical hazards.

CAUTION: DO NOT spray disinfectant directly on the electrical controller, or immerse the controller in any type of liquid. This could result in a severe electrical hazard.

Air Filters: The filter should be cleaned every 30 days. The filter is located on the bottom of the controller. Unplug the controller and place it on its front face. Snap out the plastic filter grill and remove the filter. Rinse with water and air dry. Put the filter back into the filter housing and snap filter grill into place.

WARNING: Ensure the Electrical Controller is disconnected from mains electricity.

To ensure optimal performance of your STAGE IV 2000 electronic controller, **calibration should be verified every 12 months**. Contact SenTech Medical Customer Service for calibration information.

IMPORTANT: Good filter maintenance is critical in keeping your STAGE IV MILLENNIUM 3 controller in optimal operating condition. Failure to keep the filters clean will result in system downtime and increased repair costs.

5.2 Coverlet

The top cover should be disinfected between patient use. While it is up to each facility to follow their own guidelines for infection control, SenTech recommends the cover be machine washed with detergent and an effective medical disinfectant. DO NOT use bleach.

The cover should soak in the disinfectant solution for a minimum of ten minutes. Rinse thoroughly and air-dry, or use a "non-heat" drying cycle. DO NOT dry in a dryer using a "heat" cycle. Temperatures generated by these dryers may negatively affect the therapeutic benefit of your coverlet.

CAUTION: DO NOT dry the coverlet using the "heat" cycle. Air-dry, or select a low or "non-heat" dry cycle, e.g. air fluff.

5.3 Outside Shell

Wipe down shell using an approved disinfectant, ensuring that all surfaces come in contact with the disinfectant. Rinse off with clean damp cloth and allow to air dry.

5.4 Air Cell Assembly

Wipe air cell assembly down by hand using an approved disinfectant. Allow disinfectant to soak in. Wipe, rinse thoroughly and air dry. DO NOT MACHINE WASH OR DRY!

IMPORTANT: It is recommended the system is cleaned between patients and approximately every two weeks if in constant use.

CAUTION: DO NOT machine wash or dry the air cells. The air cell assembly does not routinely need to be cleaned or disinfected between patients.

IMPORTANT: DO NOT disassemble the STAGE IV 2000 mattress, unless cleaning/disinfection is required.

If cleaning/disinfection is required, disassemble the mattress using the colour-coded zippers.

IMPORTANT: DO NOT disconnect the hoses from the air cells.

5.5 Foam Mattress

Foam mattress is fully enclosed in 10mil urethane and should be wiped down with an approved disinfectant. If foam should be compromised, contact a SenTech Medical Service Centre for a replacement.

6.0 Trouble Shooting Guide

Problem	Cause	Solution
1. Alarm light is on.	The alarm is activated if the air cells do not reach programmed pressure in less than or equal to 20 minutes. This is usually an indication of an air leak in the system.	Check the CPR connections for leaks: For the Standard CPR, make sure the CPR plugs are fully inserted into the two (2) hoses. For the Hospital Grade CPR, make sure the six (6) rubber o-rings on the CPR pull are present and not damaged and that the CPR is in the "closed" position. Be sure all hoses are properly connected to the controller. Check all hoses along the inside of the mattress. Each hose should be tightly connected. Check each air cell to ensure there are no leaks. (It will be easier to detect a possible leak if you place the system in the MAX INFLATE mode.) Once the leak has been resolved, the alarm light will automatically turn off after three cycles. To reset the system more quickly, turn the power off and then on again to reset.
2. Patient is sinking or "bottoming out" while lying flat.	The pressures may be set too low for the patient's weight.	Increase bed pressure. An increase of 3-5 mmHg is usually sufficient. However, wait at least one (1) full cycle before determining if the pressure increase was sufficient.
3. The height and weight settings appear to be reversed.	The units of measure, i.e. English or metric, may be selected incorrectly.	Select proper units of measure by pressing the ENGLISH/METRIC key and re-enter patient weight and height, if needed.
4. The pressure setting was increased, but the pressure does not appear changed.	The AUTOSET key may have been pressed by mistake which would "overwrite" all customised settings.	Re-enter pressures needed. DO NOT press AUTO SET.
5. Air is not constantly flowing into the Low Air Loss Coverlet.	The internal pump gives priority to the air cells in the mattress. Once the air cells are inflated to the selected pressure, air will then be directed to the coverlet.	Allow air cells to pressurise.

6.0 Trouble Shooting Guide (continued)

Problem	Cause	Solution
6. Display readings appear "scrambled".	Power surges can cause the controller to temporarily malfunction.	Turn the controller off for five (5) seconds and then on again to reset.
7. Display readings appear abnormally high.	May be caused by crimped or pinched hoses, which cause an uneven delivery of air.	Check all hoses and eliminate any restrictions, e.g. sharp bends, crimps, folds, etc.
8. Patient is "bottoming out" when in the sitting or inclined position.	Pressure is concentrated in the trunk region.	Activate the FOWLER BOOST to increase pressure by 20%.
9. Air controller is inoperable.	May be caused by a power surge. Or may be caused by internal damage.	If the power switch does not illuminate when the power is turned on, check the fuse(s) located in the compartment on the electrical cord socket and replace if necessary (See Section 7.0 for fuse information and ratings). If this does not correct the problem, contact SenTech Medical Service Centre on 1300 738 885 for Repair & Service information.
10. The controller sounds like it is working, but no air is coming out.	Dirt has clogged the valves due to improper filter maintenance.	Contact SenTech Medical Service Centre on 1300 738 885 for Repair & Service information.

7.0 Product Specifications

Electronic Controller

Physical Dimensions

Height	31cm (12.2 inches)
Width	36.8cm (14.5 inches)
Depth	15.25cm (6.0 inches)
Weight	7.7kgs (17lb)

Electrical Parameters

US and Canada:	Power Requirements	120V, 60 Cycle AC
	Fuse	3.1A (I fuse)*
	Maximum Current	< 1.0A
Europe and Australia	Power Requirements	220-240V AC 50/60Hz
	Fuse	2A (2 fuses)
	Maximum Current	< 0.5A

* One (1) replacement fuse is provided with your controller and islocated in the compartment on the electrical cord socket.

CAUTION: Only use fuses that have the same rating as specified above. Using fuses with higher ratings could result in damage and/or injury.

Operating Parameters

Weight Range	20-230kgs (50-500lb)
Height Range	117-198cm (46-78 inches)
Pressure Range	5-50 mmHg (Bed)
	40-95 mmHg (Chair)
Altitude	≤ 2000m

Mattress Replacement (Fully-Inflated)

Physical Dimensions

Height	21.6cm (8.5 inches)
Width	91.5cm (36 inches)
Length	203.2cm (80 inches)
Weight	10kg (22lb)

8.0 Warranty Information

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably forseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

Limited Warranty

SenTech Medical Systems Inc. warrants each of its products to perform in accordance with their established specifications for the following time periods starting from date the product was shipped from Novis Healthcare.

STAGE IV 2000

Compressor Pump	3 Years
Electronic Controller	2 Years
Soft Goods	1 Year

During the warranty period, SenTech Medical Systems, Inc. through its distributors will repair or replace any products that are not performing in accordance with their established specifications, unless the failure is due to:

1. customer negligence or misuse

or

2 unauthorized repairs.

Items not covered under warranty include, but are not limited to: staining of materials, punctures, cuts, damaged electrical cords, rips or tears, dents and lost or missing parts. **Warranty repairs must receive a prior return authorisation number and be sent to SenTech by prepaid transportation, together with information describing the product's performance**. It will be returned to the customer at Novis Healthcare's expense. Warranty repairs do not extend the life of the warranty period.

Neither SenTech Medical Systems Inc., its distributors, officers, directors, employees or agents shall be liable for consequential or other damages, including but not limited t o personal injury, loss, or any other expense, directly or indirectly arising from the use of its products. The sole remedy for breach of the limited warranty granted herein shall be repair or replacement of the SenTech Medical products.

All product specifications are subject to change without notice.

9.0 Product Return Procedure

The STAGE IV 2000 has been designed to provide you with years of trouble-free service. However, in the event that the product needs to be returned for any reason, such as calibration or repair, the following return procedure must be followed. Failure to follow this procedure may result in unnecessary delays.

Return Procedure

Before returning a product to a SenTech Medical Service Centre:

1. Contact the medical equipment distributor from where the product was purchased. Alternatively, contact Novis Healthcare to obtain a "Return Authorisation Number" (RAN) and "Return Goods Form" (RGF).
2. Package the product in its "approved" packaging.
3. Reference RAN on the packaging and delivery documents.
4. Ship product to the attention of Novis Healthcare (address details on back cover).

SenTech™
Medical Systems, Inc.

Serviced and distributed by

novis
HEALTHCARE

Novis Healthcare Pty Ltd
Unit 12/12 Mars Road Lane Cove NSW 2066 Australia ABN 45 102 735 491
T 1300 738 885 F 1300 738 886 E novis@novis.com.au
www.novis.com.au

0225 10/12