Mistral-Air®

Forced Air Warming

MA1200-PM

MA1200-QC-PM

Technical Manual

Forced Air Warming Unit

stryker

Version: INT/R960-PM/4-05/20

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Contents

1 General information

1.1 About this manual

In this manual, you can find important information about how to operate the Mistral-Air® Warming Unit MA1200 - SYK (MA1200-PM) and the (optional) Warming Unit MA1200-QC - SYK (MA1200-QC-PM) (hereafter referred to as 'the device').

The manual helps you with the operation and the maintenance of the device, in a safe and responsible manner.

Read this manual carefully. Complete all the procedures. Do the procedures in the given sequence. Always keep the manual near the device.

1.2 Indications for use

The Mistral-Air® Warming System is a forced air warming device and comprises of a warming unit and a variety of blankets. It is intended to raise and maintain patient temperature by means of surface warming.

1.3 Contact

Stryker Medical
3800 E. Centre Avenue
Portage, MI 49002
USA

E-mail: medicalcustomerservice@stryker.com
Website: www.stryker.com

1.4 FAQ and training

Please refer to our website (*www.the37company.com*) for an up-to-date overview of the frequently asked questions of the Mistral-Air® products: *home / mistral-air | frequently asked questions*.

If requested, The 37Company will provide any additional information which is required to repair the parts designated as repairable.

Warning!

The device may only be operated by trained clinicians and maintenance may only be performed by trained biomedical technicians or engineers. Both user groups must be trained by certified trainers from Stryker.

1.5 Warranty

For the warranty provisions, ask your local Stryker representative.

1.6 Authorization of personnel

Make sure that only authorized personnel use the device.

1.7 Warning, caution and note

Warning!

A "warning" tells you that there is a risk of personal injury or death.

Caution!

A "caution" tells you that:

- there is a risk of damage to the device, and/or
- there is a risk of damage to other equipment.

A "note" gives more information.

1.8 Disclaimer

The manufacturer reserves all rights. No part of this document may be reproduced or published, electronically, mechanically, in print, photographic print, on microfilm or by any other means whatsoever, without the explicit consent of The 37Company.

The content of this document has been compiled with the greatest possible care and this information can be regarded as reliable. Nevertheless, the manufacturer reserves the right to make alterations and improvements to the device. These may not yet have been described in the instructions. The manufacturer cannot be held liable for the final outcome of the patients' treatment.

This document contains proprietary information that may not be disclosed to third parties. This document may not be used without the explicit written consent of the manufacturer.

These instructions are intended for personnel authorized to work with and/or service the medical device described in this manual.

2 Maintenance

Warning!

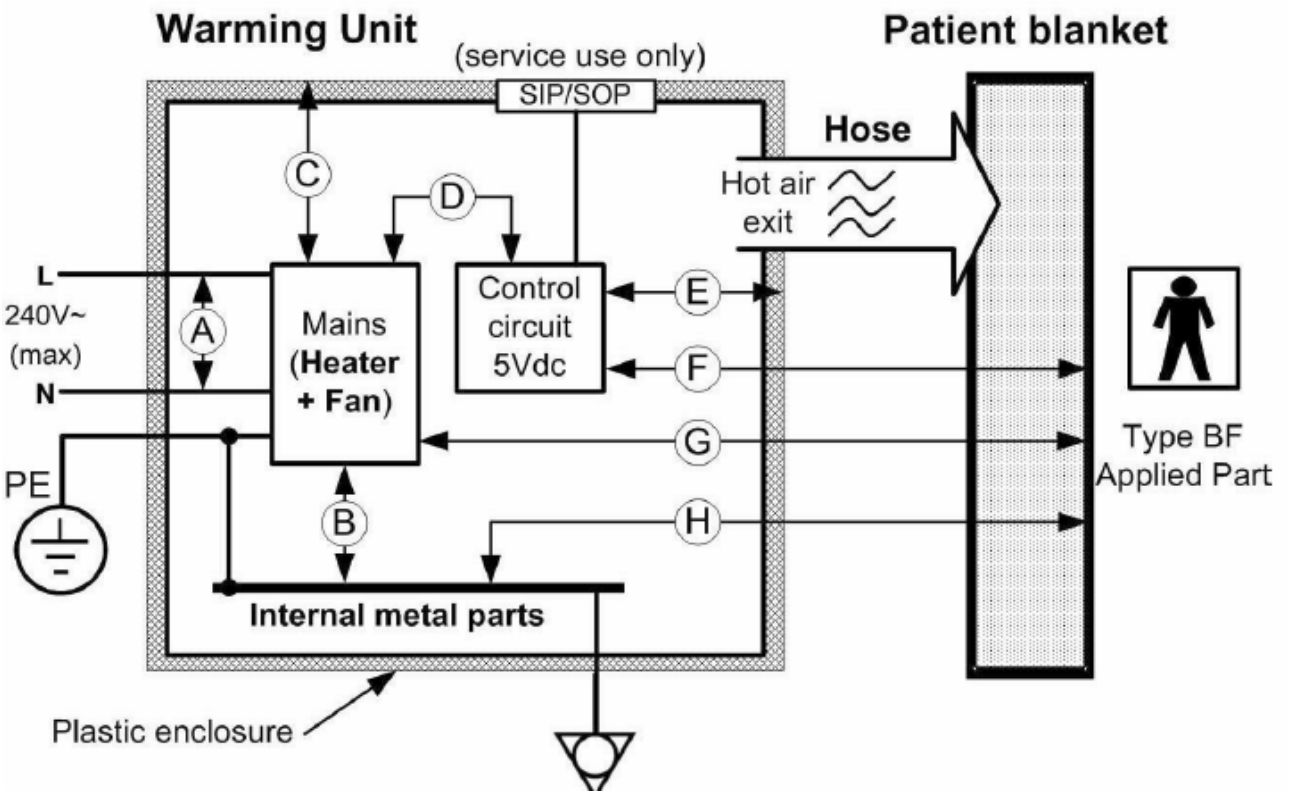
- Maintenance may only be performed by trained biomedical technicians or engineers. Both user groups must be trained by certified trainers from Stryker.
- Preventive maintenance needs to be performed on an annual basis.

Caution!

Clinical users may not repair or open the device in the event of a malfunction. This can damage the appliance and will invalidate the warranty.

Have the device serial number ready when you contact the hospital service department or the local supplier for technical support. The serial number is located on the label on the back of the device.

Before performing maintenance, consult the device insulation diagram below.



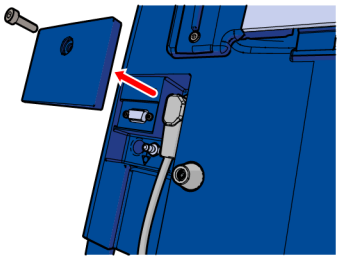
2.1 Software maintenance tool

A special software maintenance tool (MA1200 Programmer) can be provided by your local Stryker representative. This password protected tool can be set up on any PC operating on Windows 7, 8, or 10. This PC then needs to be connected to the data port protected by the mains cover at the back of the housing (see *Connecting the power supply cord* in the user manual for information on how to remove the mains cover) by an RS232 cable (and a USB converter).

The MA1200 Programmer can be used to reset the filter timer, set the device to a low fan duty cycle, adjust the setpoints to compensate for increased heat loss when using the low fan duty cycle and/or a 3 meter long hose, update the firmware and perform the after-service test protocol tests (see *After-service test* on page 13).

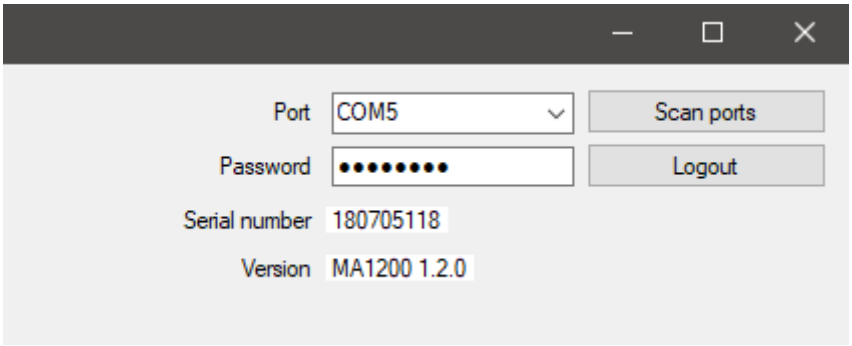
2.1.1 Establishing connection

1. Remove the mains cover from the back of the housing of the Mistral-Air®.
2. Connect the data port at the back of the housing to a COM-port of the pc with an RS232 cable (a USB to serial converter can be used when a COM-port is unavailable).



3. Connect the Mistral-Air® to the mains power supply.
4. Launch the MA1200 Advanced Programmer.
5. Press “Scan ports”.
6. Select the correct COM-port number.
7. Enter the following password: “seo3qk4b”.
8. Press “Login”.

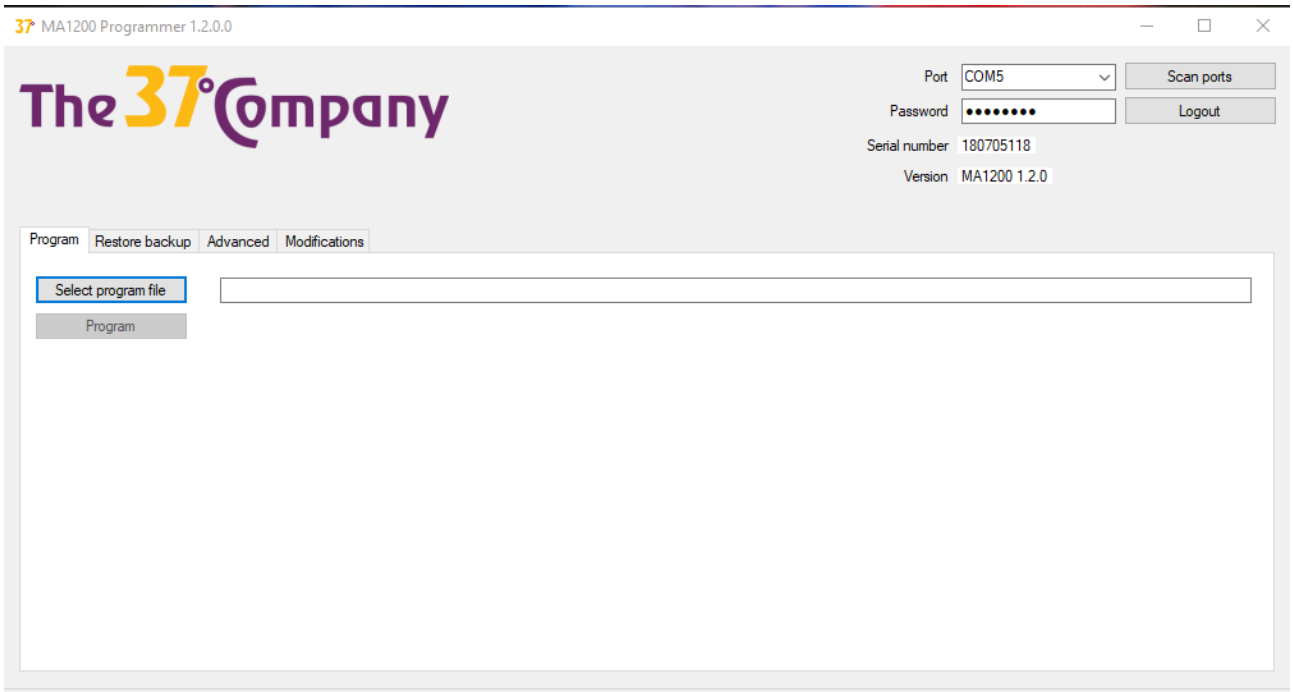
When the login is successful, the serial number and firmware version number of the MA1200 will be displayed at the top right of the interface.



2.1.2 Program Interface

The program interface can be used to install new firmware.

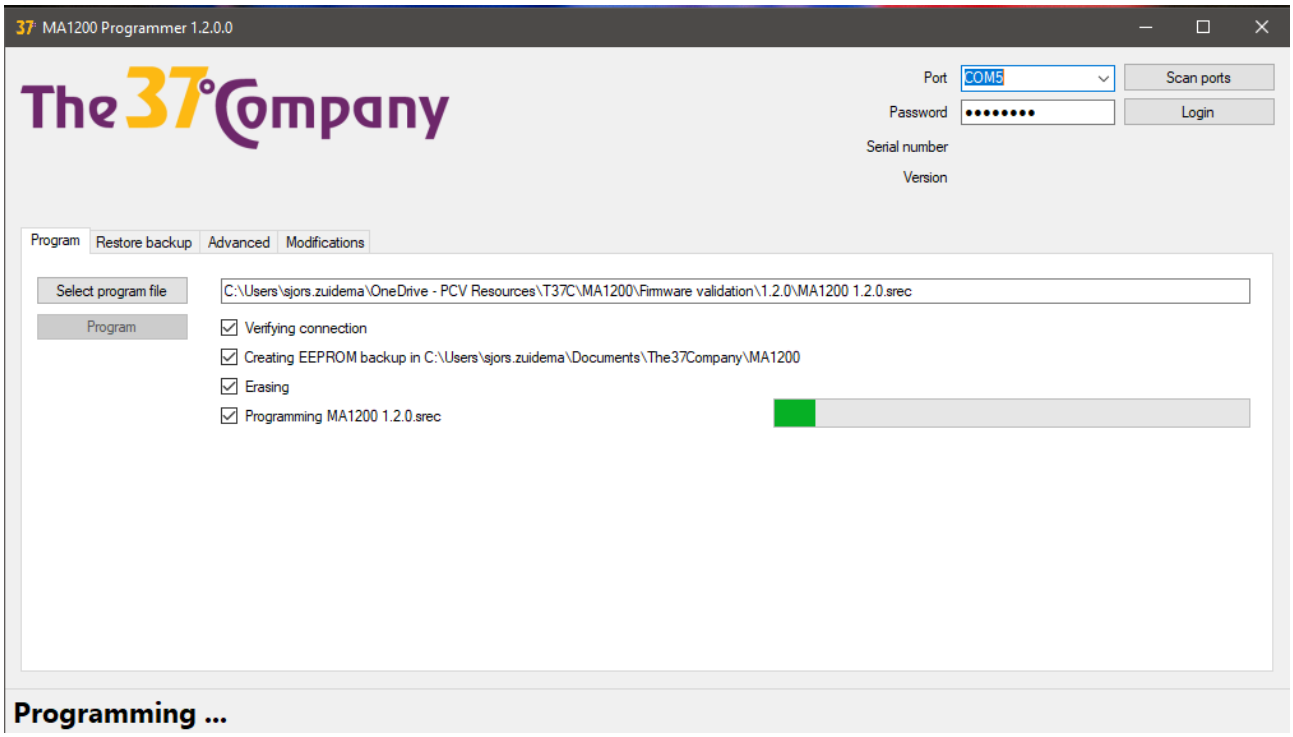
1. Make sure that the latest firmware version is downloaded from the business partner menu of the website of Stryker.



Select program file

2. Click “Select program file” and select the downloaded firmware.
3. Click “Open” and “Program”.

A status overview is shown on the screen.



Programming ...

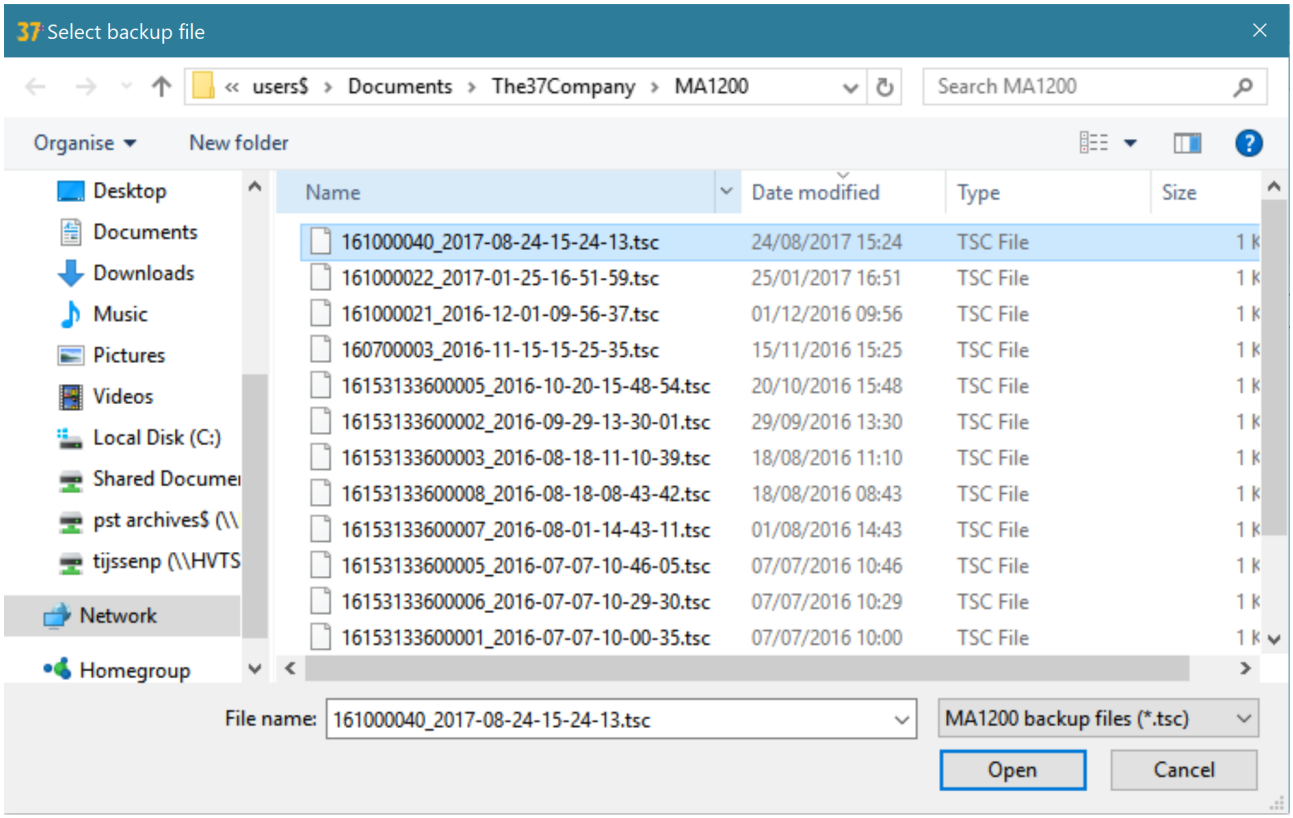
4. Wait for the programming to complete.
5. Press “Restart” and (when desired) login again.

For traceability reasons, the MA1200 programmer will send information about the device serial number and the modifications performed to the Quality Department of Stryker. This communication does not include any personal data.

2.1.3 Restore backup interface

When programming, the MA1200 Advanced Programmer stores a backup of the contents of the memory (containing for example the calibration parameters) on the hard drive of the pc. These contents can be restored to the micro controller with the “Restore backup” function.

1. Click “Select backup file” and select the correct backup file. The serial number and time of the backup are shown in the file name.

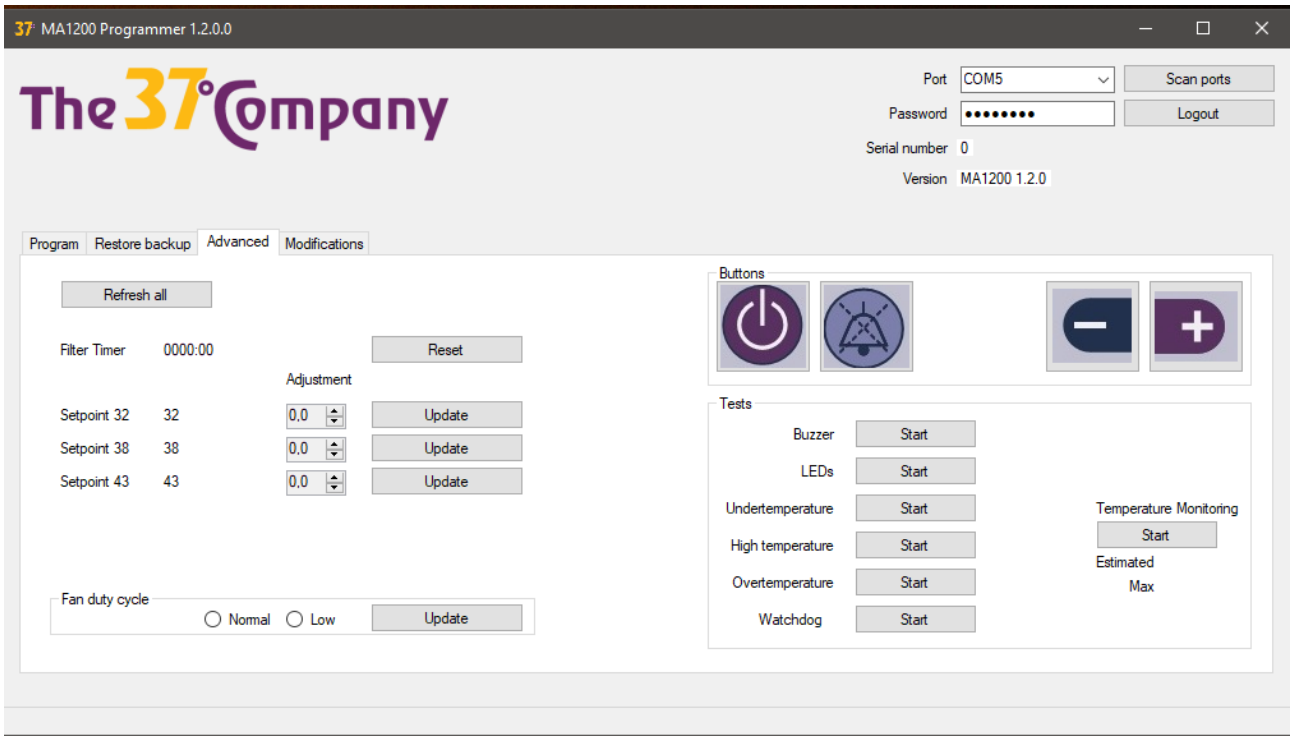


2. Click “Open” and “Restore backup”.
A programming sequence is initiated.

3. Wait for the programming to complete.

2.1.4 Advanced interface

The Advanced interface can be used to reset the filter timer, adjust the setpoints, operate the Mistral-Air® and perform the after-service test protocol tests.



Filter timer

1. Press “Refresh all” to download the calibration settings and filter timer value from the memory of the Mistral-Air®.
2. Press “Reset” to reset the filter timer.

Setpoints

1. Use the increment and decrement buttons to adjust the 32°C and 38°C setpoints by +/- 2°C .

Caution!

For safety reasons, the 43°C setpoint can only be decreased by 2°C.

Operate the Mistral-Air®

1. Use the buttons shown on the right of the interface to operate the Mistral-Air®. They function similar to the buttons on the control panel.

After-service test protocol

The tests shown at the bottom right can be used to perform self-testing. The tests described in *After-service test* on page 13 can also be activated by pressing the button combinations on the control panel. However, this menu offers some extra tests, which are built into the firmware, but which are not mandatory to perform on a yearly basis, or after service.

- The under-temperature test tests an alarm which is triggered when the temperature is more than 2°C lower than expected for 10 minutes.
- The watchdog test tests the electronic safety system which verifies correct operation of the micro controller.

When any of the alarms are triggered, control of the Mistral-Air® can only be recovered by resetting the device:

1. Disconnect the mains plug.
2. Reconnecting the mains plug.
3. Log in again.

Fan duty cycle

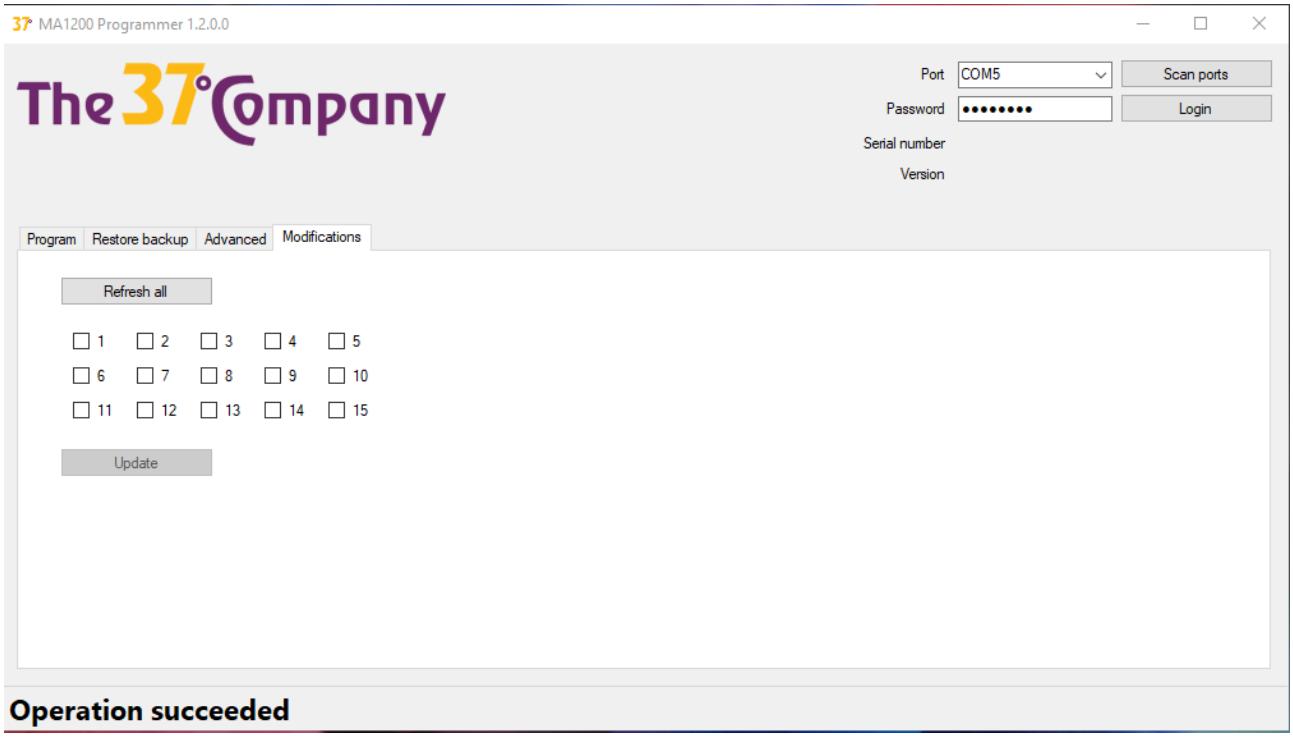
The fan duty cycle can be set to “normal” or “low”.

1. Select either button and press “update” in the bottom left area.

Selecting and applying the low fan duty cycle will reduce blower noise by approximately 3dBA, it will also lower the air flow by 10% and the End of Hose temperature by maximum 0.5°C*. This reduces slightly the net heat transfer to the patient.

* The End of Hose temperature can be adjusted in the MA1200 Programmer software to compensate for the reduction in temperature, minimizing the reduction in net heat transfer to the patient.

2.1.5 Modifications interface



- Press “Refresh all” to download the modification settings from the memory of the Mistral-Air®.
- Press any of the square buttons next to each number to toggle the modification value on or off.
- Press “Update” to write the visible modification values to the memory of the Mistral-Air®.

For traceability reasons, the MA1200 programmer will send information about the device serial number and the modifications performed to the Quality Department of Stryker. This communication does not include any personal data.

2.2 Annual maintenance

Preventive maintenance needs to be performed on an annual basis.

At every service interval, please follow these steps:

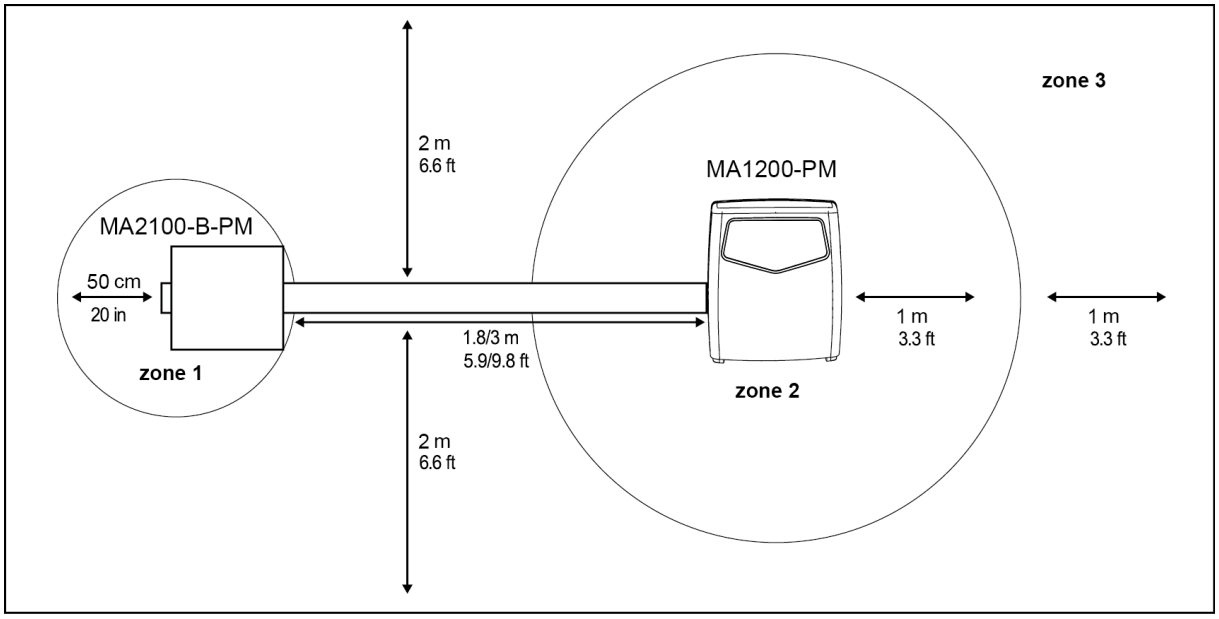
1. Clean the device (see *Cleaning* in the user manual).
2. Check if the filter is polluted. If so, replace the filter (see *Replacing the Mistral-Air® filter MA1200 - SYK (MA1200-1001-PM)* in the user manual).
3. Check if the hose is damaged. If so, replace the hose (see *Replacing the Mistral-Air® Hose - SYK (MA1100-1018-PM) or Hose XL - SYK (MA1100-1018XL-PM)* or *Replacing the (optional) Mistral-Air® QC Hose - SYK (MA1200-1018-PM) or (optional) QC Hose XL - SYK (MA1200-1018XL-PM)* in the user manual).
4. Perform the after-service test protocol (see *After-service test* on page 13).

2.3 After-service test

Caution!

All tests must be executed by using the Mistral-Air® Test Equipment - SYK (MA2100-B-PM) and the device should be set at normal fan duty cycle. The test tube inside the MA2100-B-PM represents an MA2220-PM Adult blanket. Always connect the Mistral-Air® Test Equipment - SYK to the device using a 9.8 ft straight hose (see figure below).

Before testing, verify that the Pt1000 temperature probe has a calibration due date which is not expired.



If any test fails, send the device to the technical department for repair.

Test conditions:

1. Tests must be executed at an ambient temperature of 22 ± 1.5°C.
2. The device must be acclimated to the ambient temperature.
3. Tests must be executed in a draft free room.
4. No air obstructions within 50 cm of the air outlet of the Mistral-Air test equipment (zone 1).
5. Free air inlet, no air obstructions and heat sources (e.g. laptop) within 1 meter of the device (zone 2).
6. There may be no air conditioning or climate control air outlet within 2 meters (zone 3).

Record the findings in *After-service test and preventive maintenance form* on page 21.

2.3.1 Electrical safety test

1. Execute an electrical safety test conform IEC 60601-1, for a class I, BF device.
2. Record the findings in *After-service test and preventive maintenance form* on page 21.

2.3.2 Control panel test

1. Switch the device from standby mode to on.

2. Check if all LEDs flash once and the audible alarm sounds once.
3. Check if after this self-check procedure the blower is in the 38°C heating mode, indicated by the flashing 38°C LED on the control panel.
4. Select the following different setpoints using the + and – buttons:
   - Fan only/ambient air
   - 32°C
   - 38°C
   - 43°C
5. Check if the buttons react within 0.5 seconds.
6. Record the findings in *After-service test and preventive maintenance form* on page 21.

2.3.3 Setpoint temperature test

1. Switch the device from standby mode to on.
2. Select 43°C and wait for at least 2 minutes for the temperature to stabilize. After the setpoint is reached the 43°C LED stops flashing and turns solid green.
3. Verify that no alarm is triggered.
4. Measure the maximum temperature using the device test equipment (must be between 42.5 – 47.5 °C).
5. Repeat steps 2 – 4 at 38°C (maximum temperature in test equipment must be between 37.5 – 42.5°C).
6. Repeat steps 2 – 4 at 32°C (maximum temperature in test equipment must be between 31.5 – 36.5°C).
7. Record the findings in *After-service test and preventive maintenance form* on page 21.

2.3.4 Overtemperature alarm test

1. Press and hold the audible alarm suppression button and press the standby button to enter service mode.
2. Scroll to the 43°C setpoint using the + button and confirm the test by pressing the audible alarm suppression button.
3. The 43°C LED lights up continuously.
4. Verify that the overtemperature (continuous LED) and maintenance (continuous LED) alarms are visually and audibly enabled at a temperature below 56°C measured by the Mistral-Air® test equipment and if the fan and heater switch off.
5. Verify that the audible alarm can be suppressed and reactivated using the alarm suppression button.
6. Press the standby button. Verify that it is impossible to start the device.
7. Reset the device by disconnecting the power supply cord from the mains socket.
8. After a few seconds, reconnect the power supply cord, press standby and check if the device starts normally.
9. Record the findings in *After-service test and preventive maintenance form* on page 21.

2.4 Corrective maintenance

Warning!

Maintenance may only be performed by trained biomedical technicians or engineers. Both user groups must be trained by certified trainers from Stryker.

Tools used

- 4 mm hex screw driver
- 3 mm hex screw driver
- New Front Cover with Control Panel - SYK (MA1200-1002-PM)
- Knife
- Hot-melt
- 2 new fuses

2.4.1 Replacing the fuses

Warning!

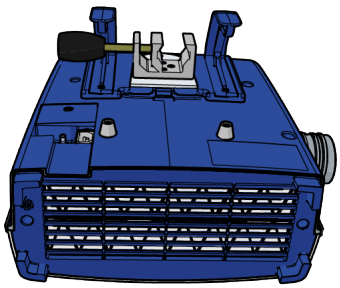
- Only use fuses supplied by Stryker as described on the spare part list on the website of Stryker. Otherwise correct operation of the fuses cannot be guaranteed.
- Before performing corrective maintenance (see *Corrective maintenance* on page 15), disconnect the power supply cord to eliminate the risk of electrocution. There are electrically live parts within the device when it is connected to a power supply.

Caution!

Use electro static discharge (ESD) protection (e.g. ESD gloves or wristband) during steps 7 through 9 to protect the internal electronics of the device.

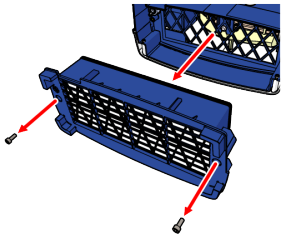
Caution!

Be careful not to scratch the front of the device.

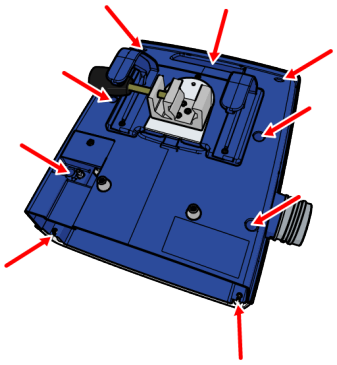


1. Disconnect the device from the mains socket.
2. Place the device face-down on a soft surface.

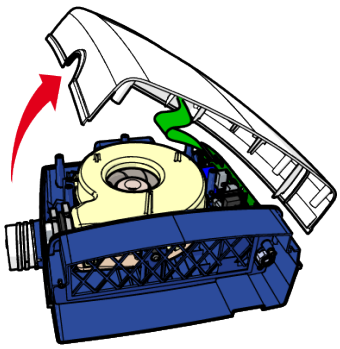
3. Remove the two screws of the filter cap with a 4 mm hex key.



4. Remove the 9 screws which connect the front and back housing using a 3 mm hex key.
5. Flip the device.



6. Remove the front housing by tilting it to the right.



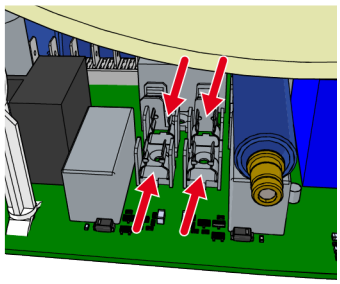
Caution!

Be careful not to damage the control panel cable.

7. Carefully remove the printed circuit board assembly (PCBA) from the clamps by using a tool to lever the PCBA.

The 4 mains fuses are now accessible for replacement.

8. Replace the fuses.
9. Reattach the PCBA.
10. Follow the previous steps in reverse order to reassemble the device. Tighten the screws using a maximum torque of 1.5 Nm for M4 and a maximum torque of 2.1 Nm for M5.
11. Perform the after-service test protocol. See *After-service test* on page 13.



2.4.2 Replacing front cover MA1200

This document lays down the instruction to replace the front cover of the Mistral-Air devices.

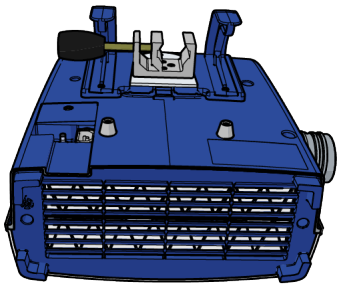
Warning!

Disconnect the power supply cord to eliminate the risk of electrocution. There are electrically live parts within the device when it is connected to a power supply.

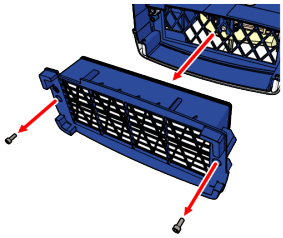
Caution!

Use ESD protection to protect the internal electronics of the device.

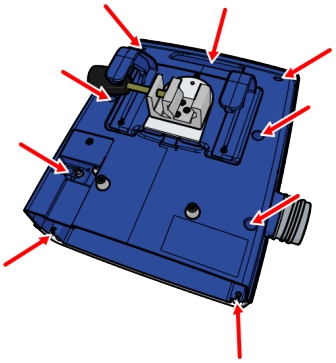
1. Disconnect the device from the mains socket.
2. Place the device face-down.



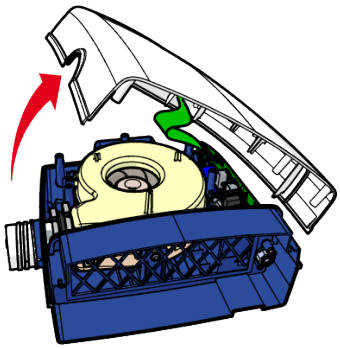
3. Remove the two screws of the filter cap with a 4 mm hex key.



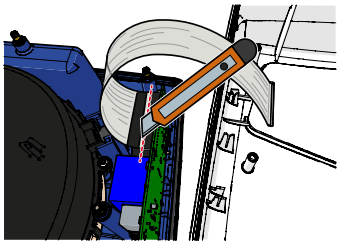
4. Remove the 9 screws which connect the front and back housing using a 3 mm hex key.
5. Flip the device.



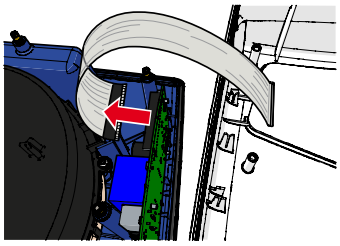
6. Remove the front cover by tilting it to the right.



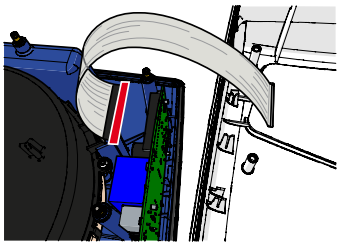
7. Use the knife to carefully cut the glue which secures the connector of control panel cable to the pins on the PCBA. Be careful not to damage the electronics.



8. Remove the connector from the PCBA and attach the connector of the new front cover.

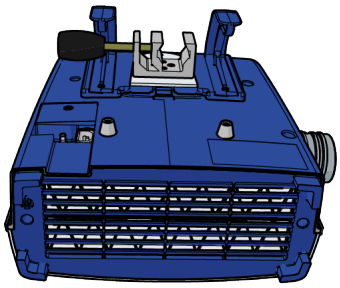


9. Secure the connector by applying hot-melt to the full width of the connector.



10. Wait until the hot-melt is cured.

11. Follow the previous steps in reverse order to reassemble the device. Tighten the screws using a maximum torque of 1.5 Nm for M4 and a maximum torque of 2.1 Nm for M5.
12. Perform the after-service test protocol.



3 Troubleshooting

Problem	Possible Cause	Action
The device does not switch on.	Unplugged or damaged power cord	Make sure power cord is plugged in and is undamaged. Replace cord if necessary. (See Mistral-Air® Warming Unit User Manual.)
	No power to outlet	Confirm power to outlet.
	Poor or loose wire connections	Ensure all connectors and terminals are secure.
	Blown fuses at PCBA	Replace fuse(s). (See *Replacing the fuses* on page 15.)
The technical alarm is activated and the warming device stopped working.	Obstructed air flow path	If this alarm occurs, check for anything blocking the air flow path (e.g. blocked inlet, blocked hose end, or kink in the hose). Remove the obstruction(s), unplug the device from mains power, reconnect it and verify if the alarm is disabled. Press standby to activate the device again. In case of a recurring alarm, open the device and check for internal damage or loose connectors. If no damage is found, contact Stryker for support.
	Poor or loose wire connections, or damaged heater or electronics	
	Large mains power dip (≥ 30%) for more than 1/60 of a second	
The microcontroller watchdog alarm is activated.	Malfunctioning electronics	Open the device and check for internal damage or loose connectors. If no damage is found, contact Stryker for support.
The device does not deliver enough air.	Obstructed air flow path	Check for anything blocking the air flow path and remove the obstacles.
	Clogged air filter	See Mistral-Air® Warming Unit User Manual to replace the filter with new filter supplied by Stryker.

Problem	Possible Cause	Action
	Fan duty cycle set at low	See *Advanced interface* on page 9 to adjust the fan duty cycle.
During testing, the device setpoint temperatures do not match to the criteria.	Device out of calibration	The specified temperature accuracy according to *Specifications of the device* in the Mistral-Air® Warming Unit User Manual is only valid at the specified ambient temperature. The setpoints of the device can be adjusted using the MA1200 Programmer (see *Software maintenance tool* on page 6).
	Faulty temperature sensors	Contact Stryker for support.
Other technical problems.	Unidentified cause	Contact Stryker for support.

4 Appendices

4.1 After-service test and preventive maintenance form

Hospital	
Location	
Serial Number	
Date	
Test Engineer	
Signature	

Test Conditions Check

Test object	**Temperature (°C)**	**Acceptable range (°C)**
Ambient temperature		20.5 – 23.5
Draft free room	Pass ❑	Fail ❑
No air outlet obstructions	Pass ❑	Fail ❑
Free air inlet	Pass ❑	Fail ❑
No air conditioner / climate control	Pass ❑	Fail ❑
Pass ❑ Fail ❑ Comment:		

Electrical safety test

During the electrical safety test, maximum values of continuous leakage and patient auxiliary currents must be measured according to the following table:

Current	**Type Body Floating (BF)**		
	Maximum values [µA] (Normal Condition (NC))	**Measured [µA]**	**Pass/Fail Normal**
Earth leakage current general	500		Pass ❑ Fail ❑
Cabinet leakage	100		Pass ❑ Fail ❑

Control Panel Test

LEDs flashing	Pass ❑	Fail ❑
Audible alarm	Pass ❑	Fail ❑
Switch on at setpoint 38 °C	Pass ❑	Fail ❑
Button check	Pass ❑	Fail ❑

Setpoint temperature check

Selected setpoint	Temperature (°C)	Acceptable range (°C)
43		42.5 – 47.5
38		37.5 – 42.5
32		31.5 – 36.5
Pass ❑ Fail ❑ Comment:		

Overtemperature alarm test

Test object	Temperature (°C)	Acceptable range (°C)
Overtemperature alarm		Below 56 Pass ❑ Fail ❑
Alarm suppression button		Pass ❑ Fail ❑
Impossible to start using standby button		Pass ❑ Fail ❑
Device starts normally		Pass ❑ Fail ❑

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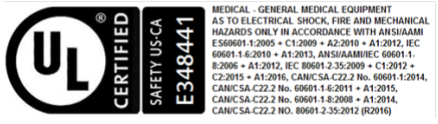

applicable to model MA1200-PM
and MA1200-QC-PM