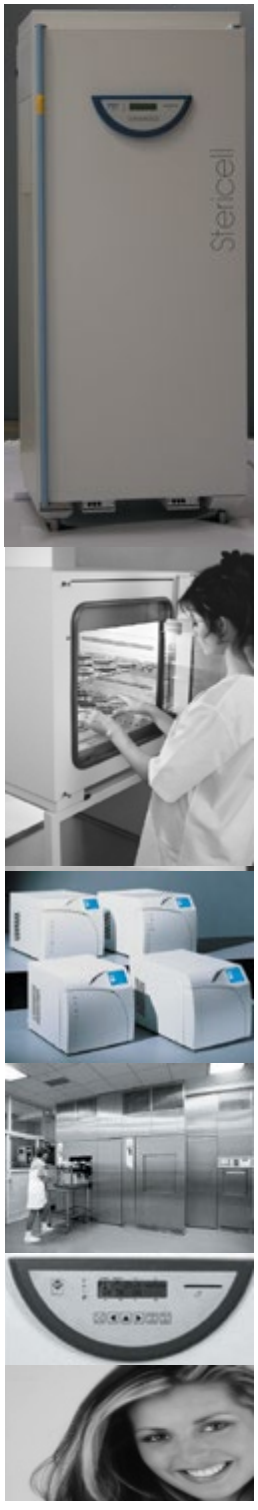
MMM Group



Instructions for use

Hot Air Sterilizer

STERICELL 22, 55, 111, 222, 222/2, 404, 404/2

CE 0123

STERICELL_np_en 1303_mmm_V2.12_B2V

CONTENTS:

26. 3. 2013

APPENDICES:

EC - DECLARATION OF CONFORMITY

1 GENERAL

Congratulations on obtaining the new medical device – hot air sterilizer. It is intended for sterilization of medical devices by means of hot air under adjustable temperature and selectable time mode.
The air flap valve enables wet material drying.
The temperature distribution is controlled by a modern microprocessor (Fuzzy - Logic) with a digital display and a PT 100 thermostat sensor. This system ensures high accuracy of temperature regulation and reliability of the tempering process.
The units comply with the technical and legislative requirements of the EU and have been designed in accordance with the respective EN standards. They are made of high quality materials using the latest technology.
Each unit undergoes a careful output control.
If you follow the instructions mentioned here, the unit will become your reliable and powerful partner.
Now these advantages will be available just for you. This unit will help you to solve your everyday problems and will certainly become a powerful assistant for you. This unit is very easy to use; nevertheless, we recommend you to read the Instructions for use carefully to be able to use all the advantages of this unit and have complete knowledge for its optimal use.

This instruction applies to all models of the device STERICELL type SCK-B2V.

1.1 INTENDED PURPOSE

The hot air sterilizer STERICELL (SC) is a device intended for use in the healthcare for sterilization process by hot air / dry heat of unwrapped and wrapped medical devices including invasive devices according to the EU directive 93/42/EEC, intended by their manufacturer for sterilization by hot air / dry heat; see article 2.2.

2 IMPORTANT INSTRUCTIONS

2.1 UNPACKING, CHECKING AND TRANSPORT

Please check after unpacking whether the unit and its accessories are complete and not damaged.

An eventual damage has to be reported to the transporting company immediately.
During the manipulation – in case of lifting the cabinet etc. – the unit must not be held by the rail or door. The units of volumes 404 shall be lifted by means of supplied hooks; the casters are designed for local moving only, not for longer transport.

A standard delivery consists of a temperature cabinet and two sieves, three chip cards formatted for program download (marked Programs – empty) and one special operations card (SO). Attention: If an SO card is used for a program download, its original function will be cancelled.

2.2 BEFORE INSTALLATION

STERICELL was designed according CZ regulation No. 195/2005 Collection of Law for sterilization process for medical devices made of metal, glass, porcelain, ceramic and stoneware. The Hot air sterilization in the CE device with forced ventilation is in compliance with the parameters defined in CZ regulation No. 195/2005 Collection of Law.

The suitability of the process and parameters for the individual medical device or instrument must be described in instructions set by the manufacturer of the medical device or instrument designed for sterilisation – see Directive No. 93/42/EEC, art. 13.1, 13.3 m), 13.6 g), h) and so adjusted accordingly.

The process of sterilization must be validated by its user according to the standard EN ISO 14937, art. 9.4.

- **Please read carefully the Instructions for use before starting the work with the unit!**
- The person responsible for the unit (user) must ensure regular and provable training of all operators regarding the operation and safe use of the unit.
- Install the unit by connecting the mains cord plug to the power mains. However, ensure at first whether the power mains parameters correspond to the unit type label and data specified in Chapter 5.1! Then the air flap position must be adjusted according to Chapter **4.6 Air Flap - Adjustment and Function**.
- Position the unit and connect it to the power mains so that the mains cord plug was accessible easily.

In one-phase models (volumes 22, 55, 111, and 222 not open-through), the mains cordt serves also for the unit disconnection.

When the unit is switched on for the first time, the heating elements and insulation will be “baked”, which is accompanied with a specific smell that passes away after several operation cycles. Nevertheless, if insulation is “baked” under temperatures of 100 °C and more, we recommend you – regarding the mentioned smell – to ensure sufficient air exchange in the room (e.g. ventilation or air exhaust).

Under temperatures of 100 °C and more, the colour of the inner surface of the chamber becomes yellowish. Such colour does not mean any defect of material or unit.

The exhaust hole on the rear wall of the unit is protected by a cap. This cap (which is placed in the unit during the transport) should be fixed behind the exhaust during installation by inserting it in horizontal holes in the rear cover under and above the exhaust.

Air filter can be attached to the suction hole – see Chapter **3.2 STERICELL – HEPA filter placement.**

The units are designed to work indoor within the ambient temperatures ranging from 5 °C up to 40 °C, at maximum relative humidity of 80 %, up to the maximum altitude of 3,000 m.

Minimum distance of the unit from the rear and side wall is 100 mm. Attention must be paid to the fact that air of temperature up to 250 °C can come out of the exhaust hole; this part is labelled by the sign  . Therefore, the closest walls must be flame-resistant.

When placing the unit, the weight-carrying capacity of the floor must correspond to the weight of the unit as such, taking account of the maximum weight of charge (see Chapter **5 Unit Parameters**).

The unit may not be placed on a material that can cause danger of fire or smouldering if hot objects fall off the unit.

No flammable, explosive, corrosive substance, or materials from which such substances could release, can be placed in the units!

The material may only be placed on the screens, not on the unit bottom!

Be careful when taking hot objects out of the unit.

The pre-heating period corresponding to the material and its quantity in one charge (see Chapter 4.2) must be set before each sterilization exposure.

No objects may be placed on the outer surfaces of the unit.

The unit is not intended for fluids heating.

The units should not be used in an environment with danger of flammable or explosive anaesthetics presence.

Any mounting and demounting of the unit parts may only be performed after the unit disconnection from the mains (by unplugging the power cord in one-phase units)! After switching the unit off by means of a switcher (button 6, fig. 4), **the unit is in a stand-by mode, but it is not disconnected from the mains!**

The mains supply must not come in contact with hot parts of the unit – cover of the exhaust hole.

Be careful when moving the upper sheet of the inner chamber out and in – careless handling can cut the chamber insulation.

Maximum admissible load: See Chapter **5 Unit Parameters.**

 During the units operation under high chamber temperatures, the temperature on their inner surface (exhaust holes and their surrounding area, and surrounding area of the chamber sealing) can exceed the maximum permitted value of 70°C, thus causing danger of burning. Please be very careful.

If the 404 l volume size units are operated under high temperatures, the inner door surface is deformed due to thermal stress, which makes the door closing difficult. If the door is opened in this situation, close it only after the chamber cools down; otherwise, there is a risk of the mechanism damaging.

Check regularly (by listening) in daily intervals whether the ventilator runs after the unit starts operation.

Chemical indicators of sterilization exposure (e.g. Browne labels or tubes) or maximum thermometers shall be used

together with the material load to check and document the proper function of the sterilizer.

- The temperature cabinet, its surroundings and the processed material are protected against an inadmissible temperature overrun by a safety thermostat. Check the function of the safety thermostat regularly (in daily intervals).
- The doors and the exhaust flap are provided with microswitchers – see details in Chapter **4.2.2 Sterilization Programme Setting and Run.**
- If you do not use the unit for a longer time, disconnect it from the mains (in one-phase units: unplug the power cord from the socket).

2.3 USEFUL SPACE

The useful space is illustrated on Fig. No. 1, where X(D) = 10 % of the inner chamber depth, X(W) = 10 % of the inner chamber width, $X(H)_1$ is the distance from the lowest tray to the bottom of the inner chamber, $X(H)_2$ is the distance from the upper most tray to the ceiling of the inner chamber. The required temperature accuracy - see chapter **5 Parameters of the unit** - is achieved only within the space defined above (in connection with DIN 12 880 - marked with thick lines, thinner lines mark the inner chamber walls). (It means, that over the last upper tray the limits from chapter **5 Parameters of the unit.**

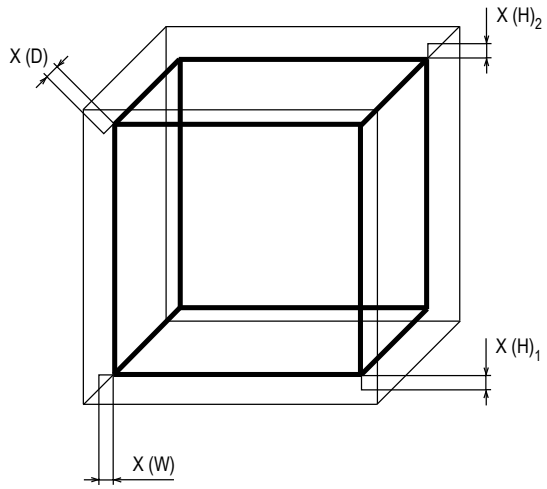


Fig. 1

3 DESCRIPTION OF THE UNIT

3.1 GENERAL VIEW

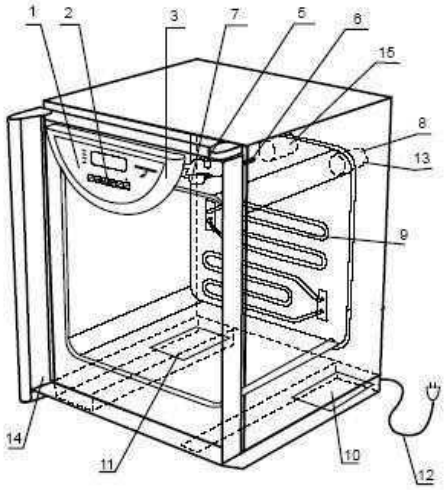
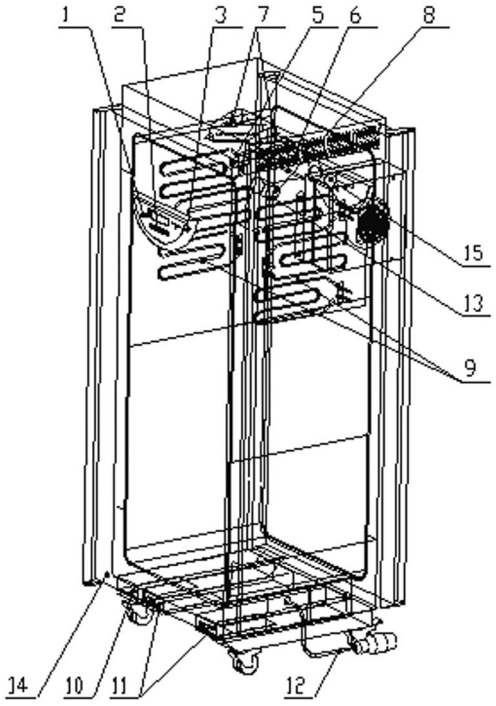
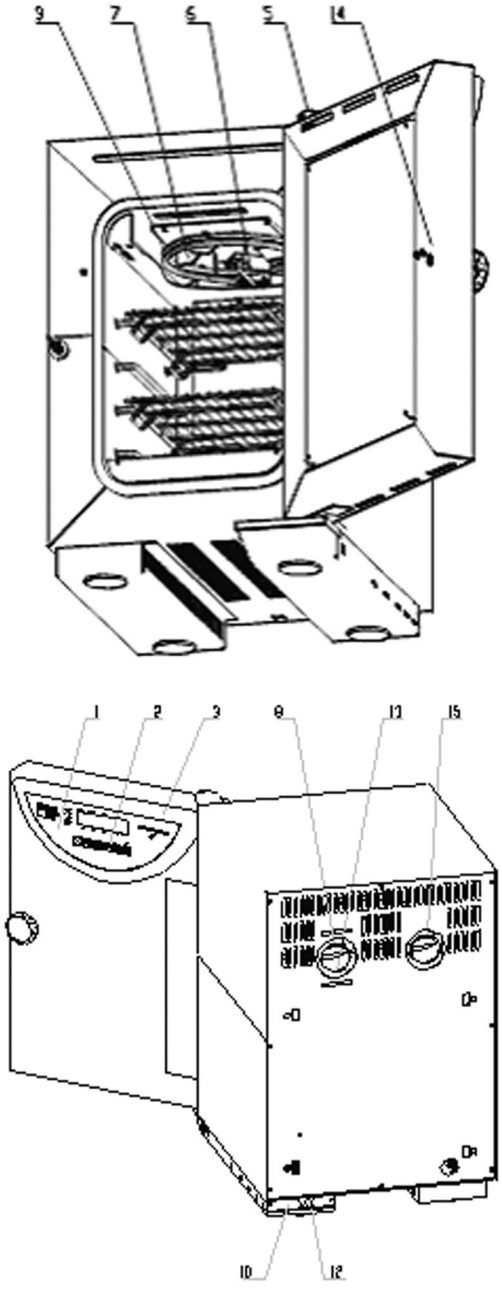


Fig. 2

1 - controller panel
2 - control keys
3 - plastic cover of the controller panel
5 - lever for air flap positioning
6 - case of PT100 sensor
7 - fan
8 - exhaust with air flap
9 - heating elements
10 - power board I
11 - power board II (only three-phase type)
12 - mains cord
13 - sensor for air flap position
14 - door sensor
15 - suction hole with air flap.



Two-door open-through model



STERICELL 22

3.2 STERICELL 22, 55, 111, 222, 404 – INSTALLATION OF HEPA FILTER, FILTER DIMENSIONS, FUNCTION AND FILTRATION CHARACTERISTIC OF THE AIR FILTER

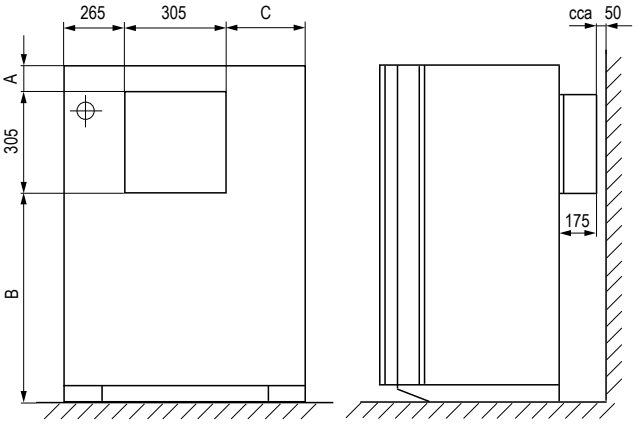
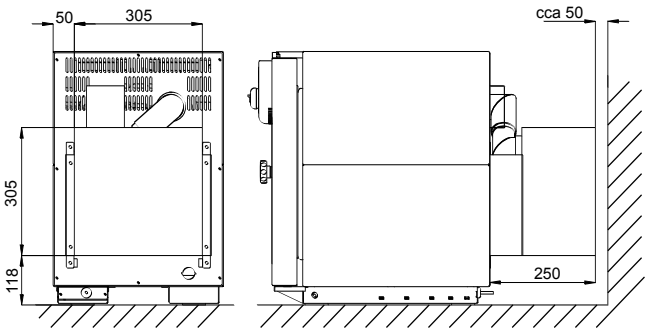


Fig. 3 (dimensions are in mm)



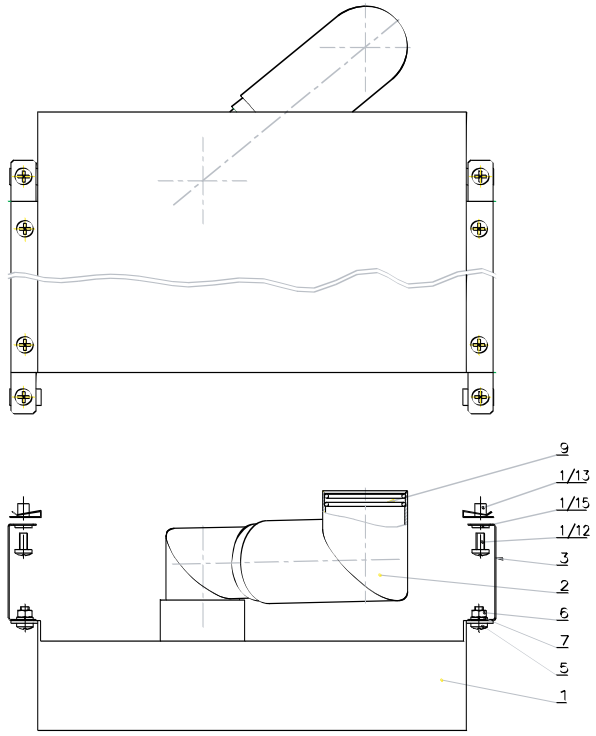
Type → Dimension↓	55	111	222	404
A (mm)	85	85	85	135
B (mm)	290	470	710	1470
C (mm)	110	250	250	250
Height A+B+305(mm)	680	860	1100	1910

Note: The minimum distance from the filter to the wall is 50 mm.

The air filter is a part of the optional accessories, it is installed when cooling STERICELL by means of forced air circulation.
The class of the HEPA filter according to DIN 24 184 is S, according to EUROVENT it is EU 12, according to EN 1822 it is H13.

HEPA filter assembly:
Insert the nuts for fixing of the HEPA filter into four rectangular holes in the rear cover. Put on a metal ring on the end of the suction flue and follow it by two rubber rings. Put the pipe of HEPA filter on the chimney. During the putting on,

please, take care of the fact so the rings would not be shifted by the pipe of HEPA filter away, but the rings must be forced into the gap between the pipes. Please, fix the put on HEPA filter with four screws. If the HEPA filter is equipped with a fan, insert its socket plug into the socket for its energy supply.



HEPA filter assembly to the apparatus of size 22:

- insert the supplied nuts into the holes in the rear wall (1/13)
- put 2 pcs of O-rings on the edge of the suction chimney
- put the air conduit on the suction chimney (2)
- put 2 pcs of O-rings on the air conduct
- put the unit of HEPA filter on the air conduct and position it into a proper position
- fix it with a screw (1/12) and washer (1/15) to the rear wall
- connect the fan connector into the socket in the rear wall (only in case of the overpressure HEPA filter).

3.3 POWER CONNECTION AND CONNECTORS

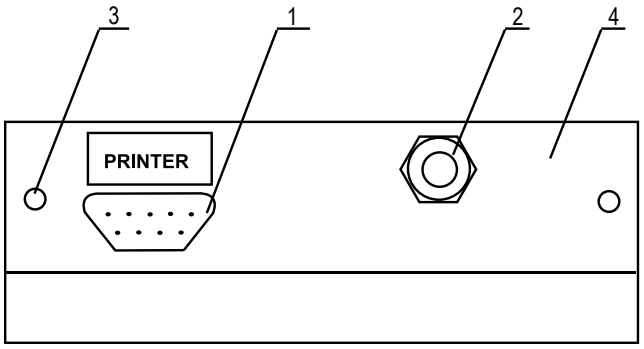


Fig. 5: Foot of the unit with mains cord – rear view (with power board I)

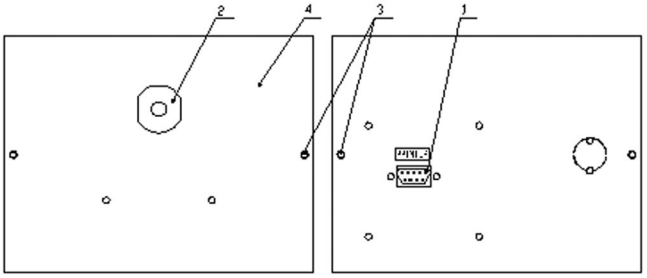


Figure 5: Covers on the unit side with the power mains cord for the two-door open-through model

1 - interface for printer
2 - mains supply
3 - screws attaching the power board
4 - power board panel

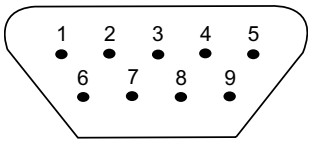


Fig. 6: 9 Canon - Interface for protocol printer

9 pin Canon connector on the case

Pin	Signal
2	RX
3	TX
5	GND
6	DSR

25 pin Canon connector in the printer

Pin	Signal
2	TXD
3	RXD
7	GND
20	DTR

The appliances, which are connected with the connector RS-232C, must comply with valid regulations in terms of electric safety and electromagnetic compatibility.

Interface parameters: Baud 9600
Stopbit: 1
Parity: none
Databit: 8

3.4 CONTROL PANEL

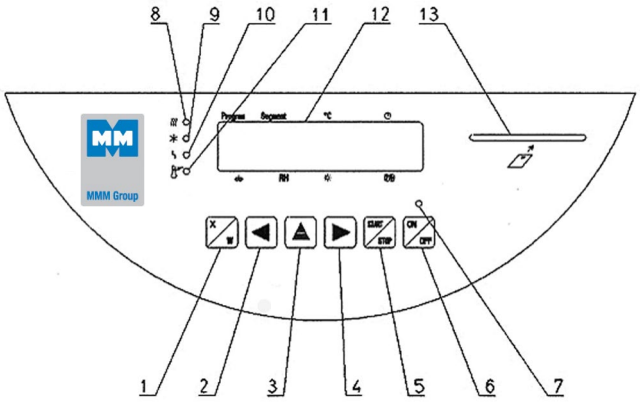
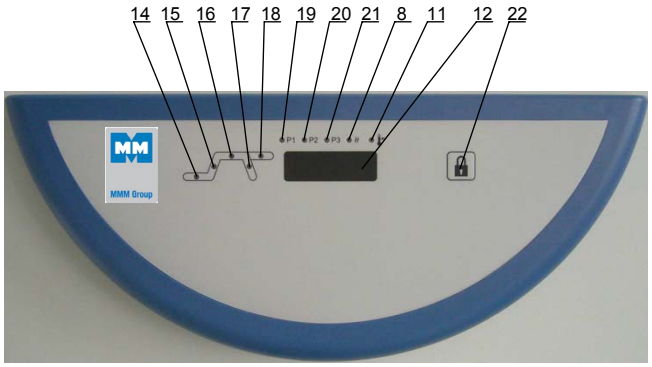


Fig. 4

1 key of activation of setting-up mode
2/4 cursor steering turning to the left/right
3 setting-up value in parameter
5 key starting the program
6 switch (ON - on, OFF - stand by)
7 indicator light - shines after switching on the switch
8 indicator light heating - shines: state of temperature regulator - heating active
9 not used
10 indicator light – failure
11 indicator light of safety thermostat - shines: temperature surpassed the limit set on the safety thermostat - heating is off / see paragraph 4.1.8 - Set safety thermostat
12 Display
13 port for inserting the chip card
Position on the display:
Program: displaying the program
Segment: partial or full graphic representation of the program coarse
°C: temperature display
: process time
: fan speed display in % (inapplicable)
RH: % relative humidity (inapplicable)
: setting-up intensity of exposition light in the door (inapplicable)
56: positions are used for specific purposes - see descriptions in text.

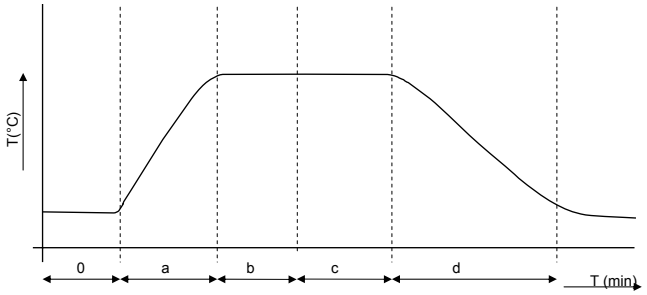
3.5 CONTROL PANEL - UNLOADING SIDE



8. Heating indicator – ON (lighting): Shows the state of the temperature regulator – the heating is active
11. Protective thermostat indicator – ON (lighting): The temperature has exceeded the pre-set protective thermostat limit – the heating has been switched off
12. Display
14. Indicator of the delayed switch-on phase
15. Indicator of the temperate rising phase
16. Indicator of the pre-set temperature maintenance phase in a pre-set cycle time
17. Indicator of the cooling phase
18. Indicator of the pre-set temperature maintenance phase in an unlimited cycle time
19. Indicator - ON (lighting) during the P1 program run
20. Indicator - ON (lighting) during the P2 program run
21. Indicator - ON (lighting) during the P3 program run
22. Button for the unloading side door blocking after the sterilized material is unloaded and the door closed.

4 FUNKTION AND OPERATION

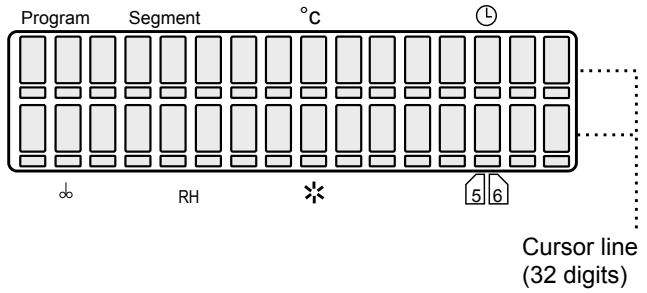
The function of the individual indicators and control keys is described in Chapter 3 – Description of the unit and 3.4 – Control panel. The figure shows the whole course of one sterilization cycle and its division to the appropriate stages.



Stage	Function
0	time-delayed switching-on,
a	rise to the temperature,
b	preheating
c	sterilization exposure
d	temperature drop after switching-off

Connection to the power mains:
Compare the nominal voltage and input of the unit specified on the type label with the voltage supplied. If the power mains parameters correspond to the unit parameters, connect the plug to the mains socket. The display switches on, the memories are checked and the device passes to the stand-by mode.

Switching the unit on:
Press the **ON/OFF** key (an indicator above it lights up); the unit is ready to operate. Proceed according to the points given below.
The unit is switched off by pressing the **ON/OFF** key (the indicator above the key switches off) and the unit passes to the stand-by mode.



The display shows all parameters at once. The cursor moves below all 32 display positions (if active) on the cursor line and is always placed below only one of 32 positions.

Parameter change:
Move the cursor in horizontal direction by means of ◄► keys. That parameter below which the cursor is positioned, can be changed by means of ▲ key.

Display of the measured values during the programme run:
In units with a larger number of measured values, not all values (temperatures) can be displayed on the LCD panel at once. Therefore, the temperature position shows the regulatory sensor temperature during the programme run while the time position shows – in turns – the time, the temperature read by the first flexible sensor (symbol “a”), the temperature read by the second flexible sensor (symbol “b”), etc. The values can also be displayed during the programme run by successive pressing of ◄ or ► key. The value is displayed for several seconds; its display can be extended by pressing the ▲ key.

Blocking of parameter changes:
This parameter is activated in the service setting of the unit type (programmes are lettered by lower-case letters p1, p2, p3). In this mode, the time of delayed switching-off can be changed only. All parameters setting can be changed after an SO chip card insertion (programme indications P1, P2, and P3 are displayed); After the chip card is pulled out, the new parameters are blocked again. If this parameter is not active (not activated in the service setting of the unit type), programmes indication is displayed by means of capital letters P1, P2, and P3.

4.1 BASIC SETTING OF UNITS

The Comfort medical technology units with a regulator offer the customers a broad range of use. Correct system switch-on is based on its optimum initial setting. Use the following service mode to set the unit.

4.1.1 SERVICE MODE ACTIVATION

Press the keys ▲► concurrently and hold them pressed for 2 seconds. The display shows Service 01. You can switch the individual services Service 01 – Service 09 upwards by means of the ▲ or ► key, or downwards by means of the ◄ key. If you want to reach the end of the service mode, press the **X/W** key. The service mode cannot be activated if the device is in the stand-by mode, or if a sterilization cycle is running.

4.1.2 SERVICE 01 – P1, P2, P3 PROGRAMMES SAVING ON THE CHIP CARD

This service allows you P1, P2, and P3 programmes saving on the unit manufacturer’s chip card. Before the parameters are recorded to the chip card, a correct card must be inserted in the unit card slot. The card may be ordered from the unit supplier.

Check whether the chip card has been inserted in the reader!

The basic procedure is as follows:
Before switching on: The display shows: “Service 01” and “Card Record”. Press the **START/STOP** key and open the programme storing service.
After switching on: The second line of the display shows what will be recorded to the chip card – all optional parameters of P1, P2, and P3 programmes concurrently – the display shows: “P1 ÷ 3 → MMM CCard”. Press the **X/W** key and the data are recorded to the chip card.
If everything is OK, the display shows “Done”. Finish and close the service by pressing the **START/STOP** button. This will allow entering in another service.
If a message “Wrong MMM Ccard” displays, check the chip card and repeat the procedure.

4.1.3 SERVICE 02 – PROGRAMMES RECOVERY/DOWNLOAD FROM THE CHIP CARD

By means of this service, P1, P2, and P3 programmes recorded previously to the chip card (see 4.1.2) can be recorded to the unit memory again. The actual programmes in the memory will be overwritten.

Check whether the chip card has been inserted in the reader!

The basic procedure is as follows:
Before switching on: The display shows: “Service 02” and “Chip Card Reading”
Press the **START/STOP** key and open the programme introduction service.
After switching on: The second line of the display shows what will be read from the chip card – all optional parameters of P1, P2, and P3 programmes concurrently – the display shows: “P1 ÷ 3 → MMM CCard”
Press the X/W key and the chosen variant is read from the chip card.
If everything is OK, the display shows “Done”. Finish and close the service by pressing the **START/STOP** button. This will allow entering in another service.
If a message “Wrong MMM Ccard” displays, check the chip card and repeat the procedure.

4.1.4 SERVICE 03 - SET THE REAL TIME AND DATE

Pressing **START/STOP** you enter the service. Set the real time and date by pressing buttons ◄ ► and ▲.

You can enter the data format setting by using the key ◄ if the cursor is on the hour setting position, or by using the key ► if the cursor is on the last position of the year setting.

Position	1	2	3	4	5	6	7	8	9	10	11	12
Scope	D	F	m	t	:	_	R	R	R	R	-	M

13	14	15	16
M	-	D	D

Cursor on the position 6: with the key ▲ selection of the date separator. The possible options are dash (-), slash (/), dot (.), colon (:). The implicit value is dash. With the key ◄ back into the date setting mode.

Cursor on the position 7: with the key ▲ selection of the date format. The possible option for Czech language are YYYY-MM-DD, YYYY-DD-MM, MM-DD-YYYY, DD-MM-YYYY. The implicit value is YYYY-MM-DD (Czech), YYYY-MM-DD (English), JJJJ-MM-TT (German), AAAA-MM-JJ (French). With the key ► back into the date setting mode.

Finish the service and close again by pressing the button **START/STOP**. Format of the data on the display: hours:min_day.month.year. Both the selected format and separator too are given into consideration on LCD display, and on the printer too.

4.1.5 SERVICE 04 – RECORDING MODE

Print interval setting at the communication interface of the printer.
The medical technology units can be equipped with an external printer allowing protocols printing with the time data in real time. The external printer is an optional accessory, is used, connected to the print interface by means of a cable – see Chapter **4.5 – Printing the Protocol**.
Enter the service by pressing the **START/STOP** key and set the print interval:

Select one of the following options by means of ▲ key:

The printer is switched off
Switched to PC (SW WarmComm application – the data are sent to a PC)
Interval 10 s
Interval 01 min
Interval 01 h

Move the cursor by means of ◄ key to the position 10/01 s, min, or h. The print interval can be changed by means of ▲ key in the following extent
10 to 50 s (10 s-step)
01 to 59 min (1 min-step)
01 to 12 h (1 h-step).

The printer selection mode is entered by pressing ◄ or ► key:
1 Citizen dot matrix printer
2 Thermal printer
(The difference is in the °sign).

Terminate and leave the service by pressing the **START/STOP** key again.

CAUTION!
One unit only is active: Either seconds, or minutes, or hours!

4.1.6 SERVICE 05 - SELECT LANGUAGE

Pressing **START/STOP** you enter the service. To select the language use button ▲ To quit the service press **START/STOP** again.

4.1.7 SERVICE 06 – SETTING THE VENTILATOR FUNCTION IN THE CHAMBER

Enter the service by pressing the **START/STOP** key. Enter the setting of the chamber ventilators V1 and HEPA filter ventilator VH. If the unit is equipped with a HEPA filter, you can switch between V1 and VH by means of ◄► keys; otherwise, V1 only is displayed.
a) “Prog” – the ventilator runs only when P1-P3 are running
b) “T50C”-“T250” – the ventilator keeps running after the programme stops until the temperature drops below the set one (temperature from 50 °C to 250 °C in 10 °C increments can be set)
c) “Door” - the ventilator keeps running after the programme stops till the door or air flap opening
d)”alws” - the ventilator keeps running until the unit is switched off by the **ON/OFF** key
e)“Off“ – the ventilator is switched off – in VH only.

Terminate and leave the service by pressing the **START/STOP** key again.
(The ventilator speed cannot be changed.)

4.1.8 SERVICE 07 – SAFETY THERMOSTAT SETTING

The safety thermostat serves to protect the cabinet, its surroundings and the processed material from any impermissible exceeding of the temperature (e.g. it prevents damage or destruction of material samples in case of the temperature regulator failure or unintended setting of a higher temperature than the allowed one for the given material).

Press the **START/STOP** key and open the service. Set your upper limiting temperature (in the range from 0 °C to +280 °C; the minimum difference from the regulated temperature is ± 5 °C) on the lower line of the display – positions 12, 13, 14 (XXX symbols on the display). Set the safety thermostat type on the position 16 (Y symbol on the display): Type 2 shall be used for SC – if the set temperature in the chamber is exceeded, the display shows Error 04 – “Safety Thermostat Activated”. The thermostat switches off the heaters. The safety thermostat indicator lights on and a sound alarm is switched on (the heaters do not work even though the heating indicators is lighting). The heating remains disconnected even after the temperature in the chamber drops below the safety thermostat limit. The safety thermostat indicator turns off; “Safety Thermostat Activated” remains displayed; sound alarm remains activated.
To renew the unit activity, you must reset the safety thermostat: by pressing the **START/STOP** key, you cancel the error message and the sound alarm. The safety thermostat is also reset after each pressing of **X/W** in Service 07.

Insert the SO chip card in the reader on the unit control panel and confirm the temperature and thermostat type setting by pressing the X/W key.

Terminate and leave the service by pressing the **START/STOP** key again.

Check of the safety thermostat function:
Set the limit temperature of 85 °C according to the procedure described in Service 07 Safety Thermostat Setting and confirm by the SO chip card. Set the temperature of 60 °C in P1 and start the programme. After the set temperature is reached, wait for about 10 minutes, stop the programme and enter the Service 07; change the limit temperature in Service 07 to 50 °C and confirm the setting by the SO chip card.

The unit will then react as described in Service 07 Safety Thermostat Setting: The display shows “Safety Thermostat Activated” etc.

4.1.9 SERVICE 48 – PRE-HEATING TEMPERATURE SETTING

This service is used if you want to pre-set a pre-heating temperature differing from the sterilization temperature.

Press **START/STOP** to open the service.

“Set Preheat T:N” will be shown on the bottom line of the display; use ▲ to switch to “Y”.

Terminate the service and close it again by means of **START/STOP** pressing.

The pre-heating temperature can be then pre-set in the program setting (pre-heating phase segment).

If you switch from the different temperature (“Y”) to the equal temperature (“N”), the original different temperature will be displayed in the program and the pre-heating temperature equal to the sterilization temperature will be displayed only after the start of the program as such.

4.1.10 SERVICE 58 - DOOR BLOCKING

This service is available only in models equipped with the door blocking function.

One-door model:

Press **START/STOP** and open the service. Select one of the following possibilities by means of ▲:

1. Inactive – the door is unblocked permanently
2. Manual – the door can be blocked and unblocked by means of ▲ and ►
3. Automatic – the door is blocked automatically after a pre-set period of time elapses after the door closing.

The time can be set within the range from 2 to 9 seconds. Unblock the door by pressing ◄ and ► buttons for 2 seconds.

You can select “C” on the last display position. In such case, the door can be unblocked only after inserting the SO card.

	S	e	r	v	i	c	e		5	8				
A	u	t	o	m	.	a	f	t	e	r		2	s		C

Two-door VENTICELL models:

After the service is started, the cursor is placed on the first left position; four statuses can be pre-set on the bottom line by means of ▲:

S	t	r	:	A	=	O	p	n		B	=	L	c	k	

This status defines the door blocking after the programme start by means of **START/STOP**.

S	t	p	:	A	=	O	p	n		B	=	L	c	k	

This status defines the door blocking after the programme interruption by means of **START/STOP**.

E	n	d	:	A	=	L	c	k		B	=	O	p	n	

This status defines the door blocking after the programme termination (the panels show “Konec Px” and “End”.

U	n	l	o	c	k		a	l	l		(	X	/	W	)

Press **X/W** to unblock both doors.

Use ◄ and ► to move the cursor between “A” = loading door, and “B” = unloading door.

Three values are defined for these options (the tables show the initial setting):

- „Opn“ – unblocked
- „Lck“ – blocked
- „Txyz“ – the door will be unblocked after the temperature in the chamber drops below “xyz”. “xyz” can be pre-set by means of ▲ in the range from 50 to 200 °C.

It is recommended to pre-set the same “xyz” value as in Service 06 (duration of the ventilator run after the programme termination).

Possible settings for individual states:

		A			B	
	Opn	Lck	Txyz	Opn	Lck	Txyz
Str	●	●	●		●	
Stp	●		●		●	
End		●		●		●

The device will be in “Stp” status only if the programme run is interrupted by means of **START/STOP**; however, this shall not be applied if an error status is cancelled by means of the said button. The door blocking will remain unchanged after the error status cancellation.

See more in the Chapter Optional Accessories.

4.1.11 SERVICE 62 – SOUNDS SETTING

Sound reaction setting for the following activities (1 switched on; 0 switched off; switching by means of the ▲ key):
After switching the unit on
Unit error
Operator’s error
Key pressing
Start of programme
End of programme
Door opened.

4.1.12 SERVICE 63 – BATCHES COUNTER

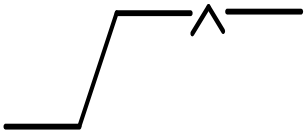
This function may only be displayed. It is incremented immediately after a programme starts running.

4.1.13 SERVICE 09 – SERVICE MODE CANCELLATION

Cancel the service mode by pressing the **START/STOP** key. Then you can modify the programmes freely and switch them on.

4.2 STERILIZATION PROGRAMMES P1, P2, AND P3 WITH A PRE-HEATING PHASE

After the **ON/OFF** key is pressed, the programme segments graph is displayed.



If you select one of these programmes in the STERICELL unit, the first and second upper position of the display shows p1 or p2 or p3. If we insert the SO chip card, P1, P2, and P3 is displayed and the programme parameters can be changed. Pre-set values – see Chapter 4.2.4.

Pre-heating duration must be set before each sterilization according to the material and its amount in the batch.

This setting should be used to ensure even heating of the batch at the beginning of sterilization. The temperature equals to the sterilization temperature.

A different temperature can eventually be set in SERVICE 48.

The pre-heating period must be determined experimentally or from the operator's experience with different materials, their amount in the batch and method of packing (storing). Default setting is 0.

4.2.1 PROGRAMME SETTING

Move the cursor to the programme position by means of ◄► keys and switch to the programme P1 or P2 or P3.
Using ► key, move the cursor to the graph and check whether the first segment – delayed switching-on in the graph is activated (if not, change by means of ▲ key).

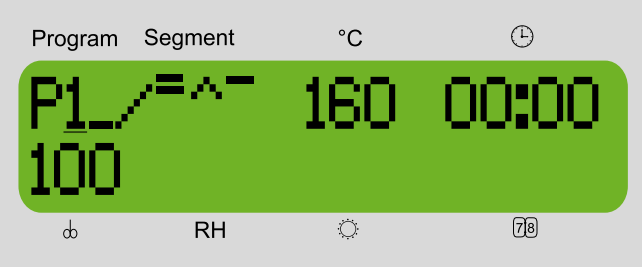
Set the delay time between 00 h 00 min and 9999 h in (you can switch from hh:mm format to hhhh format by setting 99 h, moving the cursor to hour units and pressing the ▲ key; 0100: is displayed; the time can then be set up to the maximum value of 9999 h). The delayed programme starts after the given period of time. The function ensures the unit start e.g. on weekends. Your material can thus be prepared for the first day of your return to work.

Move to the graph by means of ◄► keys and using ▲ key, switch to the second segment of the graph – pre-heating stage. Move the cursor to and set the process duration to a value between 00 h 00 min and 9999 h.

Move to the graph by means of ◄► keys and using ▲ key, switch to the third segment of the graph – sterilization exposure. Set the temperature in °C. The least temperature interval that can be set and displayed is 1 °C. Move the cursor to the position and set the process duration within the range from 00 h 00 min to 9999 h or ∞:∞ (the infinity can be set by setting 9999 h, moving the cursor to the figure 9 (ones) and pressing ▲ key). Default setting – see the table of hot air sterilization parameters in Chapter 4.2.4.

After the delayed switch-on period ends (max. 9999 h), the temperature rises to the preset value and preheating is started. The unit starts the sterilization exposure after a preset time (the temperature in the batch equals the preset sterilization temperature). The activity of the preset temperature can either be time-limited or not.

4.2.2 DISPLAY

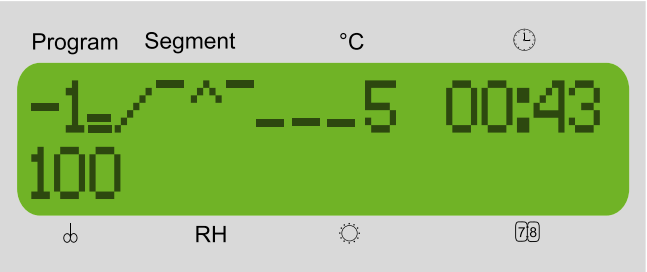


(Programme P1 is used as an example in the following text; other two programmes are similar.)

4.2.3 PROGRAMME START

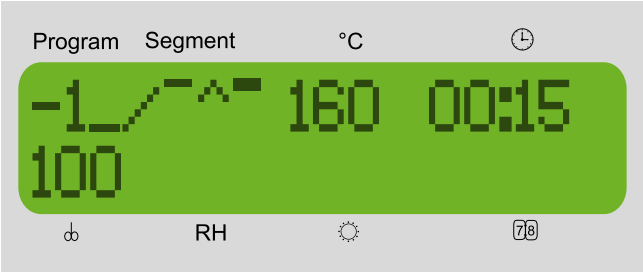
Press the **START/STOP** key. You will hear a sound alarm and the symbol of a propeller (the first sign) starts rotating clockwise.
See the following display:

4.2.3.1 P1 AND THE TIME-DELAYED SWITCH-ON IS ACTIVE



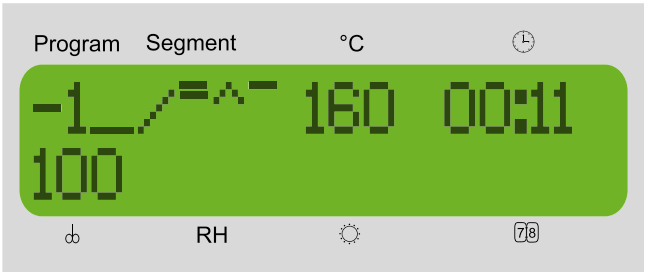
The first sign (rotating propeller symbol) = the programme is running.
The seventh to the tenth position - actual temperature in the chamber (°C).
The twelfth to the sixteenth position = programmed duration of delay; the time is counted towards zero in h:min.

4.2.3.2 P1 AND THE TEMPERATURE RISE



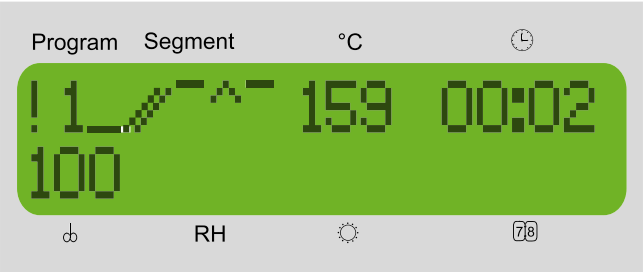
The first sign (rotating propeller symbol) = the programme is running
The seventh to the tenth position - actual temperature in the chamber (°C).
The twelfth to the sixteenth position = time lapsed from the start to the preset temperature achievement (h:min).

4.2.3.3 P1 AND PREHEATING



The first sign (rotating propeller symbol) = the programme is running.
The seventh to the tenth position - actual temperature in the chamber (°C).
The twelfth to the sixteenth position = time remaining to the preheating phase termination (h:min).

4.2.3.4 P1 AND STERILIZATION EXPOSURE



The first sign (rotating propeller symbol) = the programme is running.
The seventh to the tenth position - actual temperature in the chamber (°C).
The twelfth to the sixteenth position = time remaining to the sterilization exposure end (h:min) if the process is limited by time. If the process duration is unlimited, the lapsed time is displayed.

4.2.4 STERILIZATION PROGRAMME SETTING AND RUN

If during the delayed switch-on phase and rise to the sterilization temperature the door or the air flap is opened, the display shows the following message at the bottom: “Flap/door open” and the unit continues running without its activity interruption. The error is signalled acoustically as well (if the sound is on – see Chapter 4.1.10). The acoustic signalling can be cancelled by pressing “◄ / ▲ / ►” keys. After the air flap is closed, the acoustic signalling is reactivated; i.e. next opening will be signalled acoustically again. The acoustic signalling is also reactivated by passing to the next stage, i.e. after the delayed start termination, the preset temperature achievement, or the sterilization phase start.
After the preset sterilization temperature is reached, counting of the exposure time starts. If the door or the air flap is opened in this phase, the display shows “Flap/door open”. If you do not close the flap or the door, the unit switches off after the exposure period terminates and the display shows “Flap/door open”.
If you close the flap or the door during the exposure phase, the exposure (or the temperature rise according to the actual temperature in the chamber) restarts from the beginning.

If the temperature in the unit drops below the preset one during this phase,
a) and the drop is caused by the power supply failure, a new cycle starts after the power supply renewal from the beginning of the temperature rise;

b) and the drop has another cause, the display shows Error 02.

The default setting of sterilization parameters corresponds to the hot-air sterilization parameters:

Temperature [°C]	Sterilization exposure [min]
160	60
170	30
180	20

Note:

a) As STERICELL units are intended for sterilization purposes, the temperature deviation in the sterilization space (definition see the Chapter Work Space) ranges from -1 °C to + 5 °C within the sterilization temperatures range in accordance.
The programme ensures a steady state temperature in the centre of the chamber, corresponding to the medium of the given range, i.e. the set temperature increased by 2 °C; this temperature is showed on the display. If Service 48 is activated and the temperature drops below the given limit, the display shows Error 02; if the temperature is exceeded, the display shows Error 03.

b) Stericell devices with the option of overpressure generation in the chamber are intended for hot air sterilization. The temperature deviation in the sterilization space of the device ranges from 0 °C to +10 °C from the pre-set value.
The program ensures that, in a stabilized state, the temperature in each point of the chamber exceeds or equals the pre-set temperature.
The display shows the pre-set temperature plus 2 °C.
If Service 48 is activated and the temperature drops below the given limit, the display shows Error 02; if the temperature exceeds the given limit, the display shows Error 03.

c) For sterilization of a larger number of small packed items, you can order special holder of such items.

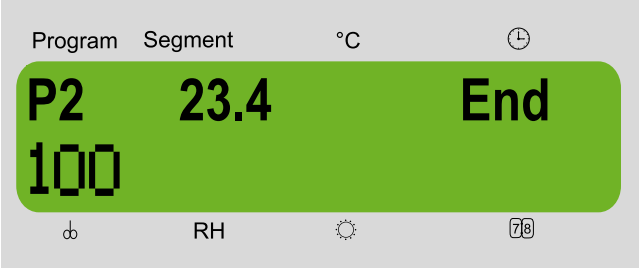
d) In special cases, the sterilization cycle can be started after reaching the required temperature on an independent flexible sensor PT2 placed by the user in a way enabling the measurement of the sterilization material temperature. The required presetting of the cabinet is done by the service technician.

e) In STERICELL, the ventilator speed cannot be adjusted; it is always set to the maximum (100 %).

4.2.5 INFORMATION ABOUT THE PRESET PARAMETERS DURING THE UNIT OPERATION

Press the **X/W** key and all information about the preset parameters are displayed at once. If the parameters are to be changed, all of them can be reset in all programmes including the actually active one.

4.2.6 INDICATION OF THE PROGRAMME END



After the programme ends, the display shows the number of the programme, temperature in tenths of °C and the text “End”.
The programme end indication (and the temperature in the chamber) disappears after any button pressing on the panel; the temperature cannot be then displayed in any way (only by means of a new programme starting).

4.2.7 P1, P2, P3 PROGRAMME STOP

Press the key **START/STOP** again.

4.3 KEYBOARD BLOCKING

This function is active only if this parameter has been activated in the service setting of the unit type; otherwise it is not functional.

- It serves to prevent any unintentional or unauthorized unit handling.
- After blocking (concurrent press of the **X/W**, ◄, ► keys), the keyboard does not react to any key strokes.
- Unblock the keyboard by pressing the same combination of keys.

4.4 ERROR MESSAGES

Error messages are displayed on the screen and have the following meanings:

Error 00	PT 1 (regulatory sensor) Call the service.
Error 01	PT 2 (flexible sensor a) Call the service.
Error 02	Temperature is below the preset lower limit. Call the service.

Error 03	Temperature above the preset upper limit Call the service.
Error 04	Protective thermostat is activated; heating is disconnected. See service 07 in the Instructions for Use.
Error 05	Protective thermostat setting. See service 07 in the Instructions for Use. This error may be caused by starting a programme whose preset temperature is out of the preset protective thermostat range, or by a HW breakdown.
Error 10	Controlling programme. Call the service.
Error 11	Communication. Call the service.
Error 12	PT 3 (flexible sensor b) Call the service.
Error 19	PT 4 (flexible sensor c) Call the service.
Error 20 *)	Door cannot be blocked. See service 58 and chapter 4.1.9 in the Instructions for Use.
Error 21 *)	Door cannot be unblocked See service 58 and chapter 4.1.9 in the Instructions for Use.
Error 27	PT 5 (flexible sensor d) Call the service.
Error 28	Great temperature difference between the regulatory sensor and protective thermostat. Call the service.

*)..... This is a soft error

**)..... Error type may be set by the user.

4.5 PRINTING THE PROTOCOL

DPT 6333 printer is recommended for records printing. Other types can be used as well, such as CITIZEN, model iDP 3110-24 RF-A. Printing into a PC application (Printer Archiv) is allowed as well.

By setting the printer interval you give the time intervals of printing actual values of temperature in the chamber. Length of this interval is displayed in the head of the protocol.

Printer interval can be set - see paragraph Basic Setting, point Service 04.

1. Connect the printer to the device by means of a cable with a serial connector (RS-232C); use the printer socket (on the rear side of the extension piece/device). Then connect the other end of the cable to the connector in the rear part of the printer. Connect the printer to the electric power mains by means of an adapter. Some types require a switch on the right side of the printer to be switched on. The POWER and SEL indicators light up. The printer is in the ON-LINE mode. Paper is fed by pressing the LF button (in the OFF-LINE mode only, i.e. after the SEL button pressing – the SEL indicator turns off. To renew the ON-LINE mode, the SEL button must be pressed – the SEL indicator lights up). The printer can print in the ON-LINE mode only!
2. Follow Service 04 – Printing Interval Setting and set the required interval either up or down.
   There is a head printed by the printer, the head comprises: type of unit, set temperature, eventually set ramp, number of cycles, ventilator rate, RH, light and the selected printing interval. Below the head following values are printed:
   time since the start of the program, real temperature in the chamber (below eventually temperature on the flexible sensor), RH.

A new head is printed if:
- the cooling incubator is started
- some parameter has been changed

3. You can stop the printing by setting the printing interval to Printer off.
4. In case of a mains fall-out and restoring the supply again there is → Mains fall-out printed. The printing intervals start to be counted since the moment of restoring the current supply.
5. In case of fall-out of the printer or switching the printer off there is no report printed after the switching on or restoring the supply.

DPT-6333-V24 does not require any microswitch setting by the user.

Setting the DIP microswitches of the printer CITIZEN iDP 3110: the second DIP microswitch from the left is in the upper position, the other three ones are in the lower position OFF.
Setting the DIP microswitches of the printer CITIZEN CBM 910: OFF / ON / OFF / ON / OFF / OFF / ON / OFF (from the left to the right).
Setting the DIP microswitches of the printer CITIZEN CBM910 II: OFF/ON/OFF/OFF/OFF/ OFF/ON/OFF (from the left to the right).
After any change of setting, the printer must be switched off and on either by the switch, or by disconnecting from the power supply.
A different type of the printer must be adjusted with the help of the printer´s manual and the data on the interface RS232C shown on the case.

4.6 AIR VALVES - ADJUSTMENT AND FUNCTION

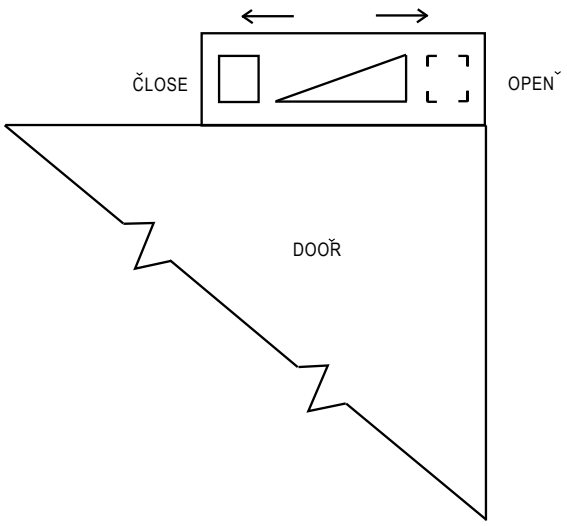
Function description:
The air valves are intended for ventilation of the chamber space of the unit, e.g. when drying wet materials.

Air flap adjustment:
Adjust the air flap when installing the unit. The control lever of the air flaps is set to the position “Closed” and the flap in the exhaust hole on the rear wall of the unit is set manually to close fully the ventilation hole.
Hold the shaft of the flap with pliers to prevent turning over.

Note:
In addition to the exhaust valves, to adjust the sucking air flap as well.

Flaps control:
If wet material is put in the units for drying before tempering (sterilization), the flaps must be set to the “Open“ position enabling the vapours to leave the chamber during drying. After finishing the drying put the air valves in the position closed.

Note:
If the units are operated with flaps open (and not just drying any wet material), power consumption is increased unnecessarily and, in addition to it, the required temperatures may not be reached in the chamber.



4.7 EXCHANGING THE DOOR SEALING AND ADJUSTING THE DOOR

Remove the sealing completely, start in the middle lower part.

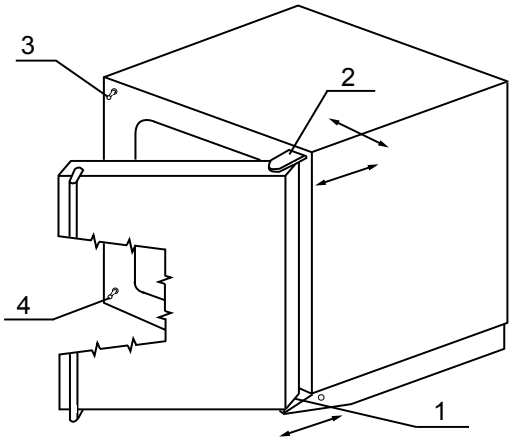
Fix the new sealing on the edge of the chamber, start in the middle lower part. Squeeze the sealing between the chamber and the outer cover.

To check up the tightness place a sheet of paper between the door and the chamber when closing the door. Pull it out slowly; you should feel a relatively strong resistance.

The door is adjustable at four points:
– in the left upper part by means of bolts and nuts – sketch position **3**
– lin the left lower part by means of bolts and nuts – sketch position **4**
– in the right upper part by means of internal hexagon screw – sketch position **2**
– in the right lower part after loosening the screw with internal hexagon adjusting in front-back direction of the door hinge is possible – sketch position **1**.

In the apparatus of the volume of 22 there is only one adjustable screw in the side of the door locking device.

Adjust the door so that the whole perimeter of the rubber sealing of the chamber is pressed to the inner metal sheet of the door. Check the sealing by inserting a sheet of paper between the sealing and the inner metal sheet before closing the door fully. After the door is closed, the sheet of paper can be pulled out against a small resistance.



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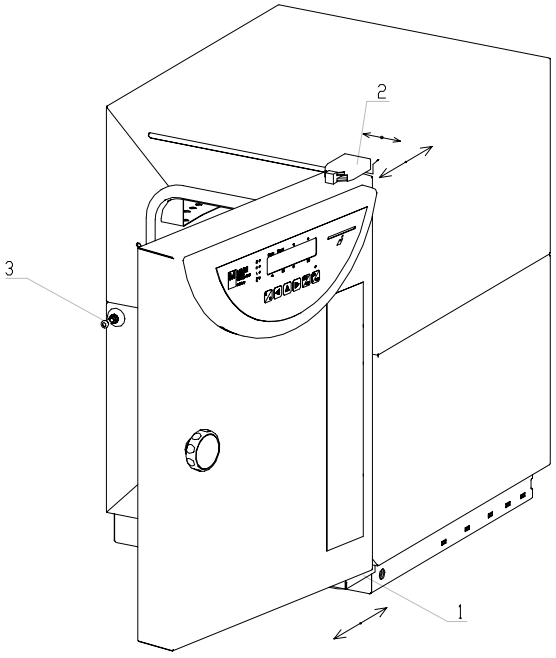


STERICELL 22

5 PARAMETERS OF THE UNIT

STERICELL (SC)							
Technical data **Interior space** - stainless steel DIN 1.4301	volume	approx. liters	22	55	111	222	
	width	mm	240	400	540	540	
	depth	mm	320	390	390	540	
	height	approx. mm	295	350	530	760	
Tray	racks distance of the wiring standard equipment	max. No mm pcs. included	4 60 2	4 70 2	7 70 2	10 70 2	
Maximal load	screens steel sheet racks in total	kg/screen kg/rack kg/case	10 10 25	20 20 50	20 20 50	30 30 70	
Bearing plate	width x depth	mm	185x265	380x335	520x335	520x485	
Door		pc.	1	1	1	1	
External dimensions (including door and handle)	width depth height (incl. feet N, and rolls K) Ø of the air branch outer/inner	mm mm mm mm	406 560 604N 52/49	620 640 680N 52/49	760 640 860N 52/49	760 790 1090N 52/49	
Package dimensions (three layers carton) - dimensions	width depth height (including palette)	mm mm mm	465 665 655	700 730 880	830 730 1050	830 860 1280	
Weight	net gross	approx. kg approx. kg	31 36	55 66	75 87	100 116	
Power supply - mains 50/60 Hz	power input [stand by]	W	5	5	5	5	
	max. power input	*kW*	0,96	1,3	1,9	1,9	
	current voltage***)	A *V*	4,2 230	5,6 230	8,3 230	5,2 400/3NPE	
	current voltage***)	A *V*	8,4 115	11,3 115	16,6 115	16,6 115	
Temperature data Working temperature (beginning of the regulation)	from 10 °C above ambient temperature up to do °C		250	250	250	250	
Temperature deviations according to DIN 12 880 **)	space deviation time deviation	*°C* *°C*	6 4	6 4	6 4	6 4	
Temperature deviations according to DIN 12 880, from sterilizing temperature 160 °C up to 180 °C **)		*°C*	-1/+5	-1/+5	-1/+5	-1/+5	
Maximum deviation of real temperature for a device with the chamber overpressure option		*°C*	-0/+10	-0/+10	-0/+10	-0/+10	
Temperature rise time to 250 °C with closed air flap and a the voltage of 230 V ± 0 V		approx. min.	28	49	53	70	
Heat emission at 250 °C		approx. W	350	590	760	990	
Air exchange rate at 150 °C		approx. per hour	45	45	49	24	

Note:
All technical data are related to ambient temperature 22 °C and ± 10 % voltage swing (if not otherwise specified).
For other parameters see section 5.1 Electric Connections.
*) Approx. 50 % of the tray area can be filled in a way a uniform air circulation is enabled inside the chamber.
**) Valid for the useful space defined in Chapter 2.3 if the air flap and door is closed. Two-door version – see Chapter 11.8
***) The mains voltage is specified on the unit type label.

	222/2	404	404/2
	540	540	540
	540	540	540
	760	1410	1410
	10 70 2	19 70 2	19 70 2
	30 30 70	30 30 100	30 30 100
	520x485	520x485	520x485
	2	1	2
	760 806 1110N 52/49	760 790 1910K 52/49	760 806 1910K 52/49
	830 860 1280	830 860 2070	830 860 2070
	105 121	150 175	160 185
	5	5	5
	3,7	3,7	5,5
	5,2 400/3NPE	5,2 400/3NPE	7,9 400/3NPE
	18,0 115/3PE	18,0 115/3PE	27,2 115/3PE
	250	250	250
	6 4	6 4	6 4
	-1/+5	-1/+5	-1/+5
	-0/+10	-0/+10	-0/+10
	33	58	43
	990	1940	1940
	24	18	18

5.1 ELECTRIC CONNECTIONS

Basic data for connection:	
Mains connection:	**230 V 50 (60) Hz** **400 V 50 (60) Hz, 3NPE** 115 V 60 Hz; 115 V 60 Hz; 3PE
(standard types are marked with bold face)	
Supply voltage fluctuation: ±10 %	
Class of protection against dangerous contact	I
Outer circuits separation	
– double insulation	
The mains supply for the three-phase units must be ensured by a switch or circuit breaker which serves for disconnection. Such a switch or circuit breaker must be: – A component part of the building installation; – Placed in an immediate vicinity of the unit and accessible easily by the operator; – Labelled as the device disconnecting element; – Rated correctly and must comply with the requirements of the standards IEC 60947-1 and IEC 60947-3.	
Protection according to EN 60529:	IP 20
Overvoltage class according to (IEC 664 - EN 61010):	
– II in case of pollution degree 2	
Used fuses:	according to corresponding diagrams in the Service Instructions
Length of the supply cable:	3 m
Ambient conditions:	
– ambient temperature:	+5 °C to +40 °C
– max. relative humidity:	80 % at 31 °C
– maximal altitude:	3000 m

6 CLEANING AND DECONTAMINATION OF THE UNIT

Clean the unit while cold and when the power supply cord is disconnected from the mains. Clean the interior walls of the chamber as well as the exterior of the unit with water and detergent, or possibly with suitable chemicals. Abrasive cleaning agents may scratch the metal sheets. If you want to clean the outer jacket of the chamber, take the inner walls of the chamber out as follows:

Shift the upper wall of the chamber out of the unit, take out the sidewalls, the bottom and the rear wall.

In a double door (pass through) model, the upper wall is composed of two halves. Each of them must be slid to one side of the device. No rear wall is used in these models.

Put the unit together in a reverse sequence after it has been cleaned, be careful and slide in the bottom and the sidewalls as far as behind the four projections in the front part of the chamber. In case some contaminated material has escaped into the chamber the user is responsible for proper decontamination of all contaminated surfaces with suitable and approved disinfecting agent.

Before using some other cleaning or decontamination method different from our recommendation, it is suitable for the user to be informed by with the producer whether the intended method cannot cause damage to the device.

Cabinet of 22-litre volume:
Remove the screws in the rear part of the chamber ceiling and bottom. After the screws are removed, swing the rear wall away.
When you perform the assembly, you insert the front bend of the bottom under the holder of the heating radiator and lock the bottom with a screw. When you perform the assembly of the ceiling you put the back part on the sensor holder, put the front bend of the ceiling on the ceiling holder and lock with a screw.

7 MAINTENANCE

No special maintenance is necessary. In case of any troubles, please, call the service.

The following actions shall be performed during common operation:
- Control and/replacement of the door sealing – see Chapter 4.7
- Control of the door setting - see Chapter 4.7
- Control of the fan function - see Chapter 2.2
- Control of the safety thermostat function - see Chapters 2.2 and 4.1.8
- Control of the door and flap microswitches function - see Chapter 4.2.4
- Checking of the parameters functionality
- Control of temperature by more sensors in places of interest of the useful space of the inner chamber [the temperature at all places must be (T_{SET}-1)]
- Sterilization test in places of interest of the useful space of the inner chamber by means of chemical indicators of sterilization exposure
- Replacement of HEPA filter approximately once in a year if such filter is used in the unit

Activities provided by a service technician:
- Calibration of PT 100 – see the Service Instructions
- Control of temperature offsets and/or their correction – see the Service Instructions.

Activities required for meeting the local valid regulations.

Inspection of electric components:
The cases of thermal technique are destined for a basic/normal environment, the manufacturer recommends the inspection period of 1 year, if not determined by local regulations otherwise.

Inspection operations:
Inspection of the electrical installation, particularly of the electric power supply, of connecting terminals and a protective terminal.
Check the integrity of the conductor insulation (for example, due to wearing through, burning etc.) and the firm connection in the terminals. The resistance of the protective connection is < 0.1 Ohm, the resistance of the supply is not included. There is measured the leakage current.

If the case is placed in a different environment, the inspection must be performed in accordance with the local standards.
The service inspection is the matter of agreement between the client and the service organization.

The authorized person (i.e. a person, who on the basis of a professional education, theoretical and practical knowledge, documented sufficient knowledge in relation to the problems of heat air sterilizers and has a certificate for service operations for STERICELL apparatuses, which is issued by the manufacturing plant performs the record into the Operating book of a sanitary instrument:
- After installing the apparatus to the extent specified by the Operating book of a sanitary instrument,
- In six month inspections
- In case of changes in the apparatus
- In case of defects of the apparatus.

8 GUARANTEE, SERVICE AND OPERATING LIFE OF THE DEVICE

The guarantee shall apply to the defects of material or workmanship under the conditions that:

- The product was installed and used in accordance with the Instructions for use;
- The defect was not caused by incorrect maintenance, unqualified intervention into the device, or damage by external influences.

The guarantee shall not be applied to the natural wear and tear of the material and to the consumables, e.g. the door seal, materials for recording equipment, accumulators, etc.).

If a defect occurs, claim your right for a guarantee repair at the nearest service centre of MMM. Specify the name and type of the device, its production number and manifestation of the defect (error message, printer output).
If you meet the guarantee conditions, the service centre will, in its discretion, either repair the device or replace the defective part free of charge.
MMM guarantees that all technical documents and spare parts will be available for the period of 10 years from the introduction of the device to the market and a safe and functional operation of the device will thus be ensured for the said period.
After termination of the said period, MMM will be able to ensure a safe and functional operation of the device only upon a further contractual agreement.
In accordance with the EU Directive no. 85/374/EEC, MMM shall be responsible for any potential damage caused by a defect of the device for the period of 10 years from the introduction of the device to the market.

9 TRANSPORT AND STORAGE

A competent person will prepare the unit for transport. The unit shall be transported and stored in its original package. If you send the device back (for repair or change in case of claim), use the original package. Otherwise you take over the responsibility for possible damage during the transport and the producer will reclaim compensation for possible additional repairs. Device can be stored in the ambient temperatures from 0 °C to 40 °C.

10 THE WAY OF LIQUIDATION OF PACKAGE AND DISCARDED UNIT

Palette – liquidation in an incineration plant;
Cardboard – recyclable waste;
Unit put out of operation – such unit shall be liquidated by a company authorized to waste disposal which provides for liquidation in accordance with the environmental legal regulations; the unit does not contain any component part dangerous to the living environment.

For member states of the European Union:

Product, which the user stops using and which becomes for the user a useless and which is

marked with a label ▬.
The user shuts down it and notifies, in case of the Czech Republic, the manufacturer, in case of other member states of EU, the dealer.
The mentioned product is not possible to be disposed to municipal refuse and it is a subject to a mode in accordance with local regulations on disposal of electric and electronic equipment, which conform to WEEE (Waste Electric and Electronic Equipment) Directive as amended.

For the countries outside of the European Union:

The mentioned-above described symbol ▬
For proper disposal of electric and electronic equipment, please, ask for detailed information at your authorities or at the dealer of the device.

11 OPTIONAL EQUIPMENT

11.1 ACCESS PORTS OF DIAMETER 25, 50, 100 MM

The access ports are normally located approx. in the middle of the side (right or left) wall of the chamber. The exact position depends on the position of the heating elements. The access ports are metallic, closed with a special plastic plug from the outer side, which enables passing

through of wires etc. from the outer space to the chamber.

Recommendation: The used unit should be provided with an access port with corresponding dimensions, if user wishes to measure temperature inside the chamber by means of sensors, connected with an independent measuring device by means of wires; the user shall run the wires through the access port.

Cases of the volume of 22 are equipped only with bushings 25 and 50.

11.2 LOCKABLE DOOR

The lock is located on the upper part of door's surface near the closing mechanism.

11.3 LEFT DOOR VERSION

This is a symmetric mirror version, the door can be opened to the other side.

11.4 INDEPENDENT PT 100 SENSOR

The independent flexible sensor is used for measurement of the material temperature directly in the chamber.
Up to four independent flexible sensors can be used. The data about the temperature on these sensors (PT2, PT3, PT4, PT5) are displayed intermittently with the time data on the time data position.
If printed, the record has the following format (the number of lines depends on the number of connected sensors):
First line – begins with figure 1 – displays the temperature on the regulator's sensor (PT1);
Second line - begins with figure 2 - displays the temperature on the sensor PT2;
Third line - begins with figure 3 - displays the temperature on the sensor PT3;
Fourth line - begins with figure 4 - displays the temperature on the sensor PT4;
Fifth line - begins with figure 5 - displays the temperature on the sensor PT5.
If PT2 is connected wrongly to the regulator, the display shows Error 01.
If PT3 is connected wrongly to the regulator, the display shows Error 12.
If PT4 is connected wrongly to the regulator, the display shows Error 19.
If PT5 is connected wrongly to the regulator, the display shows Error 27.

10.5 SUPPORTIVE SW FOR PC

10.5.1 RECORDING SW - WARMCOMM - FOR A PC UNDER WINDOWS

The program WarmComm is designed to record the temperature course in the ovens/incubators. Data obtained during the regulation are displayed in a diagram (with time on the horizontal axis and measured data on the vertical axis). The program enables to follow the regulation on-line, to store the regulation course to a file on a disc and to view the already stored files, to send e-mails in case of not receiving data from the cabinet and to send reports of excessive values being reached within the specified time interval.
The instructions for the programme use are supplied with the installation programme.
Hardware requirements: Common PC with an operational software Windows 2000, XP and higher. One free port RS 232 (COM) is required for each connected device. The maximum length of the connecting cable is 15 m.

10.5.2 RECORDING PRINTING SW - PRINTER ARCHIVE - FOR PC UNDER WINDOWS

The Printer Archive programme serves for text recording from the device print outlet. It serves as a direct substitution of a physical printer.
The data are recorded to a file on a PC disc and the programme offers more possibilities of the recorded data handling including archiving or printing on a table PC printer. Hardware requirements: Common PC with an operational software Windows 95 and higher. One free port RS 232 (COM) is required for each connected device. The maximum length of the connecting cable is 15 m. For more detailed information about HW, ask the seller.

11.6 HEPA FILTER

HEPA filter is either in a normal version – see the item **3.2 STERICELL – placing of the HEPA filter** or in the overpressure version.

The overpressure HEPA filter is equipped with the external fan, which forces the surrounding air through the HEPA filter into the chamber and thus it ensures the overpressure in the chamber as opposed to the surrounding environment by ca. 20 Pa. In case of HEPA filter operation, the thermal homogeneity parameters inside the chamber can be worsened.

11.7 POTENTIAL - FREE CONTACT FOR ALARM REPORTS

Is lead to the connector in the rear foot, the voltage up to 24 V/ 1A can be connected to it Serves for remote alarm (in Anglo-Saxon countries marked as BMS relay Building Management System relay) – i.e. the information on the failure is transmitted by a long-distance line, interrupted by the built-in relay of a potential-free contact, into a room that is distant from the place the temperature cabinet is installed in. The relay switches on in all failure conditions reported on the display.

11.8 TWO-DOOR PASSING THROUGH VERSION

It is available only for SC 222 and 404. It makes possible to load the material in one space and its unload after thermal treatment in another space (for example, loading in “non-sterile” – “dirty” – space and unloading in sterile – “clean” – space).

Through version of STERICELL is equipped with super standard elements as follows:

- as a optionally - mechanical lock of the locking device of both doors,
- as a standard - micro switches of the locking devices of both doors – a display on the panels of both doors reports about the opening of whichever doors during the sterilization with the message “open”.
- as a standard - LED chart on the panels of both doors informs about the active phase of the program.

This equipment helps to ensure a safe course of the sterilization.

In a 404 open-through STERICELL, a model with a transport and loading cart can be supplied.

Caution!

When using the passing through variant of SC (except for cleaning and maintenance) only one door can by opened at the moment. If the material still has not been sterilized, the door on the “clean” side must not be opened.

Otherwise there is a danger of the clean space contamination!

In case the rules of safe work are not followed, following nonstandard states can occur:

a) if you (unlock and) open the door during the sterilization on the “clean” side, on the display there appears the message „open“ – it means that you have caused the origin of the contamination risk of a “clean” workplace, after closing the door the sterilization cycle is repeated,

b) if you (unlock and) open the door during the sterilization on the “dirty” side, the display indicates „open“ – you have caused the origin of the contamination risk of the sterilized material, after closing the door the sterilization cycle is repeated.

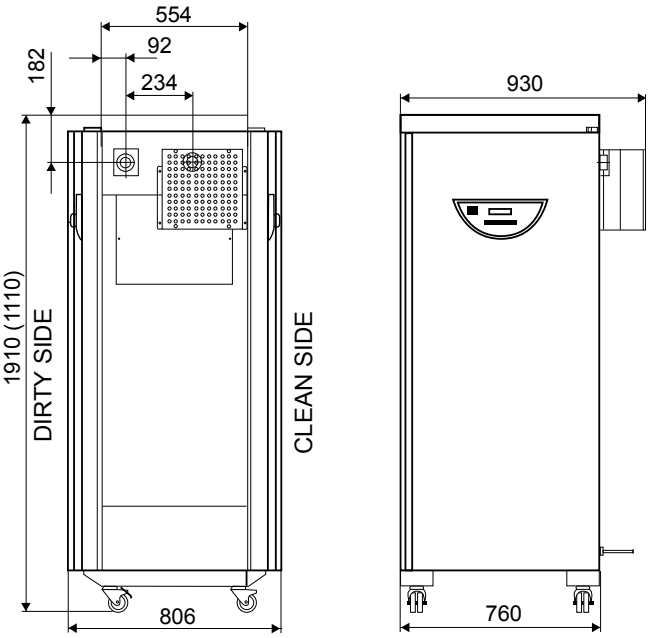
11.8.1 STERICELL 222/2 - INSTALLATION DATA

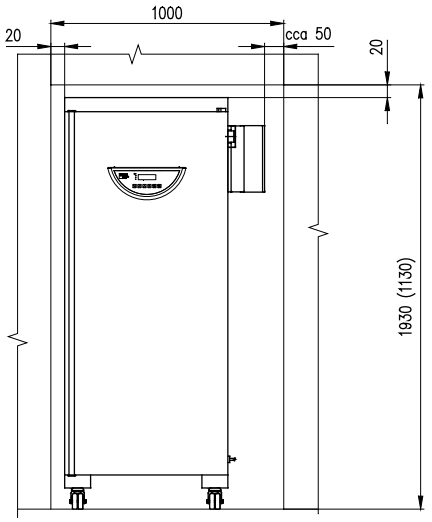
Basic dimensional data are the same as In case of the following SC 404 / 2D – with the exception of the height – see the table of parameters. The case can be placed on the floor or on an individual customer´s support.

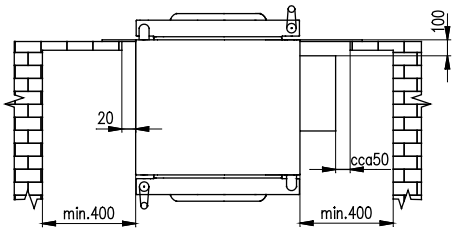
11.8.2 STERICELL 404/2 - INSTALLATION DATA

DIMENSIONS OF STERICELL 404 - PASSING THROUGH
(proportions in mm)

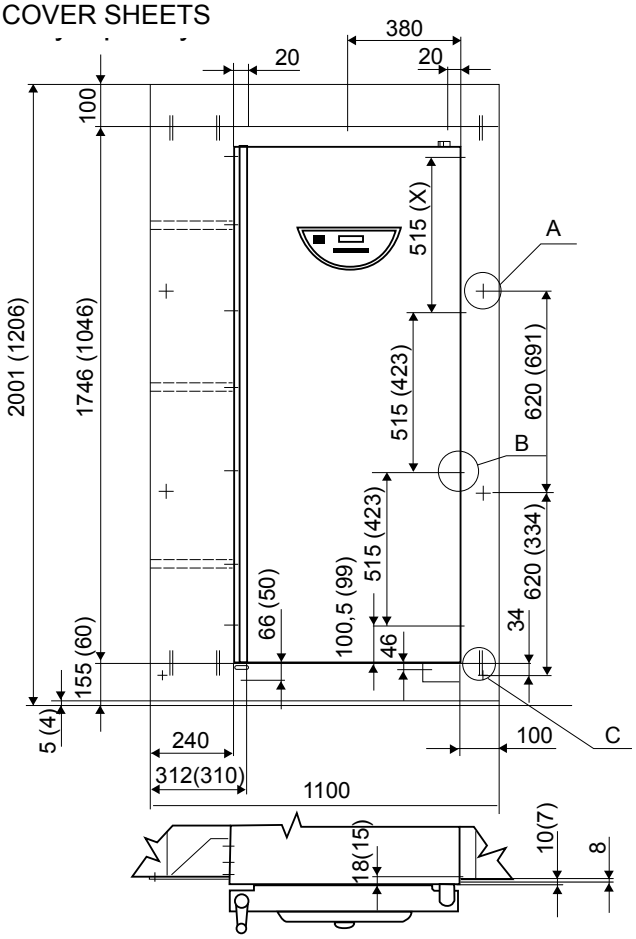
THE DIFFERENT DATA IN BRACKETS ARE VALID FOR STERICELL 222 INTERLEAVING







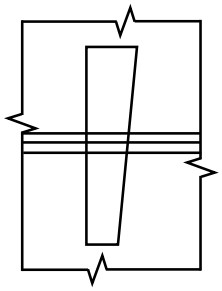
COVER SHEETS



Detail A
6x (5x) screw ∅ 4x40 with countersink head with cross groove for fixing to a wall insert dowels with a size of 8 to the wall.

Detail B
19x (15x) screw for a metal sheet ∅ 3,9x9 with a half-round head and a cross groove necessary to screw with cover sheets with holes of ∅ 3.2

Detail C
By beating the pins to the rectangular holes of the sheet borders secure them together.



11.9 DEVICES WITH THE DOOR BLOCKING FUNCTION

In this model, electrically controlled mechanism is used to prevent unwanted door opening. The mechanism remains in its position even after the device is switched off.

ATTENTION!

Blocked door may not be opened forcibly. It may damage the blocking system mechanically. If you need to open the door in case of emergency (e.g. power supply failure), follow the chapter Emergency Door Opening.

11.9.1 ONE-DOOR MODELS

Two ways of blocking can be selected in SERVICE 58:

1. Manual - The door is blocked/unblocked by pressing ◄ and ► buttons for 2 seconds.
   If you try to block an open door, you are warned of an error by a prolonged beep.
2. Automatic - Close the door. It is blocked automatically after preset time elapsing. Unblock the door by pressing ◄ and ► buttons for 2 seconds. The door is blocked only when the programme is switched on. When you unblock the door, you have a preset period of time to open it. If you do not open it, the door will be reblocked after the preset time elapsing (2 to 9 s).

The blocked door is indicated on the display by the flashing character “#”.

The door unblocking can be conditioned by the SO card insertion.

11.9.2 TWO-DOOR DEVICES

The unloading side door is blocked during the sterilization cycle. This door is unblocked while the loading side door is blocked automatically after the program end (the text “End” is displayed). The blocking function can be modified in Service 58; the setting is valid for all programs.

After the sterilized material is unloaded and the door closed, the operator presses the button on the unloading side. Thus the unloading door is blocked and the loading door unblocked; the text “End” disappears. The button is not functional until the door is opened. A subsequent cycle can then be switched on by means of **START/STOP**.

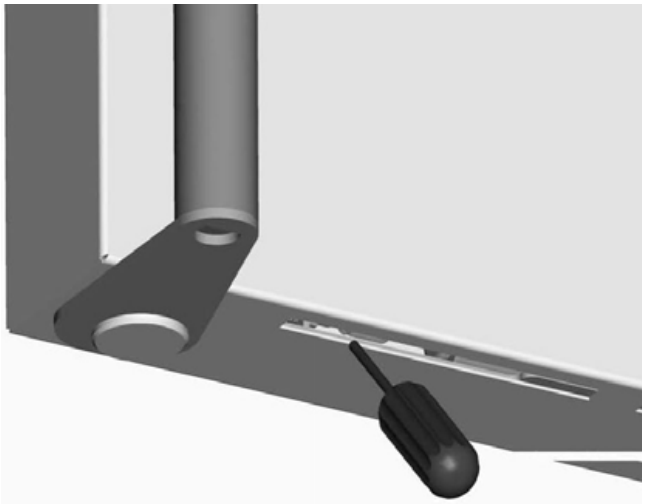
If the sterilization was performed with an opened flap or door and the display shows “Open”, the sterilization cycler must be restarted by means of **START/STOP.**

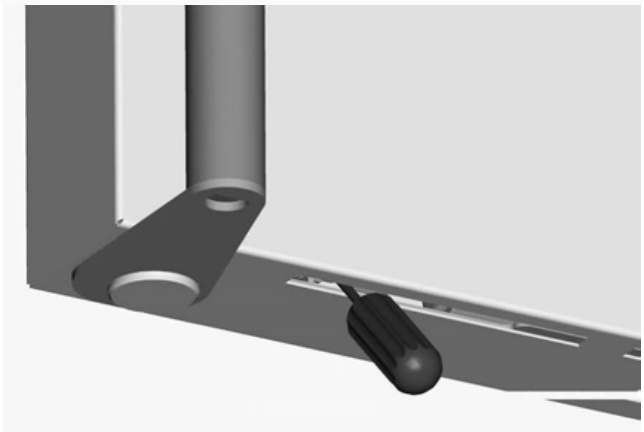
If the flap is opened in the “End” state:

1. If the device is equipped with a HEPA filter and at least one of the ventilators is running, the text “Flap opened” will be displayed on the loading side and an acoustic signaling is started. The unloading side will display (in turns) “Open” and the chamber temperature.
2. In other cases, the printer will print “Flap opened! Repeat sterilization!” and the unloading door will be blocked (the blocking will be switched to the “Stp” state). The unloading side will display the running text “Flap opened-repeat steril.” and the loading side will display “Non-sterile”. In this situation, no program can either be changed or started. Press the button on the unloading side panel; the text “Non sterile” will disappear and a new program run can be started.

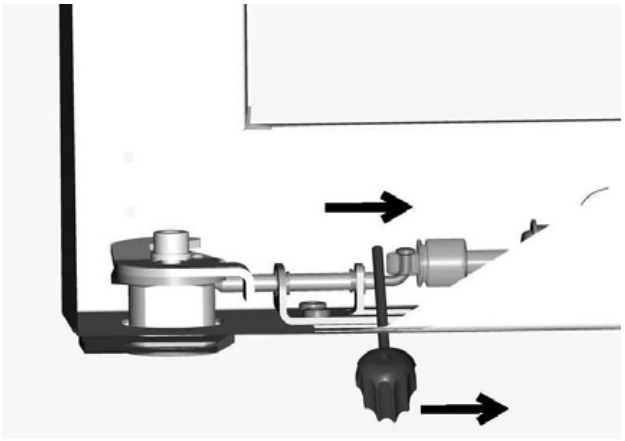
12 EMERGENCY DOOR OPENING

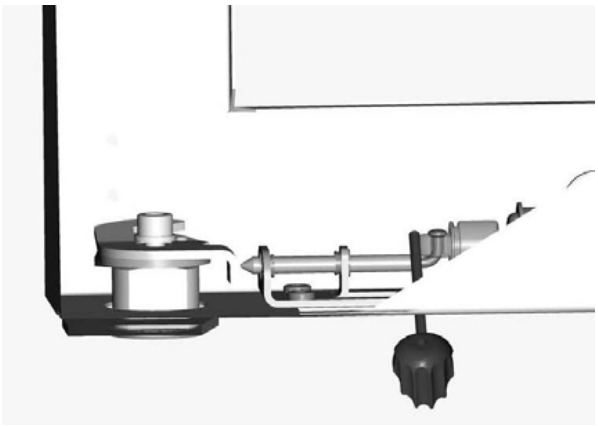
1. To insert a thin object (screwdriver, rod etc.) through the air hole of the door (in the bottom door surface) under the angle of ca 45 ° in the distance of ca 90 mm from the door edge.





2. To push in the arrow direction and thus to push away the blocking rod (10 -15 mm is enough). In case of standard model – of the right door in the arrow direction, in case of the non-standard model – of the left door – it would be reversely (always in the direction from handle to the door hinges).





3. To open the door by means of the door handle If it would be not possible to move away the blocking rod of the door – see above, then it would be necessary to unscrew the whole blocking mechanism underneath (4x M4 screws) and to push it away as a whole. After such intervention, the service work is necessary (backward blocking mechanism assembly).

EC-DECLARATION OF CONFORMITY
ES PROHLÁŠENÍ O SHODĚ

Date 2012-06-09	European Directive 93/43/EEC, Annex II Evropská směrnice 93/42/EEC, příloha II

Manufacturer / výrobce
BMT Medical Technology s.r.o.
Cejl 50
CZ 656 60 Brno
IČ: 46346996
Co. Reg. no.: C 58436, Regional Court of Brno / obch. rejstřík KS Brno, spis. zn. C 58436

declare on our own responsibility that product / prohlašujeme na vlastní odpovědnost, že výrobek

medical device / zdravotnický prostředek:	**hot-air sterilizer / horkovzdušný sterilizátor**
trade name / obchodní název:	**STERICELL**
type/typ:	**SCK-B2V**
model:	**SC 22, SC 55, SC 111, SC 222, SC 222-2, SC 404, SC 404-2**

Meets the provisions of the European Directive 93/42/EEC on medical device. An examination of the quality management system has been carried out following Annex II.3 of the directive by the Notified Body, Identification no. 0123, TÜV SÜD Product Service GmbH, Ridlerstrasse 65, D-80339 München.	Splňuje ustanovení evropské směrnice 93/42/EEC o zdravotnických prostředcích. Ověření systému managementu kvality bylo provedeno podle bodu 3 přílohy II směrnice notifikovanou osobou, číslo 0123, TÜV SÜD Product Service GmbH, Ridlerstrasse 65, D-80339 München.
The quality management systém also complies to EN ISO 9001 and EN ISO 13485.	Systém řízení jakosti je rovněž v souladu s EN ISO 9001 a EN ISO 13485.
EC-Certificate no.: **GI 11 03 31461 032, valid untill: 2015-01-31**	**EC-Certifikát č.:** **GI 11 03 31461 032, platné do: 2015-01-31**
This declaration is valid for all of the above products, that are marketed after the date of issue and is valid until changes in the facts contained therein.	Toto prohlášení je platné pro všechny výše uvedené výrobky, které jsou uvedené na trh po datu vydání a platí až do doby změn skutečností v něm obsažených.

Standards applied / použité normy:

EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements
EN 61010-2-040:2004	Safety requirement for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements Part 1: General requirements

Ing. Milan **Krajcar**
executive
jednatel

... excellence in medical and laboratory engineering

Manufactured in the EU

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