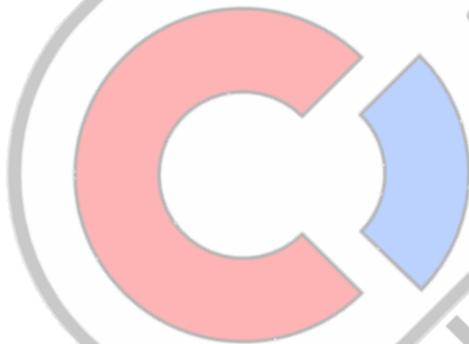


hauwo



Original operating instructions

for software version 4.02.xx



HENDERSON
BIOMEDICAL
www.henderson-biomedical.co.uk

1	INTRODUCTION	4
1.1	PREFACE	4
1.2	IMPORTANT NOTICE	4
1.3	LEGEND	5
1.4	SAFETY INSTRUCTIONS	6
1.5	CLEANING	7
1.6	CORRECT USE	8
2	COMMISSIONING	9
2.1	COMMISSIONING THE SEALING DEVICE	9
2.1.1	<i>Step 1 Inspection of the device</i>	<i>9</i>
2.1.2	<i>Step 2 Setting up the device</i>	<i>9</i>
2.1.3	<i>Step 3 Connecting the device</i>	<i>10</i>
2.1.4	<i>Step 4 Turning on the device</i>	<i>11</i>
2.1.5	<i>Step 5 Checking of the sealing parameter sensors</i>	<i>12</i>
2.1.6	<i>Step 6 Displays and functions of the main menu</i>	<i>13</i>
2.1.7	<i>Step 7 Change menu level 1 till 7 by "Swiping"</i>	<i>13</i>
2.1.8	<i>Step 8 The first sealing process</i>	<i>14</i>
2.1.9	<i>The individual levels of the device</i>	<i>15</i>
2.1.9.1	Level 1 General	15
2.1.9.2	Level 2 Printer	15
2.1.9.3	Level 3 Print Data	15
2.1.9.4	Level 4 Standby	16
2.1.9.5	Level 5 Monitoring	16
2.1.9.6	Level 6 Special Features	16
2.1.9.7	Level 7 System Configuration	16
2.2	THE SEALING SEAM TEST	17
2.2.1	<i>Locked machine due to failed Seal Check</i>	<i>18</i>
2.2.2	<i>Printing of the test parameters on a package</i>	<i>19</i>
2.2.3	<i>Printing of the test parameters on a label</i>	<i>19</i>
3	DATA INPUT	20
3.1	CREATING DATA FOR DIFFERENT LANGUAGES	20
3.2	THE ID-LIST	20
3.2.1	<i>The menu</i>	<i>20</i>
3.2.2	<i>Entry of user data/administrator rights</i>	<i>21</i>
3.2.3	<i>Removing administrator rights</i>	<i>22</i>
3.3	PACKAGING LISTS	22
	<i>Menu</i>	<i>22</i>
3.3.1	<i>The settings of a packaging list</i>	<i>23</i>
3.3.2	<i>The printer data of a packaging list</i>	<i>24</i>
3.3.3	<i>Printer data selection</i>	<i>25</i>
	1-5 OR 6-10 CAN BE SET IN THE SELECTION RANGES	25
3.3.4	<i>Example of creating a packaging list</i>	<i>25</i>
3.3.4.1	<i>Enter the package designation and determine an identification colour</i>	<i>26</i>
3.3.4.2	<i>Select the sealing temperature</i>	<i>26</i>
3.3.4.3	<i>The settings of the internal printer</i>	<i>27</i>
3.3.4.4	<i>Display the packaging list</i>	<i>29</i>
3.4	DATA LISTS	30
3.4.1	<i>The selection menu</i>	<i>30</i>
3.4.2	<i>The Processing menu</i>	<i>31</i>
4	DEVICE CONFIGURATION	32
4.1.1	Counter	32
4.1.1.1	Counter functions	32
4.1.2	Key lock	33
5	DATA RECORDING	34
5.1	DATAMATIC	34
5.1.1	<i>Activating DataMatic</i>	<i>34</i>
5.1.2	<i>Configuring DataMatic data</i>	<i>35</i>

5.1.3	Show the DataMatic data on the device display	35
5.1.3.1	The display menu.....	35
5.1.3.2	View the recordings on the USB stick.....	36
5.1.4	Show the DataMatic data on a PC.....	38
5.2	TRACELOG (LOGBOOK).....	39
5.2.1.1	The display menu.....	39
5.2.1.2	Interpretation of entries.....	39
5.3	DATA READOUT VIA ETHERNET.....	39
5.4	DATA DESIGNATOR (PREFIX) - SYMBOL OR TEXT.....	40
5.5	PRINT DATA AS A BARCODE.....	41
5.6	DIRECT CHANGE OF THE PROCESS PARAMETERS OF A SELECTED PACKAGING.....	42
5.6.1	Changing the sealing temperature.....	42
5.6.2	Changing the throughput speed	42
5.7	UDI MARKING.....	43
5.7.1	The Processing menu.....	43
5.8	EXTERNAL KEYBOARD FOR DATA ENTRY.....	44
5.9	DISPLAY.....	44
5.9.1	Standby.....	44
5.9.2	Counter status 0	44
5.9.3	Display of the set test interval.....	44
5.9.4	Maintenance indicator.....	45
5.9.5	RS 232 data interface active display	45
5.9.6	Display of password startup interlock	45
5.9.7	The display of control center.....	46
5.9.8	Display of operating data.....	47
6	SPECIAL FUNCTIONS.....	48
7	THE BARCODE SCANNER (1.490.029).....	50
7.1	COMMISSIONING THE BARCODE SCANNER.....	50
7.1.1	Step 1 Unpacking the barcode scanner.....	50
7.1.2	Step 2 Connecting the device.....	51
7.2	RECORDING DATA USING THE BARCODE SCANNER.....	52
7.2.1	Data of a created barcode list.....	52
7.2.2	General barcode data	52
7.2.2.1	Assignment of general barcode data	52
8	THE EXTERNAL PRINTER.....	53
9	SWITCH OFF THE DEVICE.....	54
10	TROUBLESHOOTING AND MAINTENANCE.....	55
10.1	TROUBLESHOOTING CHECKLIST.....	55
10.2	MAINTENANCE.....	56
10.3	SERVICE.....	56
10.4	SPARE PARTS SERVICE.....	56
10.5	REPLACING THE SEALING DEVICE INK RIBBON CASSETTE.....	58
11	TECHNICAL DATA.....	60
11.1	SPECIFICATIONS	60
12	DECLARATIONS OF CONFORMITY.....	61
12.1	CE DECLARATION OF CONFORMITY FOR SEALING DEVICE.....	61
12.2	DIN EN ISO 11607-2 / DIN 58953-7 DECLARATION OF CONFORMITY OF SEALING DEVICE	62
12.3	CE DECLARATION OF CONFORMITY FOR BARCODE SCANNER.....	63
12.4	CE DECLARATION OF CONFORMITY FOR LABEL PRINTER.....	64

1 Introduction

1.1 Preface

First of all we would like to thank you for purchasing this sealing device. In these instructions you will find information about using the device, servicing and care as well as process validation.

The sealing device is a microprocessor controlled rotary sealer with a printer for packaging sealable transparent pouches and reels (SBS = sterile barrier system).

The sealing device meets the requirements of DIN 58953-7, DIN EN ISO 11607-2 and the resulting DGSV (German Society for Sterile Supply) guideline for validating the sealing process.



Please read these operating instructions carefully before commissioning so that you are familiar with the capabilities of the device and you can make optimum use of its functions.



Always keep these instructions close to the device.

1.2 Important notice



In accordance with the intended use, the CE marking is displayed based on the following EU directives:

2006/42/EC, 2014/30/EU and 2011/65/EU.

Medical device directive 93/42/EEC is not applicable to sealing devices.

The limit values of IEC 60601-1 must not be applied in repeated electrical inspections.

The manufacturer accepts no liability whatsoever for damage caused by tests in accordance with standards not listed in the declaration of conformity.

Note

We are constantly improving our products, therefore we reserve the right to modify these operating instructions and the functions described in them.

These operating instructions apply to products from software version V4.02.00 onwards

hm 950 / NanoPak	Introduction	Chapter 1
------------------	--------------	-----------

1.3 Legend

	The exclamation mark in the triangle draws your attention to important notes in the operating instructions, which must absolutely be observed.
	This warning sign refers to measures that could result in danger to human health if they are not observed. It is compulsory to observe it.
	A hand symbol indicates important information.
	Select function
	Press the button
	Press and hold down the button
	Press the button several times
	Select data by swiping up or down

1.4 Safety instructions



Our products are in a flawless condition in terms of safety technology when they leave the plant.

To maintain this condition, the contents of these safety instructions as well as type plates, labelling and safety instructions attached to the device must be observed while handling the device (transport, storage, installation, commissioning, operation and maintenance).

This device is suitable for processing laminated films in the heat-sealing process. See also chapter 1.6 "Intended use".

Please check the packaging, and lodge a complaint for any damage with the carrier or parcel service immediately, before installing the device.

Before commissioning, ensure that the device does not show any evidence of damage. In case of doubt, contact the manufacturer or a service partner authorised by the manufacturer.

Do not operate the device if the power cable or the power plug is damaged. Do not use the device if it does not operate correctly or it is damaged in any way. If the mains cable or the device have been damaged, the device must be repaired by the manufacturer or by one of the manufacturer's authorised service partners.

The device must be connected using the mains cable included in the scope of delivery to a protective contact socket with a stable voltage. Operation on IT networks is not permitted.

Place the device on a stable base.

The device must not be installed or operated in potentially explosive areas.

If the sealing device is brought directly from a cold environment into a warm environment, condensation may form. Wait until temperature equalisation has taken place.

Repairs and the replacement of spare parts must be performed only by the manufacturer or by one of the manufacturer's authorised service partners.

Switch off the device when it is not in use, or remove the power plug from the socket.



Do not insert pointed or flat items into the import slot of the device. This can result in damage to the device and instruments.

Do not insert items into the louvres of the device. You might receive an electric shock or the device could be damaged.

Do not use the device if you have any doubts about its safety.

The device must not be installed or operated by persons under 16 years of age.

The device must not be operated unsupervised.

It is forbidden to operate the device under the influence of drugs or alcohol.



Keep hair, clothing and gloves away from moving parts.
Loose clothing, jewellery or long hair can be caught by moving parts.



The device contains valuable materials that can be recycled and reused.
The device should therefore be disposed of at a public disposal facility near you.
The device has been labelled in accordance with Directive 2012/19/EU (WEEE) on waste electrical and electronic equipment.
This directive governs the return and recycling of scrap equipment within the EU.

1.5 Cleaning

Before cleaning, disconnect the mains plug from the socket and disconnect the device from the power supply with the plug.

Clean the device only with a dry or damp soft cloth and a mild cleaning agent.

(E.g.: isopropanol, spirit, etc.)

Do not allow any water to find its way into the device.

Caution! Never wet clean the device!

hm 950 / NanoPak	Introduction	Chapter 1
------------------	--------------	-----------

1.6 Correct use

The device is intended only for commercial and industrial use, and must be used only for the intended purpose and with the following sealable materials.

SEALING MATERIALS

Sealable paper pouches in accordance with EN ISO 11607-1/EN 868-4	x
Sealable pouches and reels in accordance with EN ISO 11607-1/EN 868-5 of film and paper according EN 868-3	x
Sealable pouches and reels according ISO 11607/EN 868-5 of film and uncoated nonwoven materials of polyolefines according EN 868-9 ¹	x (approval and/or tests necessary)
Aluminium-laminate film	x (approval and/or tests necessary)
Sealable PA/PE on request	on request

NON - SEALABLE MATERIALS

Polyethylene films	Soft PVC films
Hard PVC films	Polyamide films
Polypropylene films	Coated HDPE

The correct sealing temperature for the packaging materials being used must be identified by means of test sealing's (DIN 58953-7).

The device output depends on the condition of the sealing material used.

¹Not applicable for sealable pouches and reels according EN ISO 11607-1/EN 868-5 of plastic and uncoated nonwoven materials of polyolefines according EN 868-10.

hm 950 / NanoPak	Commissioning	Chapter 2
------------------	---------------	-----------

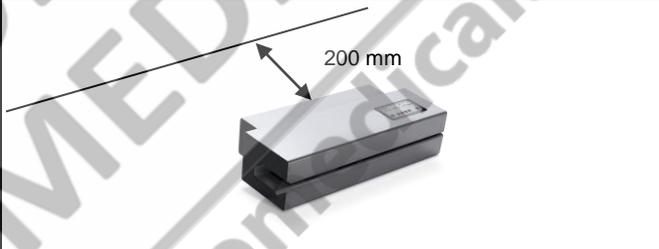
2 Commissioning

2.1 Commissioning the sealing device

2.1.1 Step 1 Inspection of the device

<p>After opening the packaging and the air-conditioning bag, check the device and its accessories for damage and completeness.</p>	<p>Sealing device</p> <p>Power supply</p> <p>Power cable</p> <p>Operating instructions</p> <p>Test report(s)</p> <p>Replacement ink ribbon</p> 
--	--

2.1.2 Step 2 Setting up the device

<p>Set up the device on a flat surface and make sure that there is at least a 200 mm spacing between the device and the wall.</p>	
---	---

2.1.3 Step 3 Connecting the device

Insert the 24V cable of the power supply ❶ into the device

Insert the power cable ❷ into the power supply ❸ and insert the mains plug ❹ into the socket



Top keyway



2.1.4 Step 4 Turning on the device

Press the Power button

The colour changes from red to green.



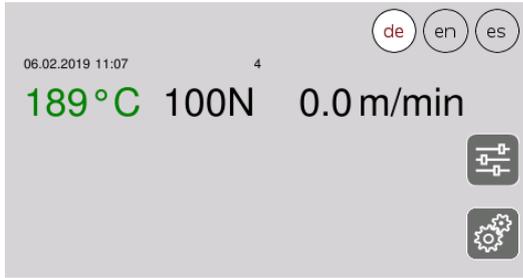
The device operating system is loaded.



When the device is turned on for the first time, the date, time, date format and languages can be reset.

hm 950 / NanoPak	Commissioning	Chapter 2
------------------	---------------	-----------

2.1.6 Step 6 Displays and functions of the main menu



Symbol	Function	Note
189°C	Displays the current sealing temperature	
100 N	Displays the current pressing force	
0.0 m/min	Displays the current throughput speed	Value > 0 only when motor is running
	Settings	
	Control center	Checking the functions of heating, DMS – module and motor as well as the device informations
	Display of the preselected languages	For better operation, the device can be switched to different languages using the three buttons during operation. A change is possible at any time via the Settings / System configuration / Language level. (See data input Chapter 3)
4	Displays the current counter / the adjusted counter	

2.1.7 Step 7 Change menu level 1 till 7 by “Swiping”

To change to another menu level, swipe across the display in the desired direction.

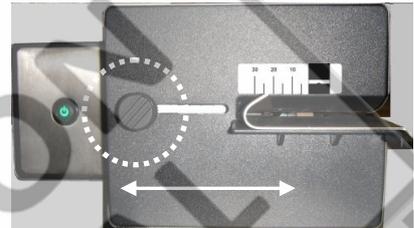


2.1.8 Step 8 The first sealing process

The default sealing temperature is 190°C and the throughput speed is 10 m/min. This ensures pouches and reels are sealed in accordance with EN 868-5 and EN ISO 11607-1. The internal printer is "active" in delivery mode, but without print data.

-  The material to be sealed must be sealed according to the manufacturer's instructions. Sealable pouches and reels must only be filled to $\frac{3}{4}$ full (DIN 58953-7). The limited filling prevents too great a load being placed on the sealing seams.

Setting the peel edge



-  After releasing the locking device, the peel edge can be steplessly adjusted by between 0 mm and 35 mm by moving the infeed section. A sufficient overhang must be present between the sealing seam and the reel interface on the extraction side (in accordance with DIN 58953-7 min. 10 mm).

Sterilisation packaging must be inserted from the left-hand side, always with the side to be printed face down. The drive is switched on automatically.

Remove the sealed sterilisation packaging and leave briefly to cool.



The correct sealing temperature must be identified by means of test sealings. (DIN 58953-7).

Sealing must be performed in such a way that the sealing seam meets the quality characteristics required in EN ISO 11607-2, even with varying material thicknesses. The following quality characteristics must be met:

- Intact sealing across the entire sealing seam width
- No channels or open seals
- No punctures or tears
- No delamination or material separation

hm 950 / NanoPak	Commissioning	Chapter 2
------------------	---------------	-----------

2.1.9 The individual levels of the device

2.1.9.1 Level 1 General

Symbol	Function	Note
	Seal Check	Performing a routine test (see Chapter 2.2.1) SealCheck, InkTest or peel test
	Login	User login/logoff
	TraceLog	Recording of all process-related data, changes, errors and settings made during operation
	Packaging List	Selecting packaging lists that have already been created
	Counter	Setting the counter for counting up/down
	Printer	Switching the internal printer on/off
	External printer	Switching the external printer on/off

2.1.9.2 Level 2 Printer

Symbol	Function	Note
	Edit Packaging Lists	Creation of packaging lists
	Prefixes	Changing data names for print data
	External Printer Configuration	Creating, editing and deleting formulas for external printer data

2.1.9.3 Level 3 Print Data

Symbol	Function	Note
	ID-List	Creating, editing and deleting ID lists
	LOT	Creating and deleting LOT numbers
	Sterilizer	Creating, editing and deleting steriliser data
	CE-List	Creating, editing and deleting CE lists
	Reference-List	Creating, editing and deleting reference numbers
	Info-List	Creating, editing and deleting stored information
	Expiry-Date	Adjust the expiry date

hm 950 / NanoPak	Commissioning	Chapter 2
------------------	---------------	-----------

2.1.9.4 Level 4 Standby

Symbol	Function	Note
	Standby	After the selected time, the device reduces the heat output and cools down to 80°C.
	ID-Standby	After a selected time, a logged-in user is logged off automatically.

2.1.9.5 Level 5 Monitoring

Symbol	Function	Note
	Test-Intervals	Setting different intervals for Seal Check, InkTest and peel test.
	DataMatic	Selection of individual DataMatic data. Fixed data: Date/time, temperature, contact pressure, speed, counter total and serial number

2.1.9.6 Level 6 Special Features

Symbol	Function	Note
	Scanner Data	Assign the scanned data to other functions. The scanner data is assigned to the batch number by default (see Chapter 7.2.2)
	ValiUp	Determining the ideal sealing temperature for the material used by means of an aid → Not activated until unlock
	Key lock	Locks the settings on the home screen so that data can only be selected but not deleted or edited.
	UDI	Creating, editing and deleting UDI data → Not activated without special dongle

2.1.9.7 Level 7 System Configuration

Symbol	Function	Note
	Date/time	Setting the current date and time
	Date formats	Changing date formats dd.mm.yyyy ● mm.dd.yyyy ● yyyy.mm ● mm.yyyy ● yyyy ● Month.dd.yyyy
	Measurement Unit	Conversion of the units of measurement from si T[°C] ● F[N] ● v[m/min] fps T[°F] ● F[lbf] ● v[ft/min]
	Default	Resetting the device to default settings (Password-protected settings)
	Language	Setting the three languages that can be preselected via the start menu The printout of country-specific characters is only possible with a 24 stylus print head! (special equipment)
	IP	Password-protected menu level for setting the IP address
	Config	Password-protected menu level for service purposes
	Update	Performing software updates via USB stick (for more details see technical data)

2.2 The sealing seam test

Testing of the critical process parameters temperature, contact pressure and sealing time by means of the sealing seam test. This test should be performed and documented before and after the daily work process and/or before/after each lot (EN ISO 11607-2). The sealing parameters are displayed during the tests.

Activating and starting the sealing seam test

1. If a user has been created in the user list, an user code must be entered before a test is carried out.

→ Otherwise this is not necessary.

2. Activate the sealing seam test

3. Select the type of sealing seam test

3.1 Seal check
 Cannot be used for packages with a side fold!
 Place the indicator strips inside the package.

3.2 Ink test
 Place the disposable cartridge inside the package

3.3 Peel test
 Cut out the test strips after sealing

4. Insert the sterilisation packaging, width min. 200 mm.

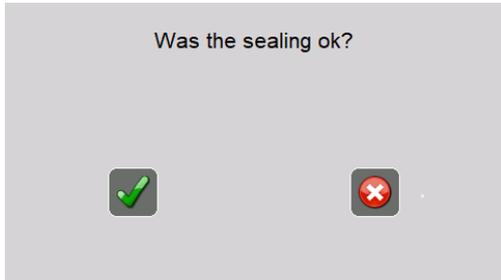
This key is used to cancel the function

hm 950 / NanoPak	Commissioning	Chapter 2
------------------	---------------	-----------

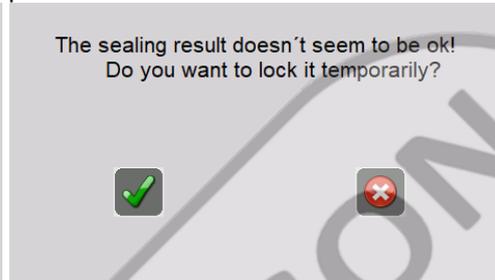
2.2.1 Locked machine due to failed Seal Check

As soon as the Seal Check has been done twice without passed result, the machine asked for lock function.

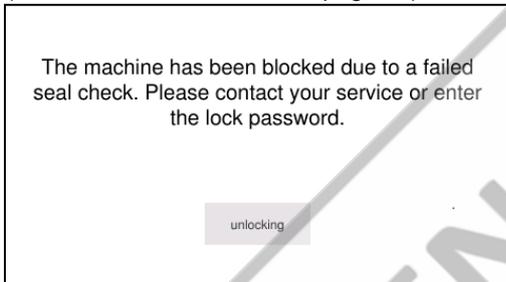
Seal Check result confirmation



Message in the screen if two Seal Check result hasn't been passed.

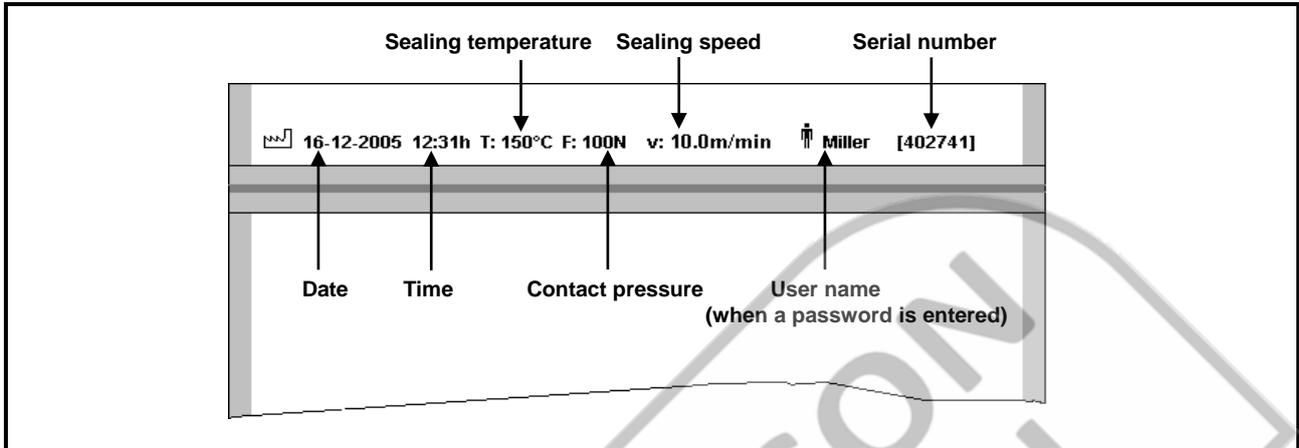


If the screen is locked due to failed Seal Check, you can unlock it by using the lock password. (see technical information on page 60)



hm 950 / NanoPak	Commissioning	Chapter 2
------------------	---------------	-----------

2.2.2 Printing of the test parameters on a package



2.2.3 Printing of the test parameters on a label

ONLY with the label printer connected!

<p>If the ValiPrint label printer is connected and switched on, a label is also printed with each test selected</p> <ul style="list-style-type: none"> Date and time T[°C] Sealing temperature F[N] Contact pressure v[m] Sealing speed User name (when entering password) Serial number 	<div style="border: 1px solid black; border-radius: 15px; padding: 10px;"> <p> 23.08.2017 12:00</p> <p>T[°C] 190</p> <p>F[N] 100</p> <p>v[m] 10.1</p> <p> U1</p> <p> 123.456</p> <p style="text-align: right; font-size: small;">Approval: _____</p> </div>
--	--

hm 950 / NanoPak	Data input	Chapter 3
------------------	------------	-----------

3 Data input

3.1 Creating data for different languages

When entering data, it should be noted that lists, names and all freely editable texts are only printed correctly after a packaging list has been selected if they have been created in the selected language.

The corresponding language in the start menu must also be selected.

This means that a text created in Japanese, for example, can only be printed correctly in a packing list if the language in the start screen has been changed to Japanese and the Japanese keyboard has been used to enter the text.

The same applies to all other languages.

3.2 The ID-List

The names and passwords of users who will be operating the device are entered into the user list. The users on the list can/must log in to the device before starting their task via the password entered into the list, i.e. they can also log out when their task is complete.

If the **User standby** function was activated in the **Settings menu**, the user is automatically logged out after a set time after which no sealing process has taken place.

- ☞ A logged in user name is automatically printed on the packaging when using the "Test" function.
- It is possible to record the user name with each sealing process using the **DataMatic** function.
- You can activate the printout of a logged in user name on the packaging in a packaging list.

3.2.1 The menu



Key	Function	Note
	Delete an entry	Only visible when the user has already been created.
	Re-enter an entry	Length of user name: max. 8 alphanumeric characters Length of a password: max. 5 digits Number of user names: max. 50, individual entry or one after another
	Activate or deactivate administrator right	A so-called administrator right can be assigned to one or more users. This authorises him/her to block or release certain functions.
	Exit menu level	
	Edit created user data	Only visible when the user has already been created.

3.2.2 Entry of user data/administrator rights

1. Activate **▪ID-List▪** menu

2. **▪Enter new ID**

3. Enter **user name**,
e.g. "User",

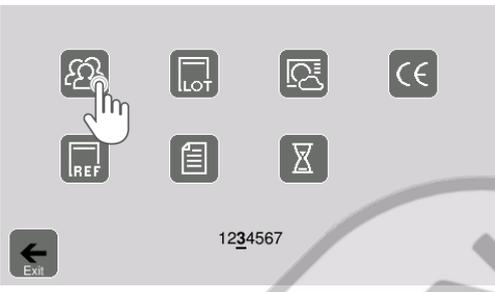
It is not possible to enter a name without a password.

4. Enter **password**,
e.g. "12345"
and administrator rights can be assigned if desired by pressing the key

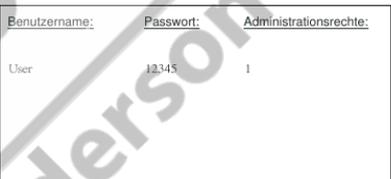
Administrator rights active 

5. End input(s) by pressing the **"Enter"** key

 Exit this menu level







hm 950 / NanoPak	Data input	Chapter 3
------------------	------------	-----------

3.2.3 Removing administrator rights

1. Select a user name, e.g. "User"

2. Press the symbol to edit selected user data.

3. Remove the administrator data and confirm by pressing the  key.

Administrator rights inactive 

 Exit this menu level



3.3 Packaging lists Menu



Key	Function	Note
	Select the packaging list menu	
	Exit menu level	back to the home screen

hm 950 / NanoPak	Data input	Chapter 3
------------------	------------	-----------

3.3.1 The settings of a packaging list

A max. of twenty lists can be created for different types of packaging.

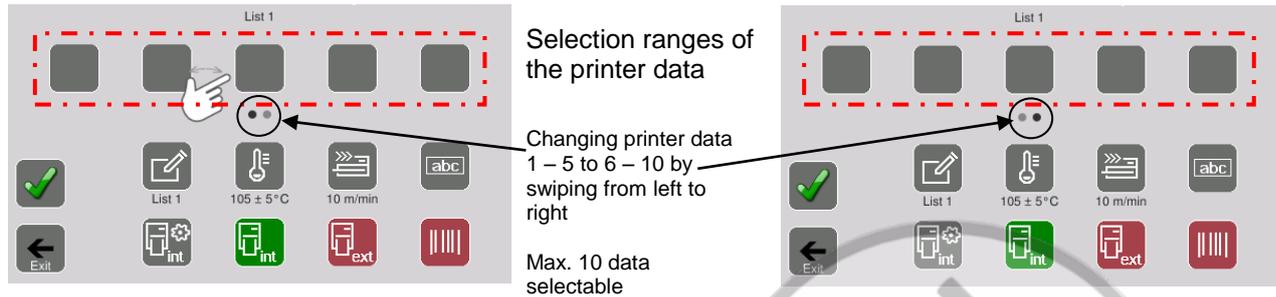
These correspond to various "formulas" with different settings from the following table.



Key	Function	Note
	Entering the packaging designation Selection of additional colour identification	alphanumeric text, max. 20 characters Colours: grey, violet, red, blue, green, white, yellow
	Selection of the sealing temperature and deactivation tolerance	[°C] 80 - 220 or [°F] 176- 428 [°C] ± 2 - ±5 or [°F] ±36 - ±41
	Selection of the throughput speed	5.0 m/min – 13.0 m/min
	Selection of data designation	Data description (prefix) Symbol: or Text: Date
	Configuration of the internal printer	<ul style="list-style-type: none"> ● Automatic character width (FontMatic) or manually adjustable character width ● Manually adjustable character spacing ● Distance from start of printing to page margin 1 mm - 100 mm ● Illustration of the print data, relative to the upper packaging edge, rotated by 180
	Activate printer activity by pressing and holding the key	Switch the label printer for the selected packaging list on or off and adjust print out information → Press button: adjustment → Press and hold button printer on/off
	Configuration of the internal printer	<ul style="list-style-type: none"> ● Automatic character width (FontMatic) or manually adjustable character width ● Manually adjustable character spacing ● Distance from start of printing to page margin 1 mm - 100 mm ● Illustration of the print data, relative to the upper packaging edge, rotated by 180
	Printer activity	Switch the internal printer for the selected packaging list on or off
	Selection of text or barcode	The selected data are printed as a barcode → Press selected data if the button is green to set the printout as barcode or not.
	Selection of data designation	Data description (prefix) Symbol: or Text: Date
	Exit menu level	

hm 950 / NanoPak	Data input	Chapter 3
------------------	------------	-----------

3.3.2 The printer data of a packaging list



Key	Data	Note
	Date	Formatting depends on the selected configuration
	Expiry-Date	Months 1 ● 3 ● 6 ● 9 ● 12 ● 24 ● 60 ● fixed date ● 1 - 365 days
	ID	Only with previously setup list (how to create described in 3.1)
	LOT	Only with previously setup list (how to create described in 3.3)
	INFO	Only with previously setup list (how to create described in 3.3)
	CE	Only with previously setup list (how to create described in 3.3)
	cntr.	
	cntr. TOTAL	counter total since the first sealing
	Time	
	Process	STEAM ● EO ● FORM ● VH2O2 ● IRRAD ● DRY
	Sterilizer	Only with previously setup list (how to create described in 3.3)
	Quantity	1 - 10
	S/N	Printout of the current device serial number
	temp.	Printout of the actual values used during the sealing process
	Press.	Printout of the actual values used during the sealing process
	Speed/dwell	Printout of the actual values used during the sealing process
	reuse	
	Note	
	Reference	Only with previously setup list (how to create described in 3.3)
	No Selection	No printout in the print sequence



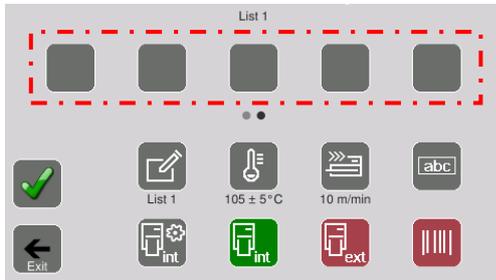
A red symbol means variable data such as sterile product storage period

hm 950 / NanoPak	Data input	Chapter 3
------------------	------------	-----------

3.3.3 Printer data selection

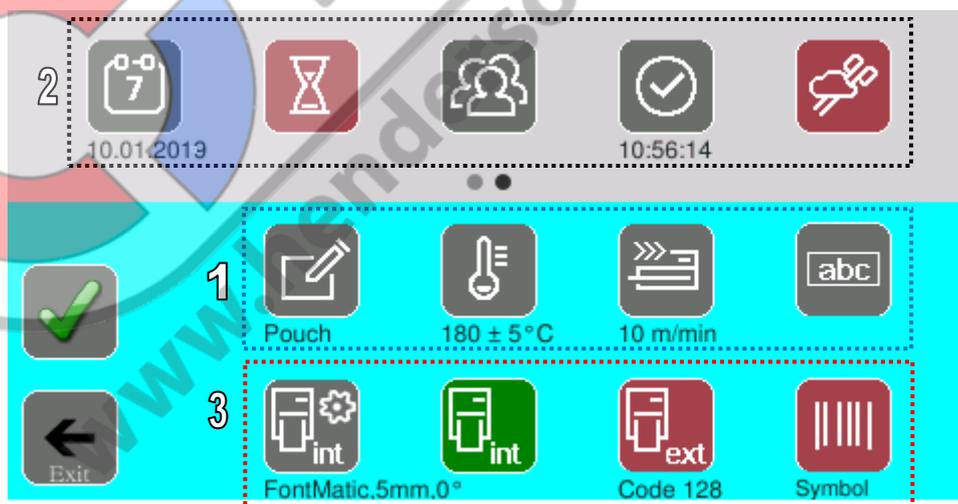
The individual printer data can be printed by pressing the desired free fields several times 1-5 or 6-10 can be set in the selection ranges.

→ Selectable data is shown and explained in Chapter 3.3.3.



3.3.4 Example of creating a packaging list

Packaging parameters	Parameter data
Packaging designation	"Pouch"
Colour identification	Blue
Sealing temperature	180°C
Switch-off tolerance	± 5°C
Sealing time	10.0 m/min
Print data of the internal printer	Representation of print data as text
5 print data on one line	Date Day's date
	Expiry period 3 months
	Operator Miller
	Time Current time
	Type of sterilisation STEAM
Configuration of the internal printer	Character width automatic, FontMatic
	Distance of the start of printing from the edge of the page 10 mm
	Relative to the upper packaging edge 0°
	Printer activity int. printer "ON"
	ext. printer "OFF"
	Selection of text or barcode text



3.3.4.1 Enter the package designation and determine an identification colour

1. Activate the **■ Designation ■** input

2. Enter packaging designation by pressing the input field

3. Press the button several times until the background colour of the packaging designation appears in the desired colour.

4. Confirm the packaging designation by pressing the Enter button.

activate

 Cancel

3.3.4.2 Select the sealing temperature

1. Activate the **■ Temperature ■** selection

2. Change the temperature and tolerance by swiping upwards or downwards

Alternatively
 Determination of the necessary temperature by using the ValiUp function

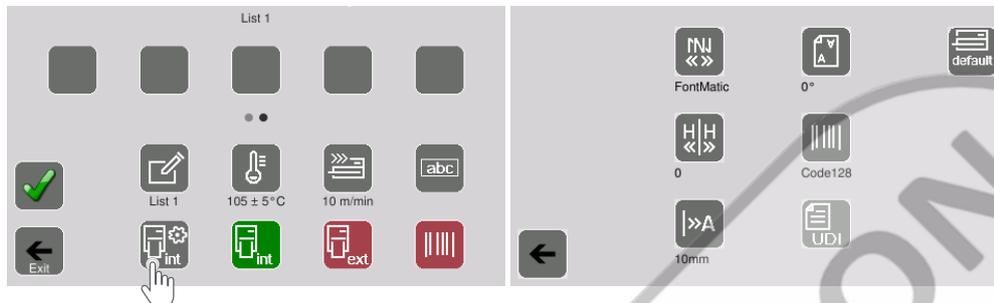
activate

hm 950 / NanoPak	Data input	Chapter 3
------------------	------------	-----------

3.3.4.3 The settings of the internal printer

 The internal printer can be set individually for each packaging list.

3.3.4.3.1.1 The menu



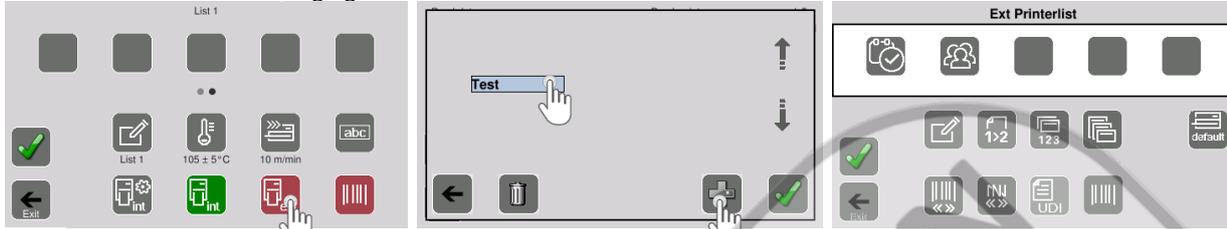
Key	Function	Note												
	Character width	<ul style="list-style-type: none"> ● FontMatic, ● character width 1, ● character width 2, ● character width 3 												
	Character pitch	Only active when FontMatic is not active <ul style="list-style-type: none"> ● character spacing 1, ● character spacing 2, ● character spacing e 3 												
	Print start	Spacing of the print line from the side edge of the packaging adjustable 1 mm – 100 mm (default setting 5 mm)												
	Print direction	Representation of the print image to the upper edge of the packaging 0° or flipped 180° (default setting 0°)												
	Barcode type	Data marked in the print sequence with the barcode character is optionally printed with <ul style="list-style-type: none"> ● code 128, ● code 39, ● code 93, ● code 2/5 (default setting code 128)												
	Print UDI	Print HIBC data Primary code (UDI-DI) and secondary code (UDI-PI) separately as rectangular data matrix (DMRE according to DIN 16578) format 12x26 and 12x36  ONLY active for device hm 950 DC-VI and with plugged-in coding key!												
	Default settings	<table border="0"> <tr> <td>Character width</td> <td>FontMatic</td> </tr> <tr> <td>Character spacing</td> <td>0</td> </tr> <tr> <td>Print direction</td> <td>0°</td> </tr> <tr> <td>Start of printing</td> <td>5 mm</td> </tr> <tr> <td>Barcode</td> <td>Code 128</td> </tr> <tr> <td>Print UDI</td> <td>Not active</td> </tr> </table>	Character width	FontMatic	Character spacing	0	Print direction	0°	Start of printing	5 mm	Barcode	Code 128	Print UDI	Not active
Character width	FontMatic													
Character spacing	0													
Print direction	0°													
Start of printing	5 mm													
Barcode	Code 128													
Print UDI	Not active													
	Exit menu level													

hm 950 / NanoPak	Data input	Chapter 3
------------------	------------	-----------

3.3.4.3.2 The settings of the external label printer

 The external label printer can be set individually for each packaging list!

3.3.4.3.2.1 The Packaging List



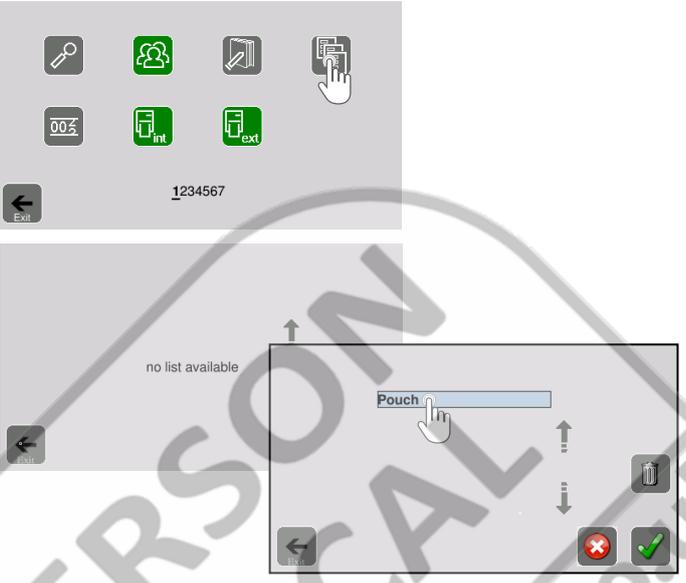
-  create new list
-  confirm
-  Delete
-  Exit menu level

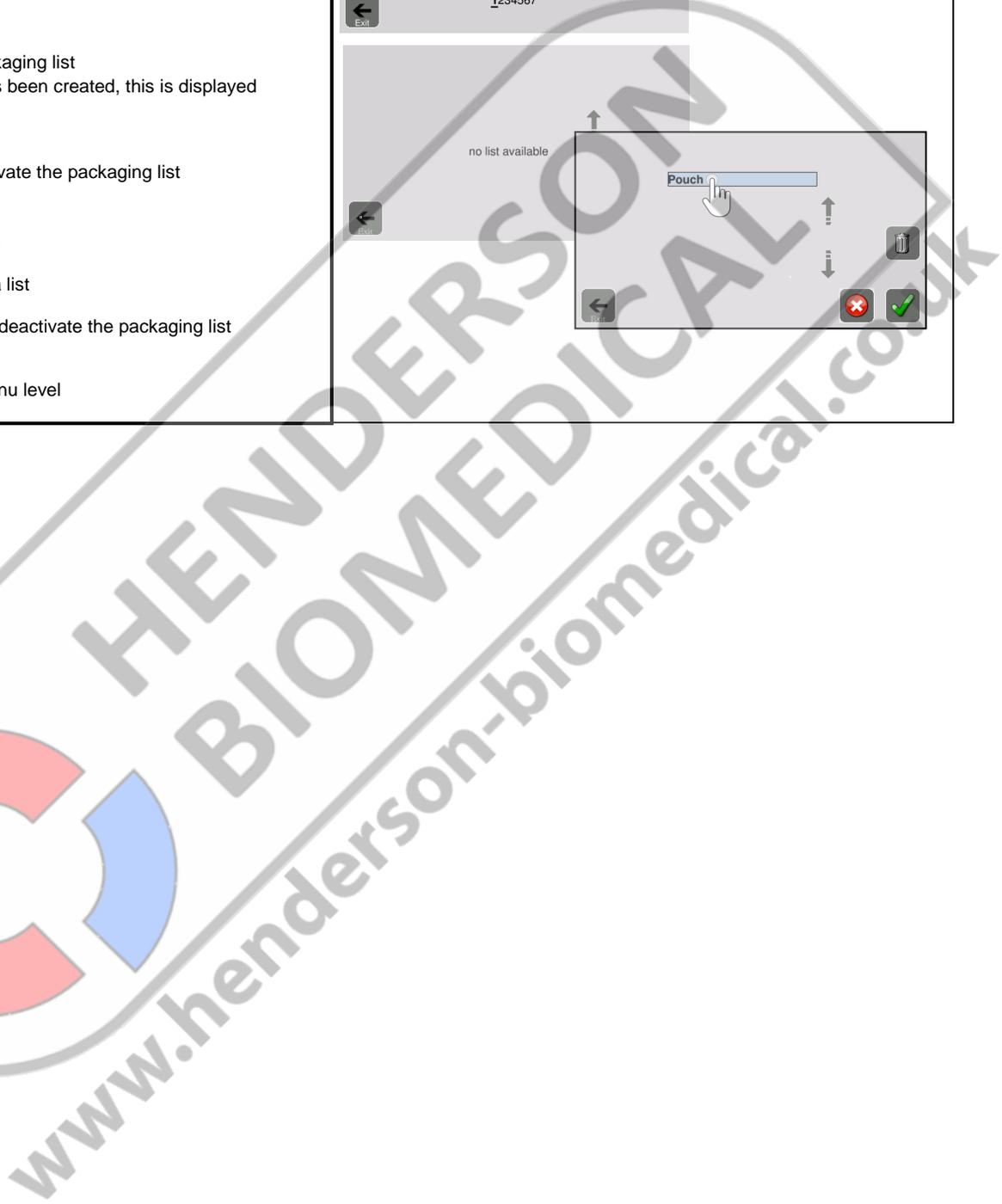
➔ The external printer is activated by pressing and holding the symbol.

-  not active
-  activated

Key	Function	Note
	Print mode	<ul style="list-style-type: none"> ● Manual label printing ● Label printing after each sealing (default setting) ● Label printing after every second seal
	Label size	<ul style="list-style-type: none"> ● 55 x 33 mm Number of lines of print without HIBC data: 5 with HIBC data: 4 ● 60 x 44 mm Number of lines of print without HIBC data: 7 with HIBC data: 5
	Character width	<ul style="list-style-type: none"> ● 1 Text ● 2 Text (default setting)
	Label quantity	Selection 1 - 10, number of printed labels
	Width of the barcode	<ul style="list-style-type: none"> ● 1  (default setting) ● 2 
	Print UDI	Print HIBC data Primary code (UDI-DI) and secondary code (UDI-PI) in one DataMatrix code  Not activated without special dongle
	Default settings	Print mode: Every seal Label size: 55 x 33 mm Character width: 2 Label number: 1 Barcode character width: 1 Print UDI: Not active
	Exit menu level	

3.3.4.4 Display the packaging list

<p>1. Activate the ■ Packaging lists ■ menu</p> <p>2. Select the packaging list → If no list has been created, this is displayed accordingly</p> <p>3. Select and activate the packaging list</p> <ul style="list-style-type: none">  activate  delete a list  Cancel/deactivate the packaging list  Exit menu level 	
---	--



hm 950 / NanoPak	Data input	Chapter 3
------------------	------------	-----------

3.4 Data lists

3.4.1 The selection menu

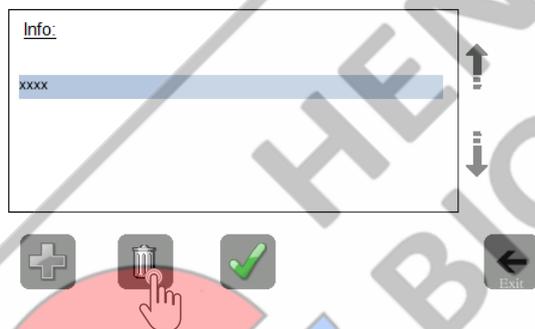
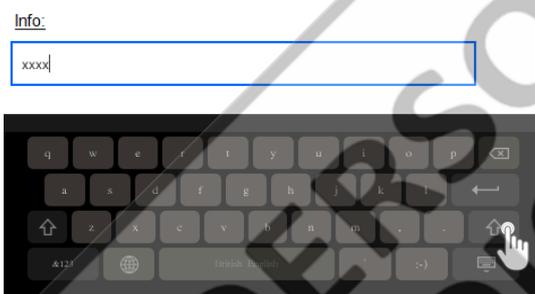
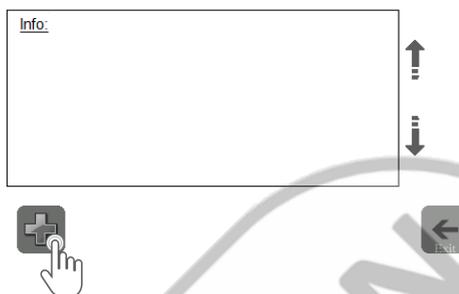


Key	Function	Example	Note
	List with user data		Length of user data: Name: 20 alphanumeric characters Password: 5 numbers Number of user entries: 50, individual entry or one after another
	List with LOT data	Lot names, lot numbers	Number would be overwritten after every input
	List with sterilizer data	Steriliser designation or serial number	Length of list texts: 20 alphanumeric characters Number of list texts: 500, individual entry or one after another
	List with CE data	EN 980	
	List with reference data	Article number, serial number	
	List with texts	Device designations, department names	
	Set expiry date		
	Exit menu level		

hm 950 / NanoPak	Data input	Chapter 3
------------------	------------	-----------

3.4.2 The Processing menu

Example of an Info-List



Key	Function
	Re-enter a list text Delete a list text
	Delete a list text
	Confirm/activate
	Exit menu level

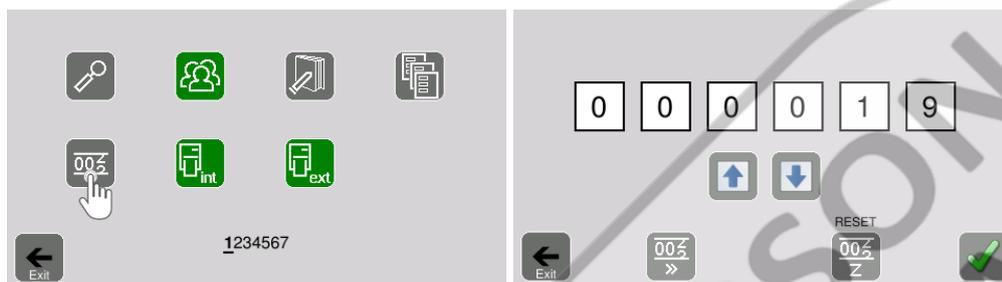
hm 950 / NanoPak	Configurations	Chapter 4
------------------	----------------	-----------

4 Device configuration

4.1.1 Counter

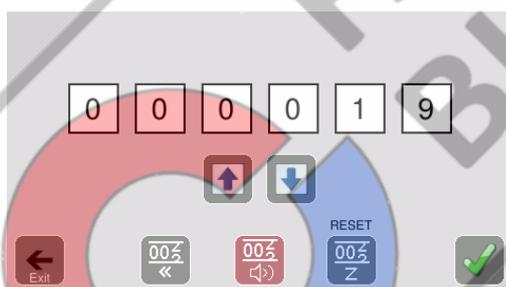
4.1.1.1 Counter functions

Counting forwards



Key	Function	Note
	0 0 0 0 1 9	Displays the current value
	Switches the counter to forwards counting	
	Sets the counter to 000000	
	Confirms the settings	

Counting backwards



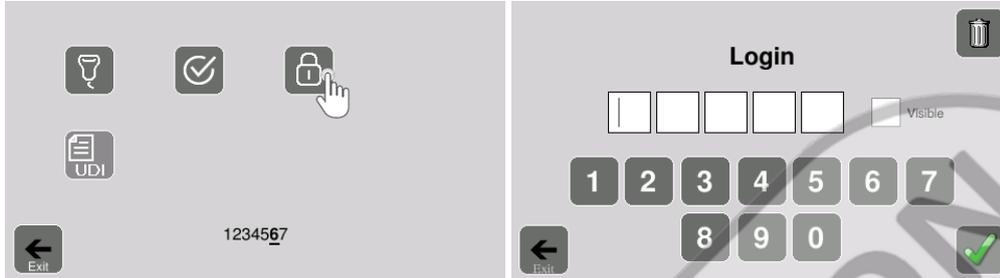
Key	Function	Note
	0 0 0 0 1 9	Displays the current value
	0 0 0 0 1 0	Select the individual digits of the counter; the respective number is highlighted in blue and the desired quantity can be set using the ↑ and ↓ arrow keys (e.g.: 10 items)
	Switches the counter to forwards counting	With a counter status of 0, the drive is blocked.
	Sound on/off if the counter limit is reached	
	Confirms the settings	

hm 950 / NanoPak	Configurations	Chapter 4
------------------	----------------	-----------

4.1.2 Key lock

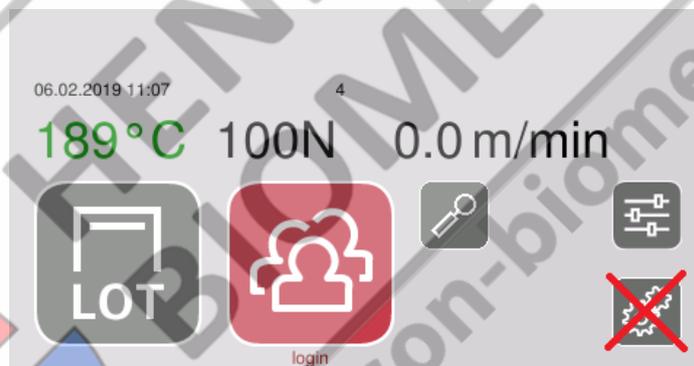


You can only lock the keys if a user list was created in which at least one person in the list has the administrator right! Selecting or scanning data is not affected.



Key	Function	Note
 	Lock deleting and editing settings.	All symbols stored on the home screen can be selected by users, but not deleted or edited. An administrator is required for this. The lock can be deactivated by entering the password of someone in the user list who has the administrator right.

-  inactive
-  active



The screen is locked for non-administration users as soon as an administrator itself is configured in the ID-List.

5 Data recording

5.1 DataMatic

If any formatted USB stick is plugged into a free USB slot and the stick is detected, a message will appear on the display indicating that the DataMatic has been activated, if it is confirmed with "yes".

If you confirm this prompt with "no", no data will be written to the USB stick. However, the activation can still be carried out later in the menu/DataMatic.

The data is written in *.csv format to the USB stick, and can be displayed in the device display, using a text editor such as the Windows Text Editor or Windows WordPad, or using a spreadsheet program such as Windows Excel.

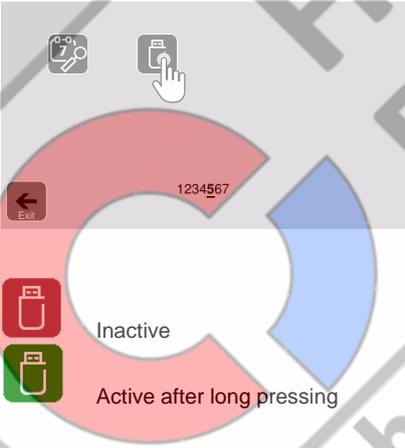
-  If the DataMatic function is activated, a sealing process can only be started if a USB stick is also plugged in!
-  The DataMatic data are output automatically via the RS 232 and Ethernet interfaces with each seal, even if the USB stick is not plugged in!

5.1.1 Activating DataMatic

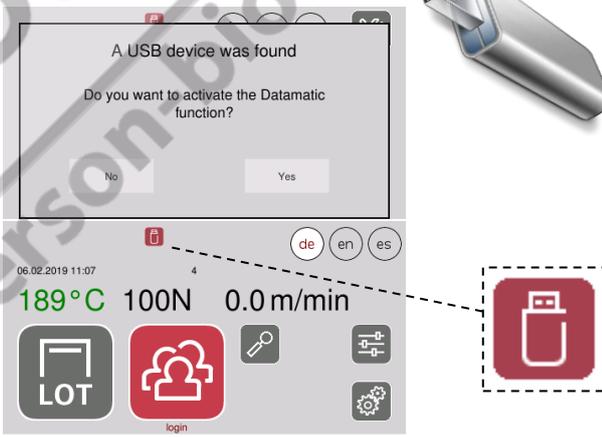
1. Insert a USB Stick into a free USB slot

2. After inserting the stick, you will be asked to activate DataMatic.

If this prompt is answered with "NO", DataMatic can also be activated later in the DataMatic menu.



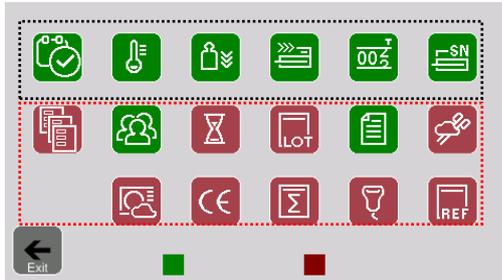
→ If DataMatic has been activated, a seal can only be started with the USB stick inserted.



hm 950 / NanoPak	Data recording	Chapter 5
------------------	----------------	-----------

5.1.2 Configuring DataMatic data

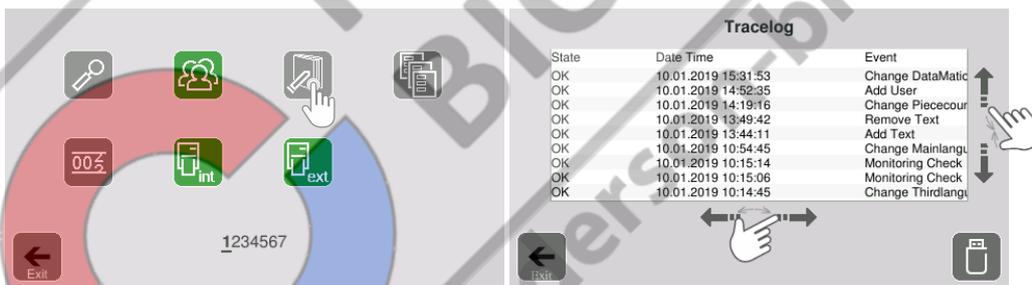


Keys	Data	Note
	Date and time Sealing temperature Contact pressure Throughput speed Unit counter TOTAL Device serial number	Fixed recording data
	Selected packaging ID Expiry date LOT Info Process Sterilizer data CE data Package content quantity Data of the barcode scanner Reference data	Optional recording data

5.1.3 Show the DataMatic data on the device display

☞ Only possible with a contacted USB stick containing recorded data!

5.1.3.1 The display menu



Key	Function	Display	Function
	Recorded TraceLog (logbook) data	10/01/2019	Date of the recording
	Scroll up and down	0 – 9	Data counter
	Scroll left and right		
	Exit menu level		
	Read the DataMatic data		

5.1.3.2 View the recordings on the USB stick

1. Activate the **TraceLog** menu

2. Activate the USB memory data view



Appears if not USB is plugged

confirm

3. Select the USB slot where the stick was inserted

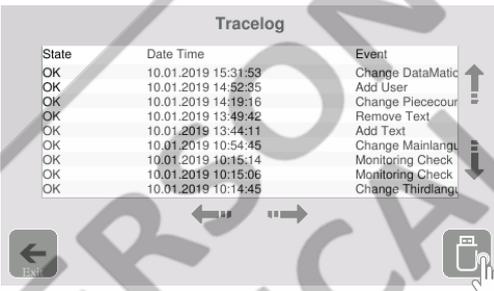
confirm

3. Select the year of the recordings, such as 2019

confirm

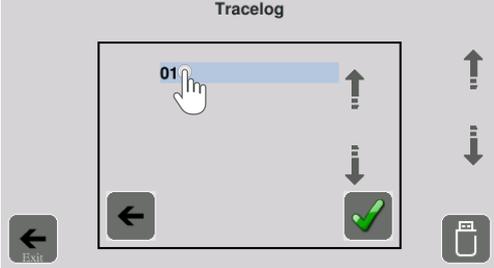
4. Select the month of the recordings, such as January

confirm

State	Date Time	Event
OK	10.01.2019 15:31:53	Change DataMatic
OK	10.01.2019 14:52:35	Add User
OK	10.01.2019 14:19:16	Change Piececour
OK	10.01.2019 13:49:42	Remove Text
OK	10.01.2019 13:44:11	Add Text
OK	10.01.2019 10:54:45	Change Mainlang
OK	10.01.2019 10:15:14	Monitoring Check
OK	10.01.2019 10:15:06	Monitoring Check
OK	10.01.2019 10:14:45	Change Thirdlang

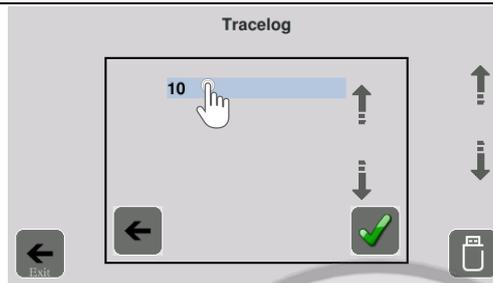




5. Select the day of the recordings, such as the tenth



confirm



5. Select the serial number of the recordings, such as



confirm



➔ Change display by swiping

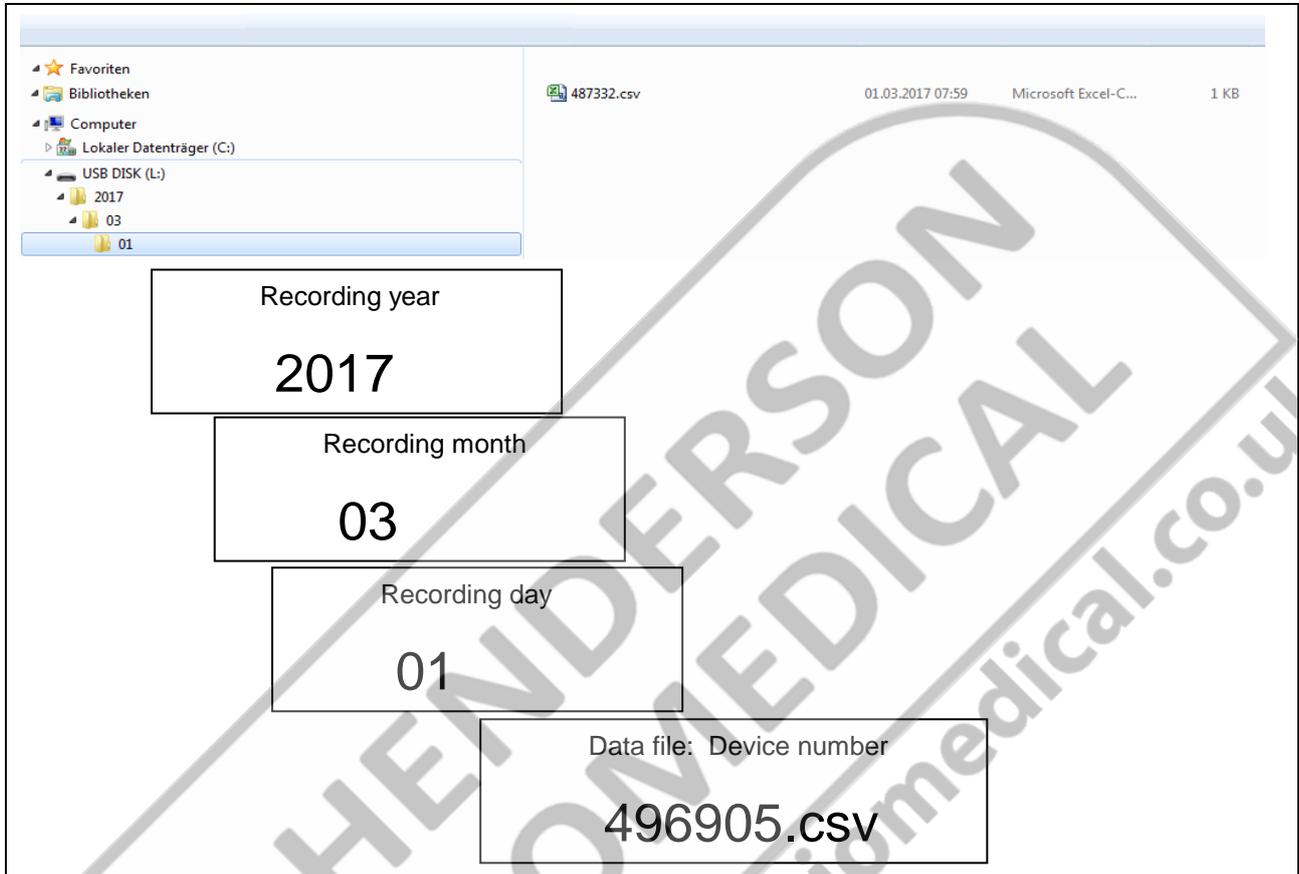
- Status of the event
- Date and time
- Event
- Temp.
- Press.
- Speed/dwell
- Counter
- Selected packaging
- ID
- Expiry date
- LOT
- Info
- Process
- CE data
- Package content quantity
- Barcode scanner data
- Reference data



hm 950 / NanoPak	Changes	Chapter 5
------------------	---------	-----------

5.1.4 Show the DataMatic data on a PC

USB stick directory with the recording data (for example: PC with Windows 7)



Display of a standard DataMatic recording, e.g. using Windows Excel

hm 950 / NanoPak	Changes	Chapter 5
------------------	---------	-----------

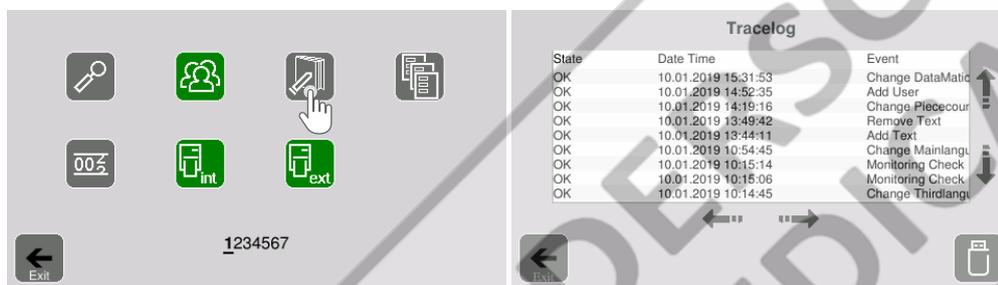
5.2 TraceLog (logbook)

This logbook contains the temporary recording of various completed actions, events and faults that have occurred on the device.

These recordings are only viewable while the device is switched on, however if a USB stick is connected for the DataMatic function, the data are stored as an add-on to the DataMatic data on it in the event of a date change and during the switch-off process.

 For reliable data transfer, the device must switch itself off after pressing the Power off button and once the shut-down period of one minute has elapsed. No "EMERGENCY STOP" must be carried out by holding the Power off button.

5.2.1.1 The display menu



5.2.1.2 Interpretation of entries

State	Date and time	Event	T	F	v
OK	10.01.2019 15:31:53	Change DataMatic	Sealing temperature at this time	Contact pressure at this time	Throughput speed at this time
OK	10/01/2019 14:52:35	Add User			
OK	10/01/2019 14:19:16	Change Piece Counter			
OK	10/01/2019 13:49:42	Remove Text			
OK	10/01/2019 13:44:11	Add Text			
OK	10/01/2019 10:54:45	Change Mains Language			

5.3 Data readout via Ethernet

If an address is assigned to the device in the Settings / System Configuration / IP menu, the corresponding CSV file of DataMatic can be read out via network connection and saved on the PC.

Caution: A direct connection between the device and PC is not possible. The device needs to be on a computer network for this.

hm 950 / NanoPak	Changes	Chapter 5
------------------	---------	-----------

5.4 Data designator (prefix) - Symbol or text



A text as a data designator is only possible for the internal printer!

The data designator for different print data can be a symbol or text.

If the text is selected as the data designator, this must be created beforehand

The prefix is defined in the individual packaging lists
See Chapter 3.3.2

Using the packaging date as an example:



The selection and entry of the data is confirmed with the "ENTER" key.



confirm
 Cancel

Key	Function	Example	Replaces the symbol
	Text date	Packaged:	
	Text for sterile product storage period	Use by:	
	Text for user name	Mr./Mrs./Miss/Ms.	
	Text for lot data	Lot:	
	Text for texts	Instrument:	
	Text for CE data	CE EN:	
	Text for reference data	Art. No.:	
	Exit menu level		

hm 950 / NanoPak	Changes	Chapter 5
------------------	---------	-----------

5.5 Print data as a barcode



The printing of data as a barcode is only possible if the language German or English has been set!
This applies for the internal printer and the label printer!

The following data are NOT printed as a barcode:

	Data		Data
	Time		reuse
	Temperature		Note
	Contact pressure		
	Speed/dwell		

1. Activate packaging list

2. Press the Barcode button
→ Symbol changes colour from red to green

inactive
 active

3. Tap data
e.g. the user code
→ The barcode symbol appears next to the ID symbol

If you wish to undo this function, it can be done in the same order!

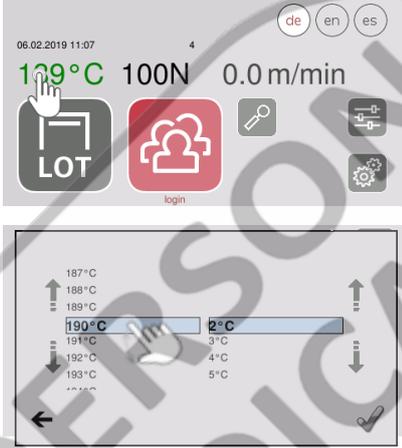
Exit this menu level

hm 950 / NanoPak	Changes	Chapter 5
------------------	---------	-----------

5.6 Direct change of the process parameters of a selected packaging

The sealing temperature or throughput speed of the packaging currently selected can be changed directly without calling up any menus.

5.6.1 Changing the sealing temperature

<p>1. Press and hold to select the temperature Press to activate the display</p> <p>2. Select the desired temperature</p> <p>3. Confirm the selection</p> <p> confirm</p> <p> Cancel</p>	
---	--

5.6.2 Changing the throughput speed

<p>1. Activate the selection of the throughput speed by pressing and holding down the display.</p> <p>2. Select the desired throughput speed</p> <p>3. Confirm the selection</p> <p> confirm</p> <p> Cancel</p>	
---	--



hm 950 / NanoPak	Changes	Chapter 5
------------------	---------	-----------

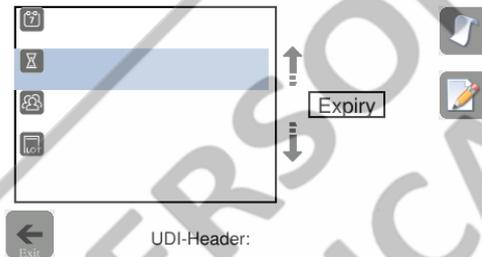
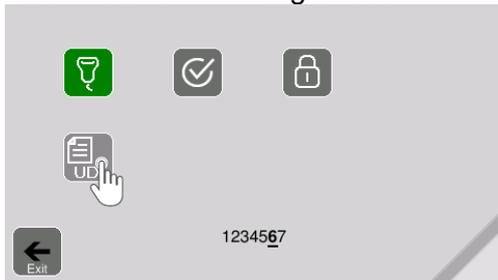
5.7 UDI marking

The marking is made using the HIBC coding system in accordance with the ANSI standard "ANS HIBC 2.5" embedded in the ISO standards for product and packaging marking ISO 22742, ISO 28219.

If the UDI marking is created and active, the primary code (UDI-DI) and secondary code (UDI-PI) are printed as separate, rectangular Data Matrices (DMRE) on the packaging and if the label printer is connected as a standard, square DataMatrix on one label.

To create or activate a UDI marking, the coding key (Art. No.: 1.561.007) must be inserted in one of the USB sockets!

5.7.1 The Processing menu



Function is not activated without special dongle

Key	Function	Note
	Enter the product code	Entry according to listing in the GUDID (USA) or EUDAMED (Europe) databases System identifier "+" is inserted automatically
	Enter data identifiers	Only use data identifiers compliant with the definitions in ASC MH 10 ISO/IEC 15418! The "/" separator is added automatically
	Exit menu level	

Example for entering the UDI header

Select the header symbol and enter the corresponding names using the keypad. Confirm with the ENTER key and finally activate with the checkmark.



- Confirm
- Cancel

hm 950 / NanoPak	Changes	Chapter 5
------------------	---------	-----------

5.8 External keyboard for data entry

A country-specific, external keyboard can be connected to enter packaging designations and the data for the various lists



5.9 Display

5.9.1 Standby

<p>Stand by is active, the sealing temperature decreases to the ambient temperature</p>	<p>The display is darker and the device cools down to the default set temperature of 80°C.</p>
<p>Reactivate device function</p>	

5.9.2 Counter status 0

<p>If the counter was configured to count backwards and the quantity reaches 000000, a message appears, and alternative a signal tone sounds and the drive is inactive.</p> <p>For further use, the counter can be stopped or set to another value.</p>	<div style="border: 1px solid gray; padding: 10px; background-color: #f0f0f0;"> <p style="text-align: center;">Specified quantity has been reached!</p> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> Counter stop start counter again </div> </div>
---	--

5.9.3 Display of the set test interval

<p>This symbol only appears if a test interval was selected</p>	<p>An individual date can be set for each test interval. See level 4 "Test intervals".</p> <div style="border: 1px solid gray; padding: 5px; background-color: #f0f0f0; margin-top: 10px;"> <p>Test Methods</p> <p><input checked="" type="radio"/> Seal <input type="radio"/> Peel <input type="radio"/> Ink</p> <p>Seal Check OFF</p> <p>Peel Test OFF</p> <p>Ink Test OFF</p> <div style="text-align: right; margin-top: 5px;"> </div> </div>
---	--

hm 950 / NanoPak	Changes	Chapter 5
------------------	---------	-----------

5.9.4 Maintenance indicator

<p>This symbol appears 30 days before the set maintenance cycle with information about the remaining days until the maintenance deadline or the days already exceeded after the maintenance deadline.</p> <p>Default setting: 12 months.</p> <p>Customer setting via the Service menu (see device technical manual)</p>	
--	---

5.9.5 RS 232 data interface active display

<p>This symbol appears if an external PC has made contact with the sealing device via the RS 232 data interface</p>	
---	--

5.9.6 Display of password startup interlock

<p>The symbol appears if the password startup interlock is active This means that the motor will only start if a previously listed password has been entered</p> <p>This function can only be activated or deactivated in service mode! (see device technical manual)</p>	
---	--

hm 950 / NanoPak	Changes	Chapter 5
------------------	---------	-----------

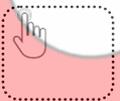
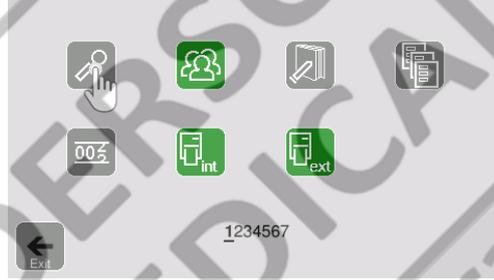
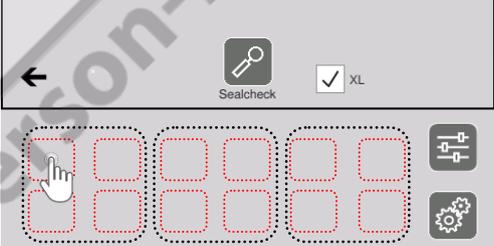
5.9.8 Display of operating data



Symbol	Display
	Device operating hours
	Device software version
	Device serial number
	Unit counter TOTAL
	Firmware version of the CPU PC board
	Date of the next maintenance

6 Special functions

Individual setting of the home screen

<p>1. Activate the setting menu</p> <p>2. Press and hold to select any symbol</p> <p>3. The size of the symbol can be changed by activating the "size XL" key.</p> <p>4. The symbols can only be freely positioned on the home screen. Only the big symbols can only be selected in two positions.</p> <p>→ For large symbols, always select the upper left corner of the respective placeholder by tapping.</p> 	    
--	---

If the symbol in the home screen is to be deleted again or the position is to be changed, the respective symbol can be edited by holding it down for a long time.

- ➔ **The position of the symbols can only be changed with small symbols.**



HENDERSON
 BIOMEDICAL
 www.henderson-biomedical.co.uk

hm 950 / NanoPak	Barcode scanner	Chapter 7
------------------	-----------------	-----------

7 The barcode scanner (1.490.029)

☞ The barcode scanner is an optional accessory and not part of the sealing device scope of delivery! A connected barcode scanner that has not been approved by the device manufacturer can cause the device to fail!

7.1 Commissioning the barcode scanner

7.1.1 Step 1 Unpacking the barcode scanner

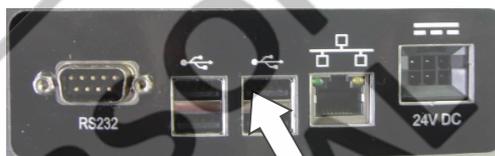
<p>Open the packaging</p> <p>Check to ensure that all parts are there and undamaged.</p>	<p>Barcode scanner with USB connection ca Art. No.: 1.490.029</p>  <p>CD Art. No.: 1.490.028</p> 
--	---

7.1.2 Step 2 Connecting the device

1. Switch off the device

2. Connect the barcode scanner's connection cable to a free USB slot

2. Switch on the device



hm 950 / NanoPak	Barcode scanner	Chapter 7
------------------	-----------------	-----------

7.2 Recording data using the barcode scanner



The capture of data with a barcode scanner is only possible if the language German or English has been set!

7.2.1 Data of a created barcode list

Only the print data of the internal printer of an activated packaging list can also be changed with a barcode scanner, provided they are activated in their print sequence.

The data are read in via a scan list that has been created with the hs 980 BR software (Art. No.: 1.490.028).

The data read in with the scanner are not saved. They are only current while the device is switched on!

Print data	Data source	Note
ID data	Scan list with user names	
Info	Scan list with texts	Assignment of general barcode data possible
LOT	Scan list with LOT data	Assignment of general barcode data possible
Sterilizer data	Scan list with sterilizer data	Assignment of general barcode data possible
CE data	Scan list with CE data	Assignment of general barcode data possible
Reference data	Scan list with reference data	Assignment of general barcode data possible

7.2.2 General barcode data

Data	Data source	Note
General data	All alphanumerically readable data	If not changed, they are always read in as a LOT number.

7.2.2.1 Assignment of general barcode data

All data collected by the scanner is assigned to the previously selected function.

This means that data captured by the scanner can be scanned and updated independently of editing the packaging list.

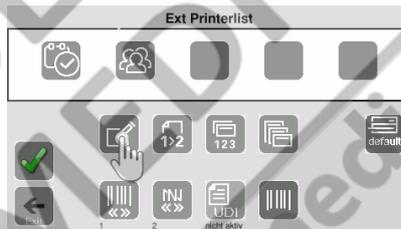
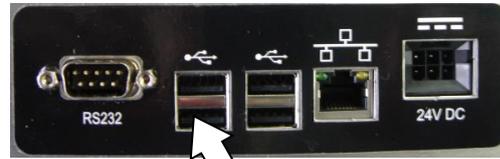
8 The external printer

1. Connect the external printer according to the instructions supplied with the printer and connect it to one of the USB slots on the back of the device.

2. Only then switch on the device

3. Open menu level 2 "Printer" and select the symbol for the external printer

4. Configure the external printer and save it under the desired formula name using the save function.
For the creation of formulas and their function see also Chapters 3.3.2 and 3.3.3



Key	Function	Note
	Name of the external printer formulas	
	Print mode	<ul style="list-style-type: none"> ● Manual ● Each seal ● Every 2nd seal
	Label quantity	Freely selectable from 1-10
	Label size	<ul style="list-style-type: none"> ● 55 x 33mm ● 60 x 44mm
	Width of the barcode	<ul style="list-style-type: none"> ● 1 (default setting) ● 2
	Character width	<ul style="list-style-type: none"> ● 1. Text ● 2. Text (default setting)
	Print UDI	Print HIBC data Primary code (UDI-DI) and secondary code (UDI-PI) separately as rectangular data matrix (DMRE according to DIN 16578) format 12x26 and 12x36 ONLY active for device hm 950 DC-VI and with plugged-in coding key!
	Barcode type	Data marked in the print sequence with the barcode character is optionally printed with <ul style="list-style-type: none"> ● code 128, ● code 39, ● code 93, ● code 2/5 (default setting code 128)
	Default settings	Print UDI Not active
	Exit menu level	

9 Switch off the device

Short press the Power button



The device is switched off directly by holding the Power button

Do not use if a USB stick is connected!
Data loss!



≈5 s



The colour of the Power button changes from green to red



hm 950 / NanoPak	Troubleshooting and maintenance	Chapter 10
------------------	---------------------------------	------------

10 Troubleshooting and maintenance

10.1 Troubleshooting checklist



The malfunction corrections highlighted in grey may only be performed by authorised service technicians!

Malfunction	Possible display	Possible cause	Possible malfunction correction
Open the front flap		Front flap open display	Close front flap
monitoring function check The sealing temperature is not reached after switch-on or it is outside of the set tolerance limit		Temperature sensor defective Control card defective Heating cartridge defective	Replace defective component <i>Inform Service</i>
monitoring function check After switch-on the contact pressure is outside of the set tolerance limit		DMS module defective Control card defective	Replace defective component <i>Inform Service</i>
monitoring function check After switch-on the throughput speed is outside of the set tolerance limit		Optical sensor "Engine start" defective Control card defective Motor defective	Replace defective component <i>Inform Service</i>

hm 950 / NanoPak	Troubleshooting and maintenance	Chapter 10
------------------	---------------------------------	------------

10.2 Maintenance

Like all technical devices, your device is subject to technical wear. In order to guarantee continuous operational readiness, your device should be inspected regularly by a competent person and cleaned, serviced and calibrated at least once per year by the manufacturer or by one of the manufacturer's authorised service partners.

10.3 Service

	Your hawo customer service is available from Mon-Fri 8:00 to 17:00 at the following number: +49 (0)6261-9770-0.
---	---

10.4 Spare parts service

	Conveniently order parts via e-mail service@hawo.com Fax +49(0)6261 9770 45 Simply copy the order form on the following page and enter the following information:
---	---

	Address, e-mail address or fax number Enter order number Enter device type Enter serial number Mark articles required Enter quantity required Sign order Send order
--	--

To:		Sender:	
E-mail: Fax no.:			
Your order No.:		Date:	
Device type:		Serial number:	
<input checked="" type="checkbox"/>	Designation	Art. No	Qty.
<input type="checkbox"/>	Device printer ink ribbon	6.813.104	
<input type="checkbox"/>	Device printer ink ribbon, red	6.813.224	
<input type="checkbox"/>			

Signature _____



10.5 Replacing the sealing device ink ribbon cassette

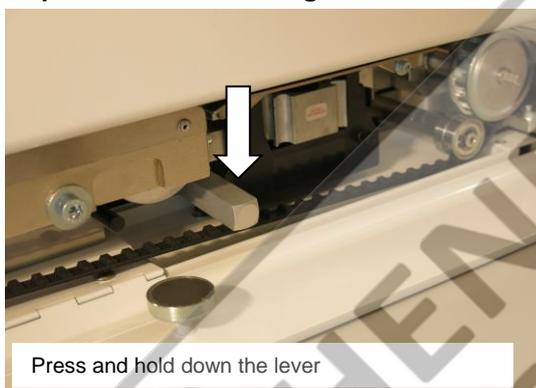


Switch off the device and DISCONNECT THE POWER SUPPLY

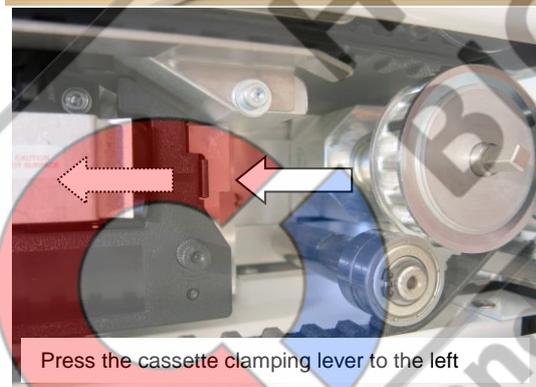
Step 1 Sliding the infeed section forward and opening the front flap



Step 2 Removing the ink ribbon cassette



Press and hold down the lever



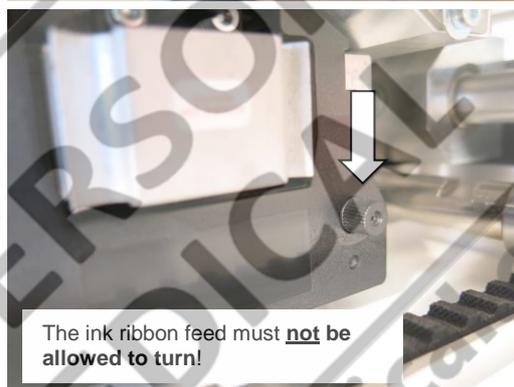
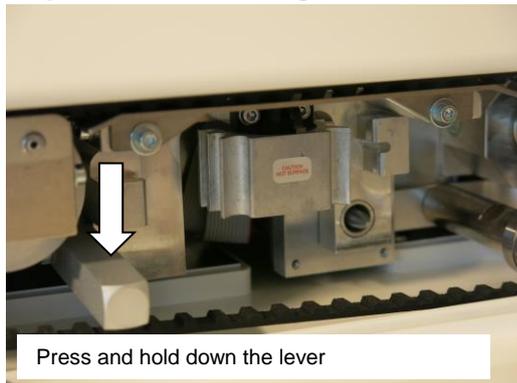
Press the cassette clamping lever to the left



Remove the ink ribbon cassette



Step 3 Installing a new ink ribbon cassette



HENDERSON BIOMEDICAL
www.henderson-biomedical.co.uk

hm 950 / NanoPak	Technical data	Chapter 11
------------------	----------------	---------------

11 Technical data

11.1 Specifications

Connection data

Mains connection	[V]	100 - 240
Mains frequency	[Hz]	50 / 60
Power consumption	max. [W]	200

Mechanical system

Dimensions	Length	[mm]	560
Including	Width		250
Infeed section	Height		145
Housing cover	Stainless steel AISI 304, powder-coated		
Housing bottom	Metal, powder-coated		
Weight	[kg]		14
Seal distance from edge	[mm]		0 – 35
Sealing seam width	[mm]		12
Sealing system	hawoflex™		
Sealing seam length	[mm]		Unlimited
Distance from medical product	[mm]		>30 (as per DIN 58953-7)

Process parameters/sealing parameters

Sealing temperature	max. [°C]	220
Tolerance for sealing temperature	[°C]	± 2 – ±5 (adjustable)
Contact pressure	[N]	100
Contact pressure deactivation tolerance	[%]	±20
Throughput speed	[m / min]	5 -13
Switch-off tolerance		±10
Throughput speed	[%]	
Temperature ranges		1
Temperature standard tolerance	[%]	±2

Electronics and communication systems

System		Microprocessor
Interfaces		RS-232 USB A Ethernet (LAN)
Transfer speed (baud rate)	[Bd]	9,600-115,200
Serial RS-232 interfaces and Ethernet		
Electrical protection class		1

Environmental parameters

Ambient temperature	[°C]	5-25
Heat output	[kJ/s]	0.1
Relative humidity	[%]	30-80 non-condensing
Noise intensity acc. to Machinery Directive 2006/42/EC Appendix I 1.7.4.2 u.)	[dB/ A]	<70

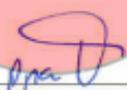
Passwords

Passwords for lock function due to failed Seal Check		29815
--	--	-------

hm 950 / NanoPak	Declarations of conformity	Chapter 12
------------------	----------------------------	------------

12 Declarations of conformity

12.1 CE declaration of conformity for sealing device

 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration "CE" de Conformité Declaración de conformidad de la C.E. Dichiarazione di conformità - Declaração de conformidade	9.694.038C																				
Gültig ab: 20.06.2017 Valid from:		Seite 1/1 Version 1.01																				
<p>Hiermit erklären wir, daß die Folienschweissmaschinen: Herewith we declare that the Foil sealing unit: Par la présente, nous déclarons que la gamme de Soudeuse de films plastique: Por la presente certificamos que las máquinas embolsadoras modelos: Dichiariamo con la presente che le macchine per saldatura di fogli: Por este meio se declara que as máquinas de selagem de folhas de plástico:</p> <p style="text-align: center;">NanoPak hm 950 DC-V / hm 950 DC-VI</p> <p>folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen: complies with the requirements of the following regulations and harmonised standards: corresponde aux dispositions suivantes et standards harmonisés: objeto de esta Declaración cumple con las siguientes disposiciones: Sono conformi alle seguenti disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p> <table border="0"> <tr> <td>EG - Maschinenrichtlinie Machinery directive Directive "CE" rel. aux machines Directiva de Maquinaria de la CE Direttiva CE sulle macchine nella versione Directiva da UE relativa a maquinaria</td> <td>2006/42/EG</td> <td></td> <td></td> </tr> <tr> <td>EMV-Richtlinie Directive CEM Direttiva CEM</td> <td>EMC-directive Directiva da CEM Directiva CEM</td> <td>2014/30/EU</td> <td></td> </tr> <tr> <td>WEEE-Richtlinie Directive WEEE Directiva WEEE</td> <td>WEEE-directive Directiva da WEEE Directiva WEEE</td> <td>2012/19/EU</td> <td></td> </tr> <tr> <td>RoHS-Richtlinie Directive RoHS Direttiva RoHS</td> <td>RoHS-directive Directiva de RoHS Directiva RoHS</td> <td>2011/65/EG</td> <td></td> </tr> <tr> <td>Harmonisierte Normen Standard harmonisé Norme armonizzate</td> <td>Harmonized standards Las normas armonizadas Normas harmonizadas</td> <td>EN ISO 12100:2010-11 EN ISO 13857:2008-06</td> <td>EN 60204-1/A1:2009-02 EN 61000-6-2/2005-08 EN 61000-6-3/A1:2011-03</td> </tr> </table> <p>Verantwortliche Person für die Technischen Unterlagen siehe unten Responsible person for technical documentation see below La personne responsable pour la documentation technique est mentionnée au-dessous</p> <p> Torsten Ehrhardt Prokurist / authorized officer</p> <p>hawa GmbH, Obere Au 2, D-74847 Obrigheim, Germany</p>			EG - Maschinenrichtlinie Machinery directive Directive "CE" rel. aux machines Directiva de Maquinaria de la CE Direttiva CE sulle macchine nella versione Directiva da UE relativa a maquinaria	2006/42/EG			EMV-Richtlinie Directive CEM Direttiva CEM	EMC-directive Directiva da CEM Directiva CEM	2014/30/EU		WEEE-Richtlinie Directive WEEE Directiva WEEE	WEEE-directive Directiva da WEEE Directiva WEEE	2012/19/EU		RoHS-Richtlinie Directive RoHS Direttiva RoHS	RoHS-directive Directiva de RoHS Directiva RoHS	2011/65/EG		Harmonisierte Normen Standard harmonisé Norme armonizzate	Harmonized standards Las normas armonizadas Normas harmonizadas	EN ISO 12100:2010-11 EN ISO 13857:2008-06	EN 60204-1/A1:2009-02 EN 61000-6-2/2005-08 EN 61000-6-3/A1:2011-03
EG - Maschinenrichtlinie Machinery directive Directive "CE" rel. aux machines Directiva de Maquinaria de la CE Direttiva CE sulle macchine nella versione Directiva da UE relativa a maquinaria	2006/42/EG																					
EMV-Richtlinie Directive CEM Direttiva CEM	EMC-directive Directiva da CEM Directiva CEM	2014/30/EU																				
WEEE-Richtlinie Directive WEEE Directiva WEEE	WEEE-directive Directiva da WEEE Directiva WEEE	2012/19/EU																				
RoHS-Richtlinie Directive RoHS Direttiva RoHS	RoHS-directive Directiva de RoHS Directiva RoHS	2011/65/EG																				
Harmonisierte Normen Standard harmonisé Norme armonizzate	Harmonized standards Las normas armonizadas Normas harmonizadas	EN ISO 12100:2010-11 EN ISO 13857:2008-06	EN 60204-1/A1:2009-02 EN 61000-6-2/2005-08 EN 61000-6-3/A1:2011-03																			
hawa GmbH Obere Au 2-4 74847 Obrigheim / Germany	T + 49 (0) 6261 / 9770-0 F + 49 (0) 6261 / 9770-69 info@hawa.com www.hawa.com	Amtsgericht Mannheim: HRB 441011 Geschäftsführer: Christian Wolf Firmensitz: Obrigheim	This document and its contents hereof are considered proprietary and confidential information of hawa and disclosure to unauthorized individuals or dissemination, publication, or copying is prohibited without prior written consent by hawa GmbH, 74847 Obrigheim, Germany.																			

hm 950 / NanoPak	Declarations of conformity	Chapter 12
------------------	----------------------------	------------

12.2 DIN EN ISO 11607-2 / DIN 58953-7 declaration of conformity of sealing device

 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration de Conformité Declaración de conformidad Dichiarazione di conformità - Declaração de conformidade	9.694.038D
Gültig ab: 01.02.2019 Valid from:	Seite 1/1 Version 1.02	
<p>Hiermit erklären wir, daß die Folienschweissmaschinen: Herewith we declare that the Foil sealing unit: Par la présente, nous déclarons que la gamme de Soudeuse de films plastique: Por la presente certificamos que las máquinas embolsadoras modelos: Dichiariamo con la presente che le macchine per saldatura di fogli: Por este meio se declara que as máquinas de selagem de folhas de plástico:</p> <p style="text-align: center;">NanoPak hm 950 DC-V / hm 950 DC-VI</p> <p>folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen: complies with the requirements of the following regulations and harmonised standards: corresponde aux dispositions suivantes et standards harmonisés: objeto de esta Declaración cumple con las siguientes disposiciones: Sono conformi alle seguenti disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p> <p>Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. KRINKO / BfArM Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention(KRINKO) beim Robert Koch-Institut(RKI) und des Bundesinstitutes für Arzneimittel und Medizinprodukte(BfArM) Bundesgesundheitsblatt 2012 55:1244-1310</p> <p>Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte – Teil 2: ISO 11607-2:2019 Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens Packaging for terminally sterilized medical devcies – Part 2: Validation requirements for forming, sealing and assembly processes Emballages des dispositifs médicaux stérilisés au stade terminal – Partie 2: Exigences relatives aux procédés de mise en forme, de fermeture et d'assemblage</p> <p>Sterilisation – Sterilgutversorgung – Teil 7: DIN 58953-7:2010 Anwendungstechnik von Sterilisationspapier, Vliesstoffen, gewebten textilen Materialien, Papierbeuteln und siegelfähigen Klarsichtbeuteln und -schläuchen Sterilization – Sterile supply – Part 7: Use of sterilization paper, nonwoven wrapping material, textile materials, paper bags and sealable pouches and reels Stérilisation – Approvisionnement en produits stériles – Partie 7: Utilisation de papier pour stérilisation, de matériaux d'enveloppe en non-tissé, matériaux textiles tissés, de sacs en papier, de sachets et gaines scellables</p> <p style="text-align: center;"></p> <p>Torsten Ehrhardt Prokurist / authorized officer hawa GmbH, Obere Au 2, D-74847 Obrigheim, Germany</p>		
hawa GmbH Obere Au 2-4 74847 Obrigheim / Germany	T + 49 (0) 6261 / 9770-0 F + 49 (0) 6261 / 9770-69 info@hawa.com www.hawa.com	Amtsgericht Mannheim: HRB 441011 Geschäftsführer: Christian Wolf Firmensitz: Obrigheim <small>This document and the contents hereof are considered proprietary and confidential information of hawa and disclosure to unauthorized individuals or dissemination, publication, or copying is prohibited without prior written consent by hawa GmbH, 74847 Obrigheim, Germany.</small>

9 510 007, Version 2.01

12.3 CE declaration of conformity for barcode scanner



DECLARATION OF CONFORMITY

CE 09

EC-053

Rev.: 1

Pag.: 1 di 1

Datalogic Scanning Group Srl
Via S. Vitallno, 13
Lippo di Calderara di Reno (BO)
40012 Italy

dichiara che
declares that the
déclare que le
bescheinigt, daß das Gerät
declare que el

Gryphon D41xx Black and Gryphon D41xx White

e tutti i suoi modelli
and all its models
et tous ses modèles
und seine Modelle
y todos sus modelos

sono conformi alle Direttive del Consiglio Europeo sottelenate:
are in conformity with the requirements of the European Council Directives listed below:
sont conformes aux spécifications des Directives de l'Union Européenne ci-dessous:
den nachstehenden angeführten Direktiven des Europäischen Rats:
cumple con los requisitos de las Directivas del Consejo Europeo, según la lista siguiente:

2004/108/EC EMC Directive

Basate sulle legislazioni degli Stati membri in relazione alla compatibilità elettromagnetica ed alla sicurezza dei prodotti.
On the approximation of the laws of Member States relating to electromagnetic compatibility and product safety.
Basée sur la législation des Etats membres relative à la compatibilité électromagnétique et à la sécurité des produits.
Über die Annäherung der Gesetze der Mitgliedsstaaten in bezug auf elektromagnetische Verträglichkeit und Produktsicherheit entsprechen.
Basado en la aproximación de las leyes de los Países Miembros respecto a la compatibilidad electromagnética y las Medidas de seguridad relativas al producto.

Questa dichiarazione è basata sulla conformità dei prodotti alle norme seguenti:
This declaration is based upon compliance of the products to the following standards:
Cette déclaration repose sur la conformité des produits aux normes suivantes:
Diese Erklärung basiert darauf, daß das Produkt den folgenden Normen entspricht:
Esta declaración se basa en el cumplimiento de los productos con las siguientes normas:

EN 55022 (CLASS B ITE), SEPTEMBER 1998:
AMENDMENT A1 (CLASS B ITE), OCTOBER 2000:

LIMITS AND METHODS OF MEASUREMENTS OF RADIO DISTURBANCE
CHARACTERISTICS OF INFORMATION TECHNOLOGY EQUIPMENTS

EN 55024, SEPTEMBER 1998:

INFORMATION TECHNOLOGY EQUIPMENT
IMMUNITY CHARACTERISTICS
LIMITS AND METHODS OF MEASUREMENT

Lippo di Calderara, July 7th, 2009

Ruggero Cacioppo
Quality Assurance Manager

Ruggero Cacioppo

12.4 CE declaration of conformity for label printer

MANUFACTURERS DECLARATION OF CONFORMITY

Product identification Product: Thermal Printer
Type: CG2
Grouping Model: CG208 DT, CG212 DT
 CG208 TT, CG212 TT

Means of conformity

The product is in conformity with the **EMC Directive 89/336/EEC, 92/31/EEC and 93/68/EEC** based on test results using harmonised standards.

EMC standards used: EN 55024:1998 + A1:2001 + A2:2003
 EN 61000-4-2:1995 + A1:1998 + A2:2001
 EN 61000-4-3:2006
 EN 61000-4-4:2004
 EN 61000-4-5:2006
 EN 61000-4-6:1996 + A1:2001
 EN 61000-4-8:1993 + A1:2001
 EN 61000-4-11:2004

Test report N°: S68427

Emission Test report: EN 55022:2006 (Class B)
 EN 61000-3-2:2006
 EN 61000-3-3:1995 + A1:2001 + A2:2005

Test report N°: E68427-1

Test carried out by: Cosmos Corporation; 3571-2, Ohnogi, Watarai.cho, Mieken 516 2102, Japan
Issued: July 17, 2008

The product is in conformity with **Low Voltage Directive 73/23/EEC** based on test results using harmonised standards.

standards used: IEC 60950-1:2005 (2nd Edition) and/or
 EN 60950-1:2006

Test carried out by: Nemko GmbH&Co. KG; 76318 Pfingsttal, Germany
Certificate No: 105311
Date: July. 18th, 2008

Manufacturer: SATO Malaysia Electronics Manufacturing Sdn. Bhd.
 Lot 20, Jalan 223, 46100 Petaling Jaya
 Selangor Darul Ehsan, Malaysia

EC Representative: SATO International Europe NV; Leuvensesteenweg 369
 1932 Sint-Stevens-Woluwe
 Belgium

Function: Managing Director
Date: 01.09.2009

Signature: Dave Joyce





LABORATORY EQUIPMENT MAINTENANCE, REPAIR, CALIBRATION AND SALES

Established in 1987, Henderson Biomedical is the UK's leading laboratory equipment sales and service provider. Our knowledgeable team can provide you with excellent sales advice on a range of different types of laboratory equipment including centrifuges, refrigerators, freezers and heat sealers.

Henderson Biomedical is also able to provide you with first class after-sales service and calibration of your laboratory equipment. We are an **ISO 17025 (UKAS) accredited calibration test laboratory** and our team of Field Service Engineers cover the whole of the United Kingdom.

Please contact us for more information on the types of equipment we supply and the different after-sales services we can offer.

Henderson Biomedical

Unit 3, Swan Close
Croydon CR0 2DZ
United Kingdom

Tel: 020 8663 4610

**For sales enquiries: sales@henderson-biomedical.co.uk
For all other enquiries: info@henderson-biomedical.co.uk
www.henderson-biomedical.co.uk**

