

Memograph M RSG45 digital recorder and Field Data Manager (FDM) reporting software for secure data management and visualization

Manual for HTST recorder/controller per
PMO (Pasteurized Milk Ordinance) installations



Introduction & System description

The Memograph M RSG45 data manager hardware and FDM field data manager software by Endress+Hauser enables reliable, secure measured data recording, electronic record management, batch report creation, archiving and transmission as specified in the FDA 21 CFR Part 11 and compliance to PMO and process authority requirements. Recorded data is stored on RSG45 in internal memory (SD card) or on removable USB memory stick. The std 256mB internal memory hold approximately 6 weeks of data when used as STLR/SFLR with 1 sec recording interval. The FDM reporting software is installed on local SQL server and connected to RSG45 via LAN (Ethernet TCP/IP) for instant access to current and recorded data. Operator can enter annotations directly on recorder or on local server workstation. Records and annotations are available directly on RSG45 for review and approval. The FDM provide a platform for supervisors, regulatory, quality etc to access records and annotations as well as workflow to approve and save records securely on company servers. Printing of records is available. Typical applications are:

- Continuous pasteurization in HTST, UHT and Aseptic
- ESL Applications
- Juice Pasteurization
- Egg Pasteurization
- Cold Product Recording
- Product tank/silo temperature and level
- Clean-In-Place (CIP)
- Clean-Out of-Place (COP)
- Retort, low acid
- General Process Recording and Monitoring

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Compliance to the general requirements of FDA 21 CFR Part 11 (electronic records) and PMO

The recording system comprised of the Memograph M RSG45 and FDM (Field Data Manager) software fulfills the general requirements of FDA 21 CFR part 11 related to system security, data traceability and integrity. Further details are laid out in the Whitepaper: *Memograph M RSG45 and FDM FDA 21 CFR part 11* (supplement WP01028L).

Data integrity & system overview

The graphic data manager Memograph M RSG45 securely records, archives, stores and transmits all relevant information it reads from connected device(s): measured values are recorded, limit values are monitored, and information is securely stored in the internal system memory.

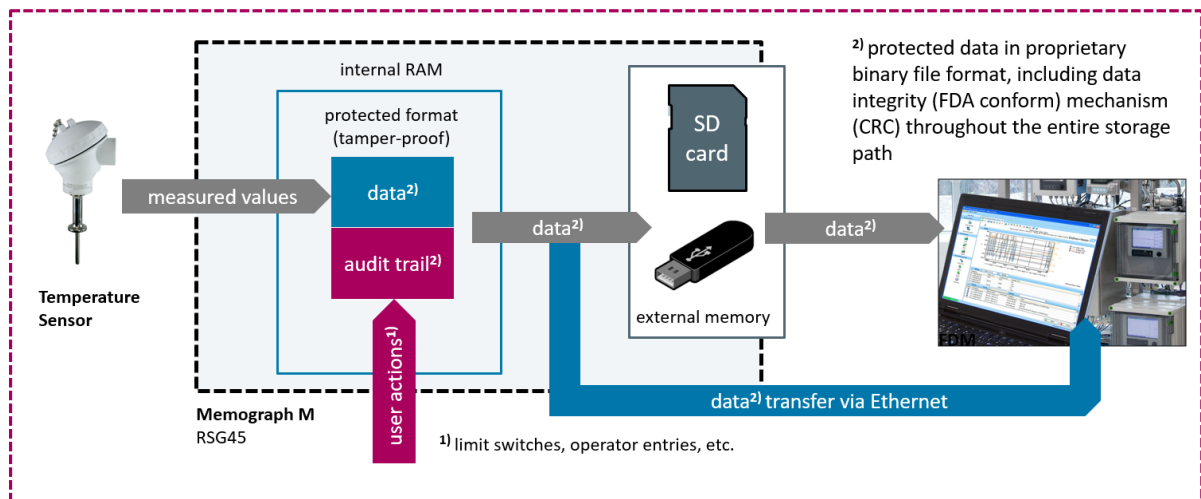


Figure 1: Data integrity from sensor to batch reporting

The data - as defined by measured values and electronic records of audit trail per FDA 21 CFR part 11 - is stored in a proprietary binary file format to protect against tampering. The integrity of the electronic records in the data manager is ensured by means of cyclic redundancy check (CRC). The CRC code is part of the raw data file.

PMO manual for ordering, commissioning and operation of RSG45 data recorder and FDM software

1. Purchasing and scope of supply

1.1. Memograph M RSG45 order code

[illegible]

Note: slot 5 option D must be selected if 2 x 4-20mA output is needed for retransmission. Option “D” Profinet or “E” Ethernet/IP in position 100 should be selected to retransmit measured values to PLC (write function is disabled when sealed)

1.2. Software revision

The firmware revision for PMO applications is ENX200A 2.06.00 (bugfix index)

RSG45 device including PMO specific firmware is ordered via option 570 Service “9 special version”, TSP no. 71631208

For questions on ordering or any support regarding PMO applications please contact Endress+Hauser USA:

Endress+Hauser Inc.

2350 Endress Place
Greenwood, IN 46143

1-888-363-7377

1.3. Identification of device

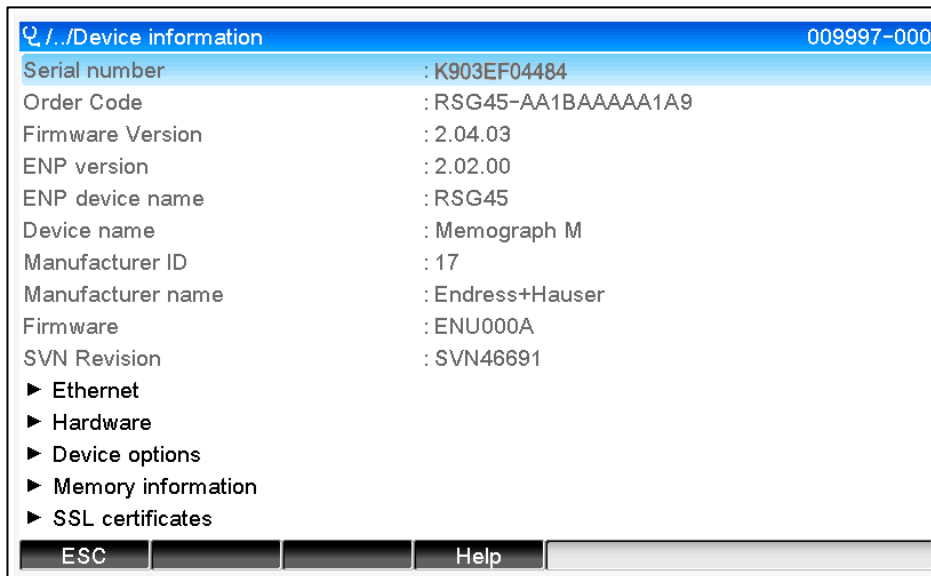
All device information like serial number, order code and firmware version are printed on the type plate of the RSG45. The device can be uniquely identified, and the ordering options can be compared with the options allowed for PMO applications. M-b Memoranda index printed on the type plate.

Made in Germany 2015, D-87484 Nesselwang	
Memograph M	Endress+Hauser 
Ord. cd.: RSG45-13W9/0	Front: IP65 Rear: IP20
Ser. no.: K903EF04484	M-b-3XX
Ext. ord. cd.: RSG45-AA1BAAAAA1A9	
100-230 V AC $\sim$ ($\pm 10\%$) 50/60Hz 40VA	
-10°C (14°F) < Ta < +50°C (122°F)	
FW: 2.04.03	
MAC: 00-07-05-31-42-2E	
	
	

All device information can be displayed during operation by selecting:

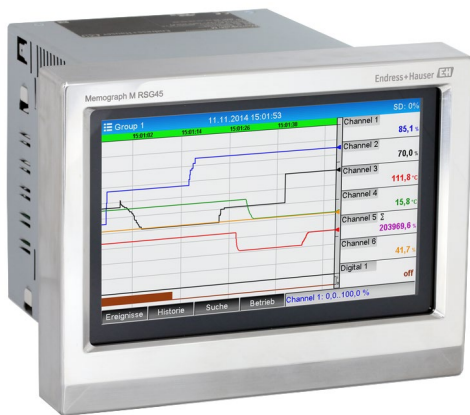
Menu -> Diagnostics -> Device Information

The screen display with all information will appear as shown below*



1.4. Device housing types

For PMO applications the RSG45 Memograph M with display is available in two different housing types. See order code for RSG45 order option 80 A/B



Stainless steel front with touch display (preferred version)

Operation, user guidance and menu structure is identical for both device types. The difference lies in the input of data, e.g. touch screen operation vs. navigator wheel with selection function and confirmation push button. A wired keyboard can be added for user convenience to the zinc diecast version.

1.5. Visualization

What is visible on screen:

By utilizing signal groups, displayed and recorded values is defined by administrator during set-up. Any single or multiple values can be displayed on screen and up to 10 signal groups (screens) that are easily accessed manually by swiping left/right or set to automatically toggle on selectable time intervals. See Examples in fig 1....4

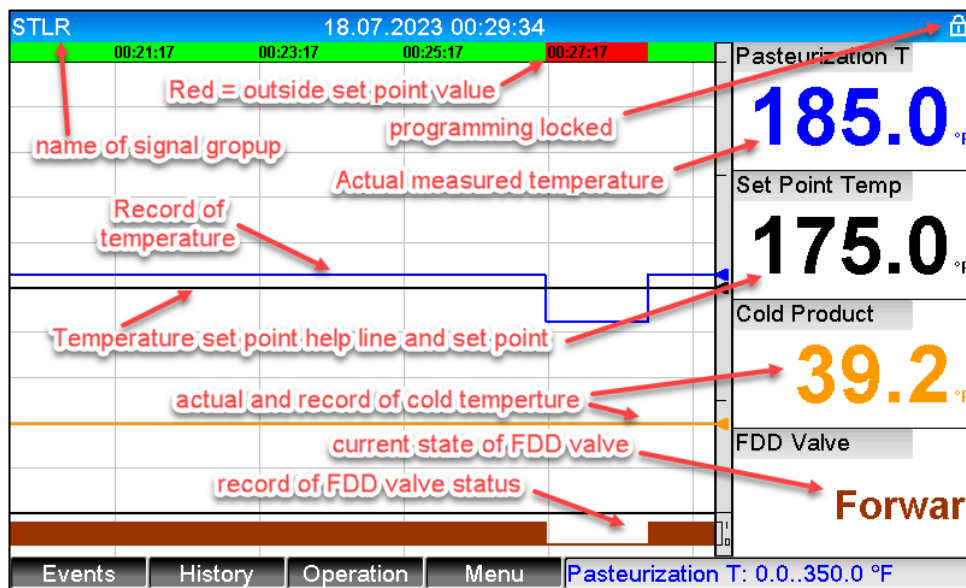


Fig 1 STLR (Safety Thermal Limit Record) screen

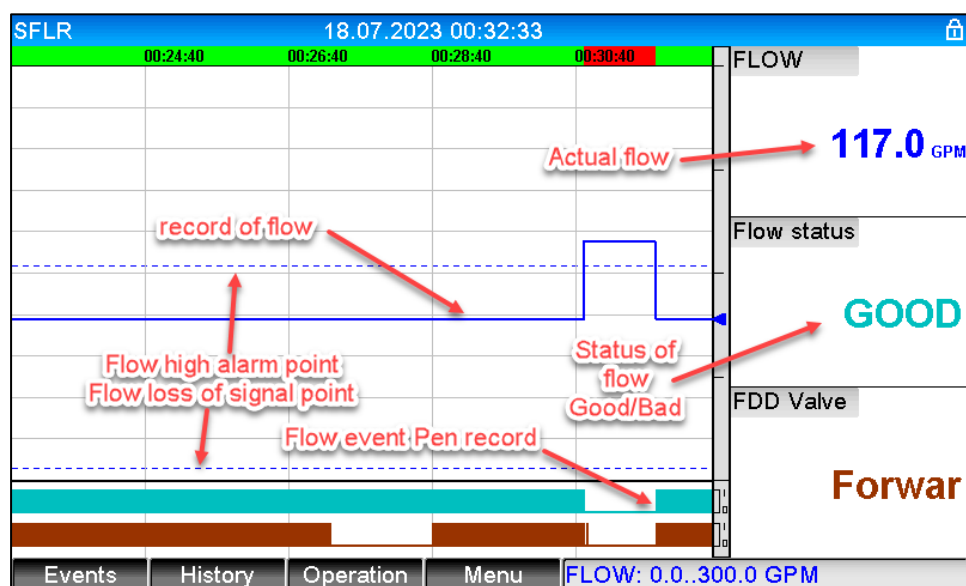


Fig 2 SFLR (Safety Flow Limit Record) screen

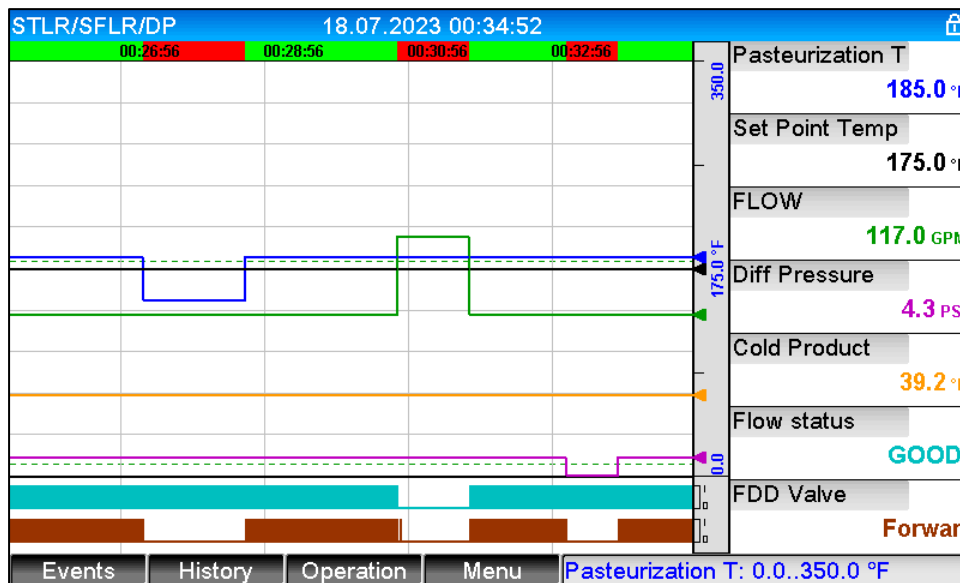


Fig 3 Combined screen with Temperature, Flow, Diff pressure & cold product.

Optional, the RSG45 can be used as differential pressure switch, both sides and diff pressure are displayed and recorded.

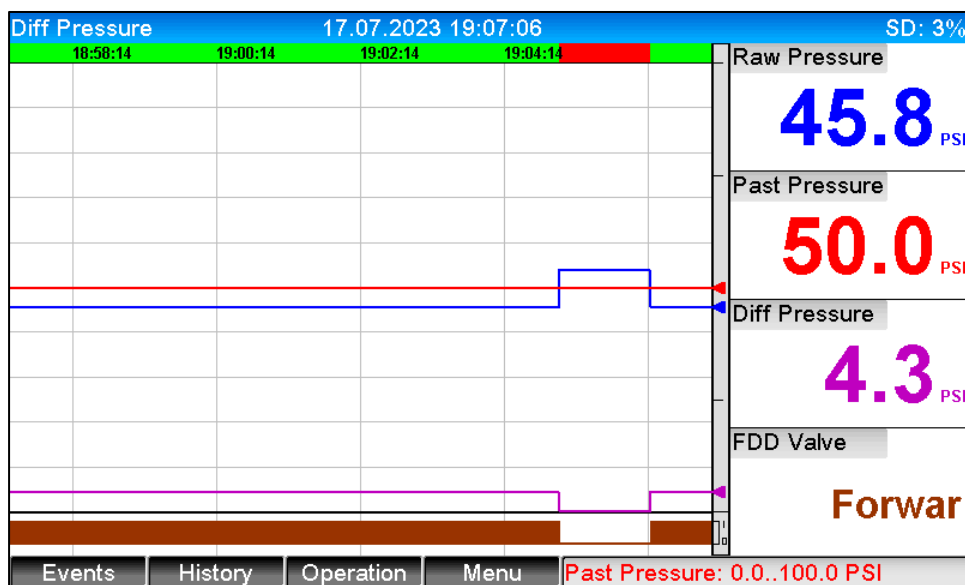


Fig 4 Differential pressure

1.6. Wiring instructions

Wiring of power supply, relay outputs and lock-out jumper

Power unit type	Terminal		
			
100-230 VAC	L+	N-	PE
	Phase L	Zero conductor N	Ground
24 V AC/DC	L+	N-	PE
	Phase L or +	Zero conductor N or -	Ground

Power supply terminal L/+ N/- (PE, ground)

PMO required lock out jumper connect jumper between terminal – and GND and + to Digital input D11 – see figure 5

Relay 2 R21/R22 – output contact for temperature set point (cut out)

Relay 3 R31/32 – output for flow loss of signal

Relay 4 R41/R42 – output for Flow high alarm

Relay 5 R51/R52 – output for Differential pressure switch (if used)

6 additional relays can be ordered in slot 5 if required for a total of 12 relays

Ground (-) bridge -> black wire
Protection jumper (+) to D11 -> white wire

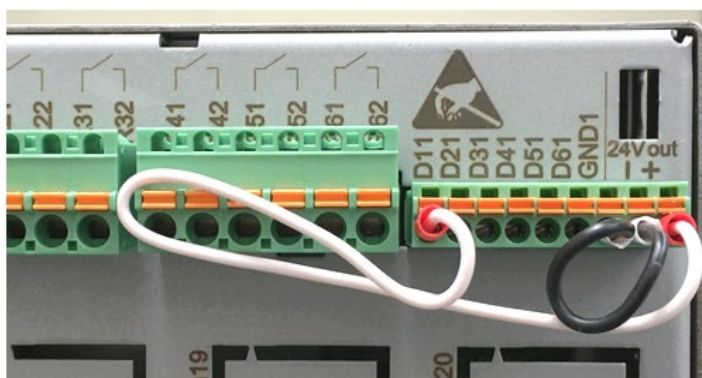
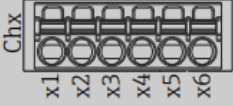
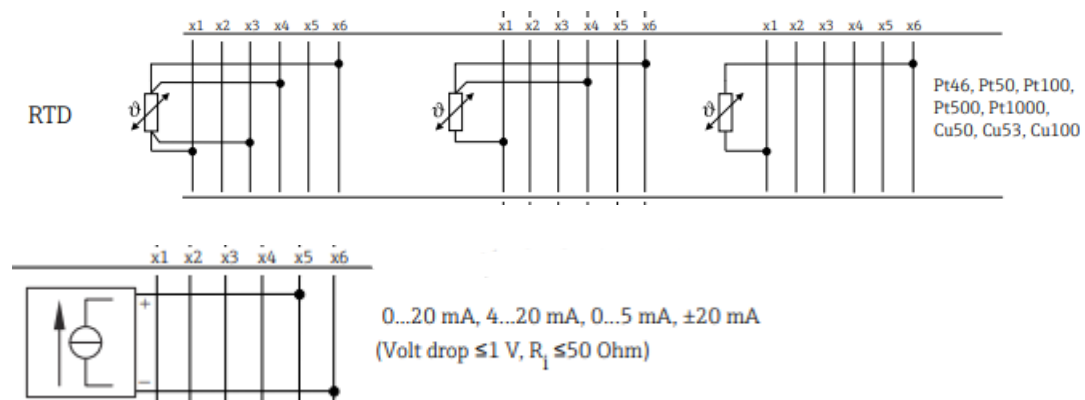


Fig 5 Lock out jumper - this must be disconnected to allow any program changes

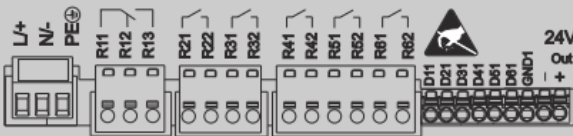
Wiring of inputs (up 20 analog inputs in 5 slots with 4 channels each)

Type	Terminal					
						
	x1	x2	x3	x4	x5	x6
Current/pulse/frequency input ¹⁾					(+)	(-)
Voltage > 1V		(+)				(-)
Voltage ≤ 1V				(+)		(-)
Resistance thermometer RTD (2-wire)	(A)					(B)
Resistance thermometer RTD (3-wire)	(A)			b (sense)		(B)
Resistance thermometer RTD (4-wire)	(A)		a (sense)	b (sense)		(B)
Thermocouples TC				(+)		(-)



- Ch 1 – 4-wire rtd from hold tube, ensure use of shielded cable
- Ch 2 – 4-20mA from Magnetic flowmeter (flow velocity) (SFLR)
- Ch 3 – 3 or 4 wire Pt100RTD from cold product sensor
- Ch 4 – 4-20mA from Pasteurized side pressure sensor (if used)
- Ch 5 – 4-20mA from Raw side pressure sensor (if used)

Wiring of digital inputs – FDD valve feedback, remote change of set point

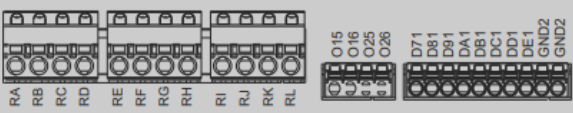
Type	Terminal			
				
Auxiliary voltage output, not stabilized, max. 250 mA			24V Out -	24V Out +
			- Ground	+ 24V ($\pm 15\%$)

 If the auxiliary voltage is to be used for the digital inputs, the **24 V out -** terminal of the auxiliary voltage output must be connected with the **GND1** terminal.

Ch 1 (D11) is used for the required lock out – see figure B

Ch 2 (D21) is used for FDD feedback (open/closed) – see chapter 2.2.8.

Wiring of 2 x 4-20mA re-transmission outputs, optional slot 5 card must be installed.

Type	Terminal			
				
Analog output 1-2	O15	O16	O25	O26
	Analog output 1 (+)	Ground, analog output 1 (-)	Analog output 2 (+)	Ground, analog output 2 (-)

2. Commissioning

The following instructions describe the settings that must be made for PMO applications. For the general setup and further details of the RSG45 please refer to the RSG45 user manual. See www.endress.com

Note, some screenshots below are from RSG45 screen, we recommend using the webserver for faster and easier commissioning as well as saving, up/downloading of programs. Menu terminology and location is identical when using web server

2.1. User administration according to FDA 21 CFR Part 11

For PMO applications it is mandatory to use the user administration according to FDA 21 CFR Part 11 which is implemented in the RSG45.

The RSG45 manages 50 user accounts in 5 authorization levels (administrator, main user, operator 1/2/3) and assigns access rights for the respective accounts. For PMO applications, the only user roles that will be used are “Admin” and “Main User”. We recommend 2 or more individuals with “admin” admin rights. Main users can be added/deleted without breaking regulatory seal. FDA user roles and access authorization:

User administration and authorization in compliance with FDA 21 CFR Part 11					
	Admin	Main user	Operator Level 1	Operator Level 2	Operator Level 3
Setup change	yes	no	no	no	no
Limit (Set point) change	yes	yes	no	no	no
Post protocol	yes	yes	yes	no	no
Quit messages	yes	yes	yes	yes	no

FDA user roles and access authorization

Setup change: change the parameter settings for RSG45, for units with regulatory seal installed, the seal must be broken to make programming changes and lock jumper removed. See Fig B under wiring.

Limit (set-point): The set-point values are defined and entered in “admin” mode only. In Main user mode, only predetermined set point values can be selected by operator. For PMO this is e.g. the divert set-point temperature

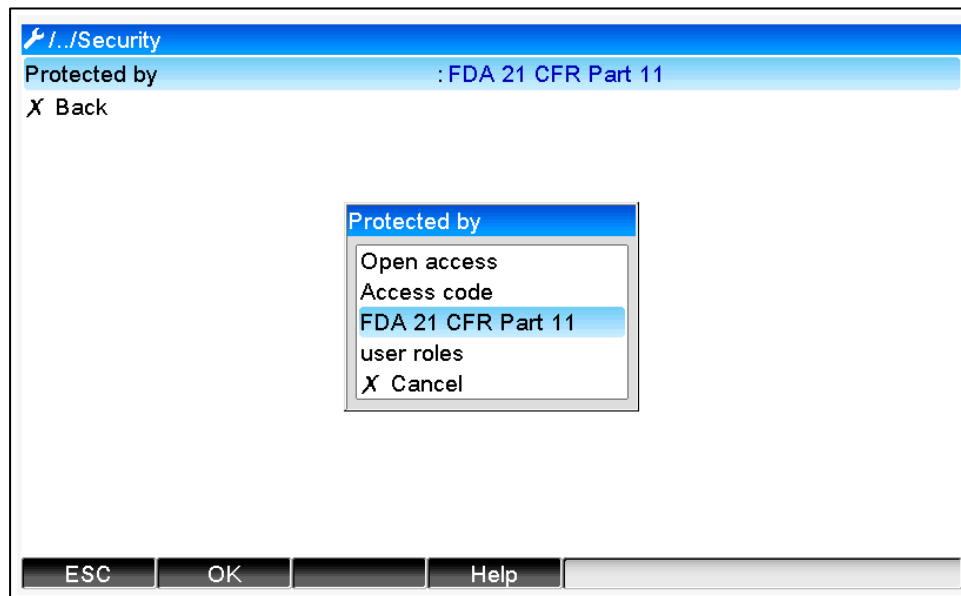
Post protocol: subsequent text entries during or at the end of production batches

Quit messages: confirming of error messages.

2.1.1 Activation of FDA user administration

Select the setting for **FDA 21 CFR Part 11** administration under:

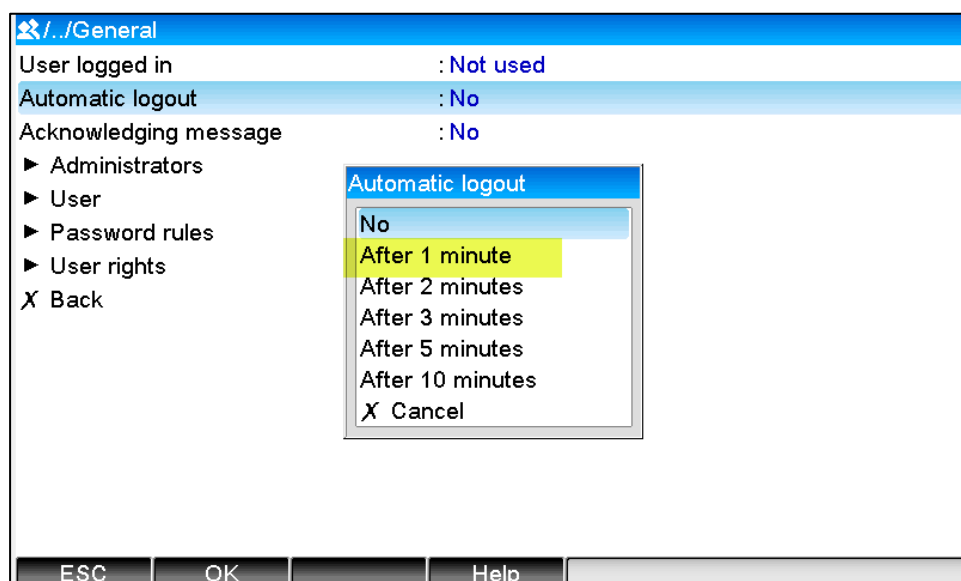
Menu -> Setup -> Advanced setup -> System -> Security -> Protected by



2.1.2. Creation of user accounts and assigning of rights

Step 1: Set up the general FDA administration settings like password rules, log off times, etc.

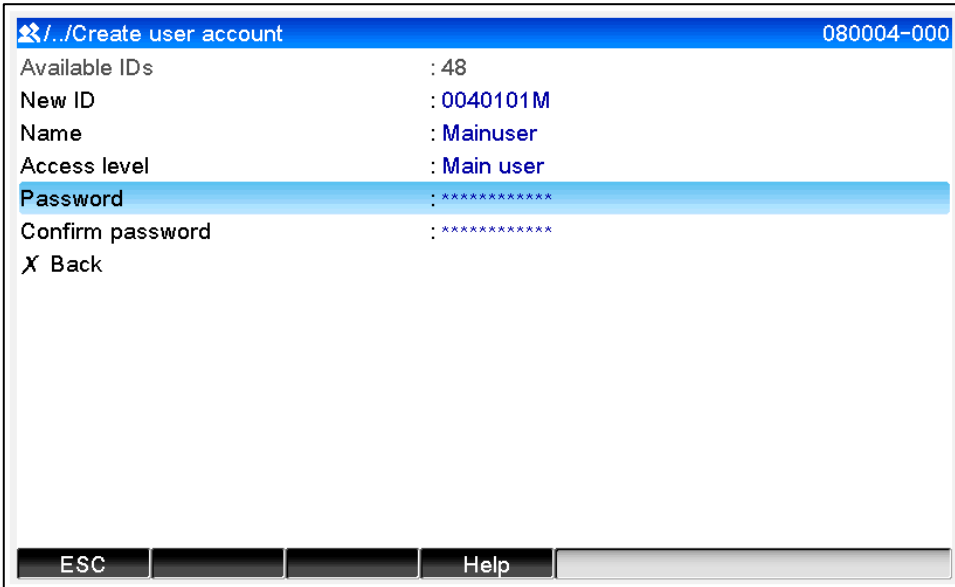
Menu -> User administration -> General



Step 2: Create all user accounts with ID, name, access level and password

Menu -> User administration -> Create user account -> New ID

Important: Once the FDA administration is activated only the admin can manage user accounts. If user name /password of the admin is lost, hard reset code from factory is required for any administration or setup changes. All data/settings will be lost - make sure to remember log-in credentials.



././Create user account 080004-000

Available IDs : 48

New ID : 0040101M

Name : Mainuser

Access level : Main user

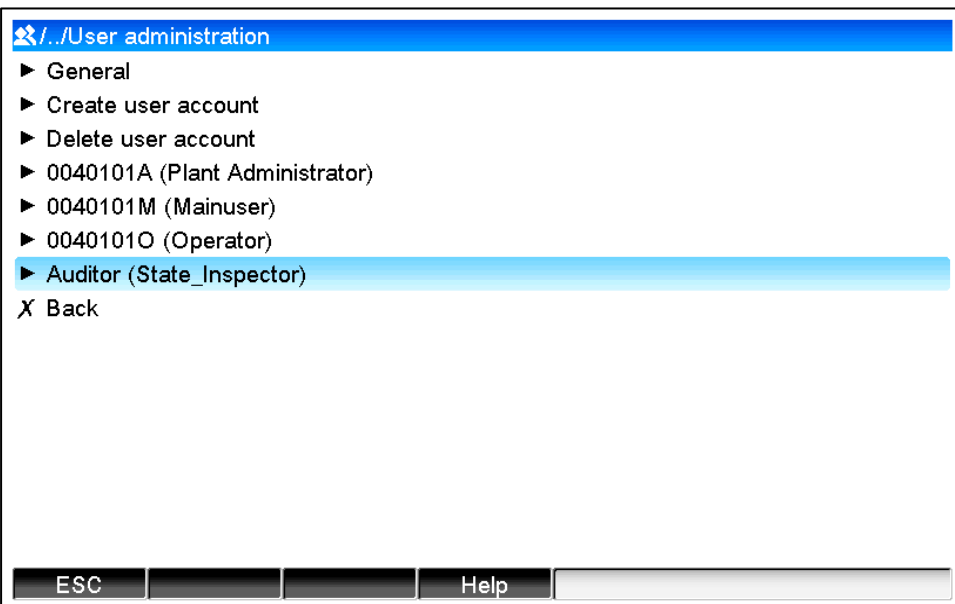
Password : *****

Confirm password : *****

X Back

ESC Help

Example: FDA user role main user



././User administration

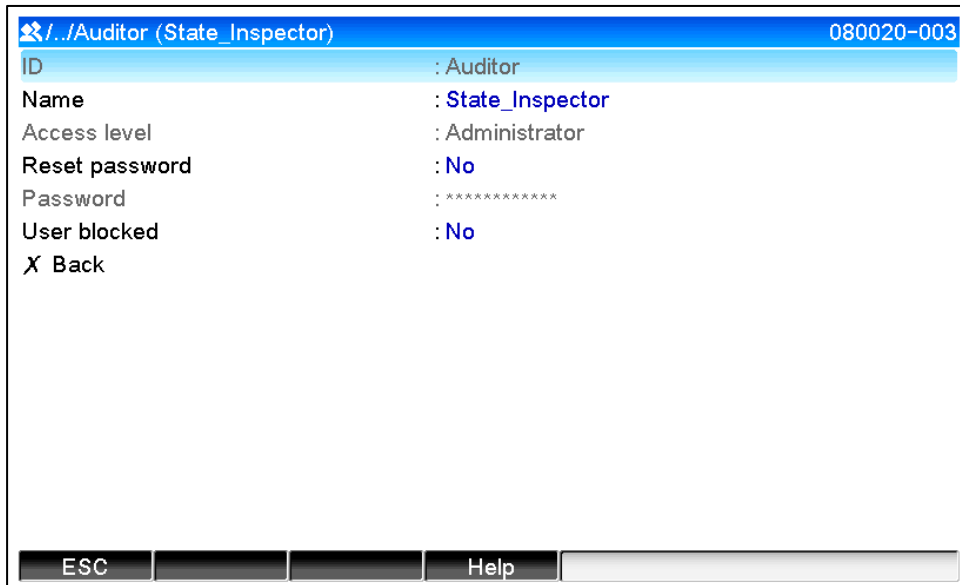
- ▶ General
- ▶ Create user account
- ▶ Delete user account
- ▶ 0040101A (Plant Administrator)
- ▶ 0040101M (Mainuser)
- ▶ 0040101O (Operator)
- ▶ Auditor (State_Inspector)

X Back

ESC Help

Example: overview all created accounts

Remark: To give a state inspector (as an auditor) access to the system and check all parameter setup settings, the plant administrator should create log on credentials for state/FDA inspectors (auditor) (see screenshot above) with an initial password. At the first audit of the system the auditor should change the initial password to a personal password



./Auditor (State_Inspector)		080020-003
ID	: Auditor	
Name	: State_Inspector	
Access level	: Administrator	
Reset password	: No	
Password	: *****	
User blocked	: No	
X Back		

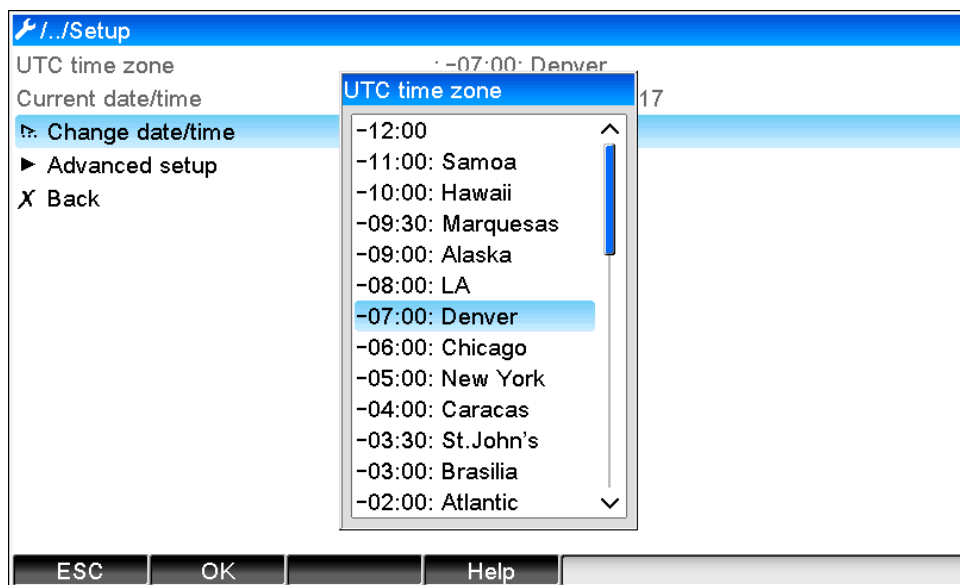
ESC Help

2.1.3. Set up of real time clock

All data records (measured values, operator inputs, events, etc.) are signed with a unique time stamp by activating the integrated real-time clock. In conjunction with the operator authentication, a complete and non-tamperable audit trail is created in accordance with the requirements of FDA 21 CFR part 11.

To set up the real-time clock, please proceed as follows:

Menu -> Setup -> Change date/time



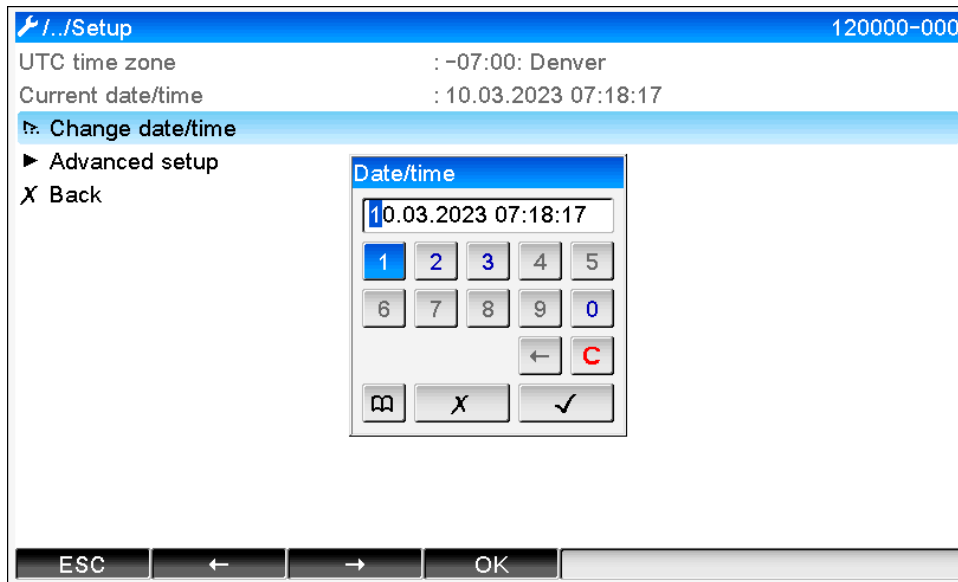
./Setup		-07:00: Denver
UTC time zone		
Current date/time		
Change date/time		
Advanced setup		
X Back		

UTC time zone

- 12:00
- 11:00: Samoa
- 10:00: Hawaii
- 09:30: Marquesas
- 09:00: Alaska
- 08:00: LA
- 07:00: Denver
- 06:00: Chicago
- 05:00: New York
- 04:00: Caracas
- 03:30: St. John's
- 03:00: Brasilia
- 02:00: Atlantic

ESC OK Help

Select the UTC time zone



Adjust date/time details if necessary

2.2. Safety Temperature Limit Recorder (STLR)

For PMO compliant application as a STLR the device parameter set up has to be executed as described in the following chapters below.

2.2.1. Example set up for a temperature measurement value

To record a measured temperature value, please proceed as follows:

Menu -> Setup -> Advanced setup -> Inputs -> Universal inputs -> Add input

Select physical input by number, set up channel name (e.g. Pasteurization), define measurement and display range, etc. For all details, please refer to the RSG45 operating manual.

Temperature sensors for PMO applications can be analog 4-20mA sensors or 3/4-wire RTD sensors. Example configurations see below:

/.../Pasteurization T (1) (active)		220000-000
Signal	: Current	
Range	: 4-20 mA	
Channel ident.	: Pasteurization T	
Plot type	: Instantaneous value	
Engineering unit	: °F	
Decimal point	: One (X.Y)	
Range start	: 32.0 °F	
Meas. range end	: 215.0 °F	
Zoom start	: 32.0 °F	
Zoom end	: 215.0 °F	
Damping	: 0.0 s	
► Totalization		
► Linearization		
Copy settings	: No	
X Back		
ESC		Help

Example: setup of 4-20mA analog temperature sensor

/.../Pasteurization T (1) (active)		220002-000
Signal	: Resistance therm., RTD	
Range	: Pt100 (IEC)	
Connection	: 4-wire	
Channel ident.	: Pasteurization T	
Plot type	: Instantaneous value	
Engineering unit	: °F	
Decimal point	: One (X.Y)	
Range start	: -328.0 °F	
Meas. range end	: 1562.0 °F	
Zoom start	: 32.0 °F	
Zoom end	: 215.0 °F	
Damping	: 0.0 s	
► Totalization		
► Linearization		
Copy settings	: No	
ESC		Help

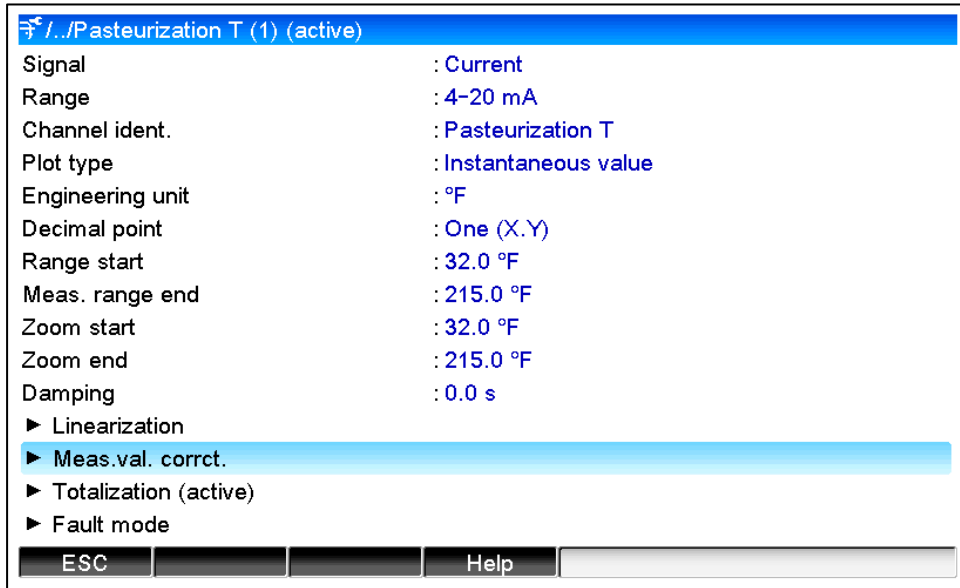
Example: setup of 4-wire RTD analog temperature sensor

2.2.2. Temperature Offset

To ensure compliance of the recording thermometer reading versus the indicating thermometer reading (DRT), an offset can be entered. The configuration for 4-20mA and RTD sensors is slightly different.

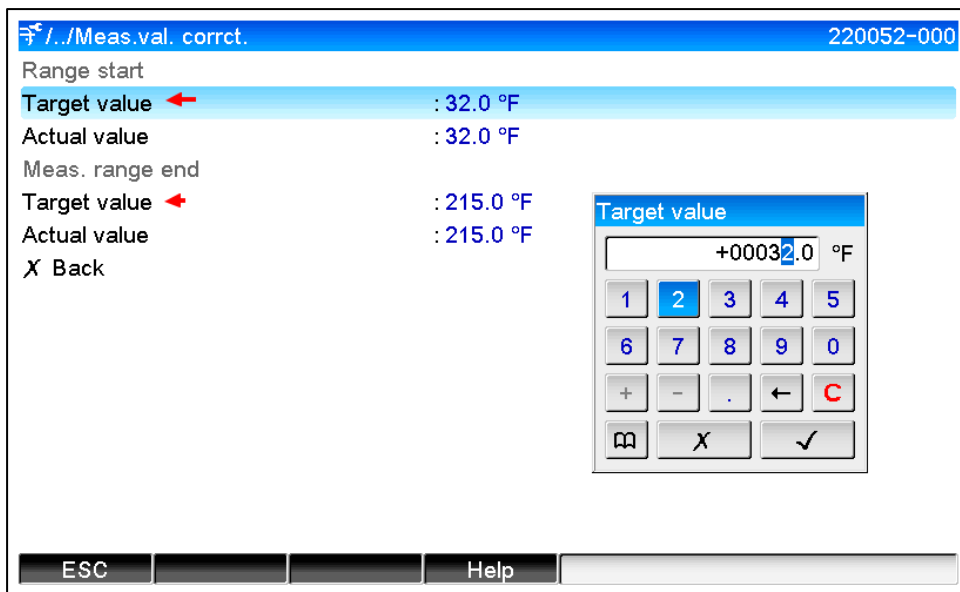
For 4-20mA sensors please proceed as follows:

Menu -> Expert -> Inputs -> Universal inputs
-> **select the temperature (4-20mA) sensor**



././Pasteurization T (1) (active)	
Signal	: Current
Range	: 4-20 mA
Channel ident.	: Pasteurization T
Plot type	: Instantaneous value
Engineering unit	: °F
Decimal point	: One (X.Y)
Range start	: 32.0 °F
Meas. range end	: 215.0 °F
Zoom start	: 32.0 °F
Zoom end	: 215.0 °F
Damping	: 0.0 s
▶ Linearization	
▶ Meas.val. correct.	
▶ Totalization (active)	
▶ Fault mode	
ESC	Help

Select ***“Meas.val.correct.”***



././Meas.val. correct.		220052-000
Range start		
Target value	: 32.0 °F	
Actual value	: 32.0 °F	
Meas. range end		
Target value	: 215.0 °F	
Actual value	: 215.0 °F	
X Back		
		Target value +00032.0 °F 1 2 3 4 5 6 7 8 9 0 + - . ← C ⏮ X ✓
ESC	Help	

The target values entered should be the same delta versus the respective actual values. This will ensure a constant offset across the entire 4-20 mA range.

Remark: offset correction is an expert parameter which can only be done by a plant administrator when setup lock jumper is removed

For RTD sensors please proceed as follows:

Menu -> Expert -> Inputs -> Universal inputs -> select the temperature (RTD) Sensor

./Pasteurization T (1) (active)	
Signal	: Resistance therm., RTD
Range	: Pt100 (IEC)
Connection	: 4-wire
Channel ident.	: Pasteurization_T
Plot type	: Instantaneous value
Engineering unit	: °F
Decimal point	: One (X.Y)
Range start	: -328.0 °F
Meas. range end	: 1562.0 °F
Zoom start	: 32.0 °F
Zoom end	: 215.0 °F
Damping	: 0.0 s
► Linearization	
► Meas.val. correct.	
► Totalization	
ESC Help	

Offset

+00000.5 °F

1	2	3	4	5
6	7	8	9	0
+	-	.	←	C
⏏	X	✓		

Enter a value with the indicated offset.

2.2.3. Limit switches (divert set-point) for temperature measurement.

Monitoring the process temperature is the most important aspect in heat treatment process applications. The measured value can be monitored with limit values. Limit value violations are logged in the audit trail and displayed in the recording. Setting up a divert set-point temperature for a measuring channel:

Menu -> Setup -> Advanced setup -> Application -> Limits -> Add limit value

./Divert set-point (1) (active)		450003-000
Channel/value	: Pasteurization T	
Type	: Lower set point	
Identifier	: Divert set-point	
Set point	: 178.0 °F	
Hysteresis (abs.)	: 1.5 °F	
Time delay	: 0 s	
Switches	: Relay 1	
LV messages	: Do not acknowledge	
Save event	: Yes	
Event text LV on	:	
Event text LV off	:	
Record duration of LV on	: No	
Save cycle	: Normal	
Draw help line	: Yes	
Copy settings	: No	
ESC Help		

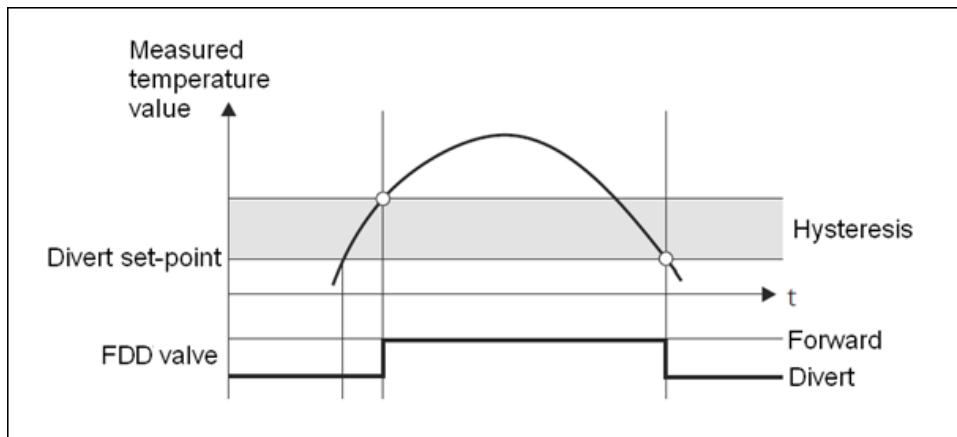
Hysteresis (abs.)

000001.5 °F

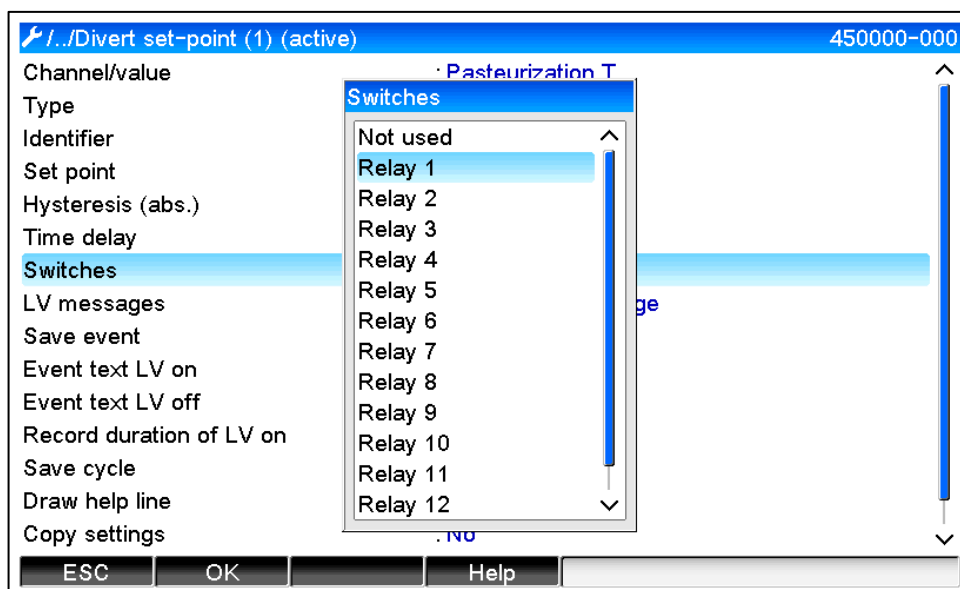
Min: 0

1	2	3	4	5
6	7	8	9	0
.	←	C		
⏏	X	✓		

A positive hysteresis of up to 1.5degF can be applied to divert set-point value monitoring. If the temperature is exceeded, the FDD-valve is switched according to picture below, if the measured temperature falls below the divert set-point this is done immediately. All Relays should be set to “opening” to ensure failsafe mode in case of power failure or other errors.



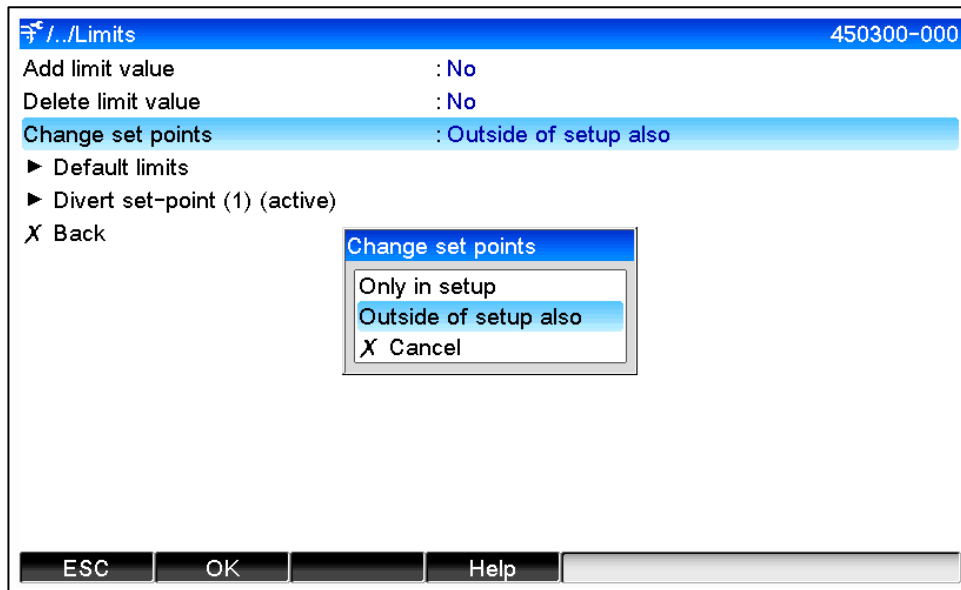
To switch a relay indicating the divert set-point temperature has been met to the public health controller, select one of the onboard relays.



Important: to give operator ability to select a new divert set-point during operation activate the access as follows:

Menu -> Expert -> Application -> Limits

-> Change set points -> “Outside of setup also”

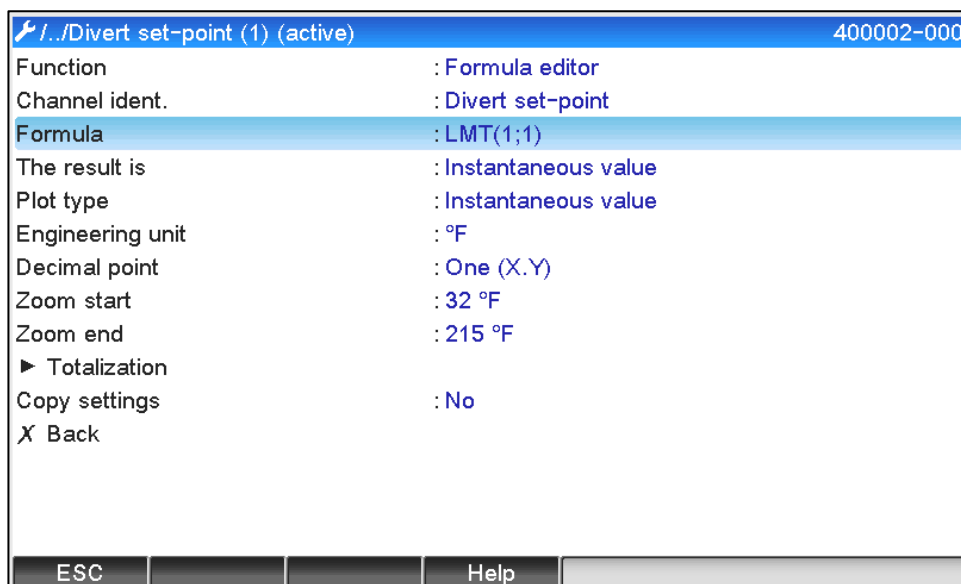


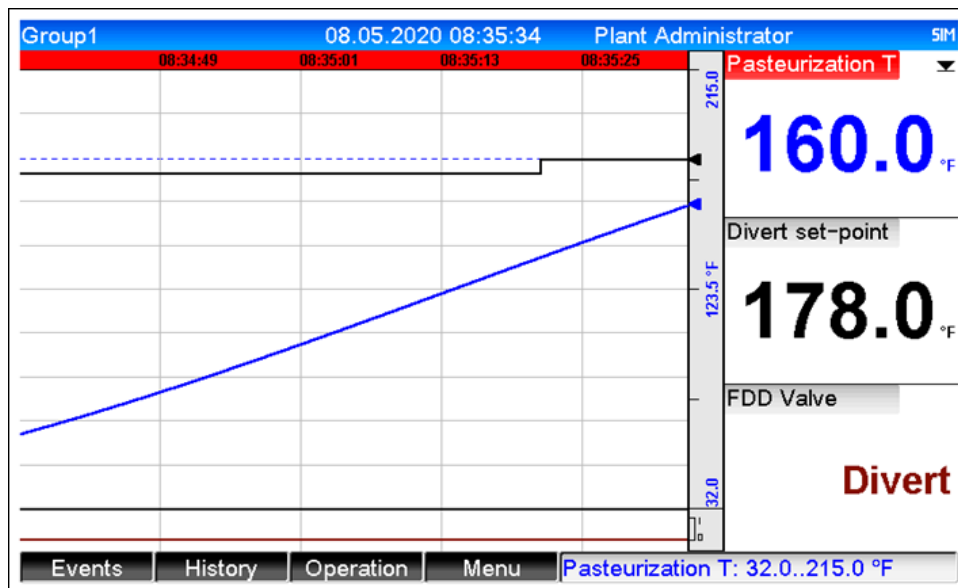
2.2.4. Draw line for divert set-point for temperature measurement

To visualize the actual divert set-point temperature on the main screen, a mathematic function can be used .

Input example to set up a draw line for limit switch , e.g. Pasteurization_T:
Menu -> Setup -> Advanced setup -> Application -> Maths

The formula LMT(1;1) assigns the set point (1) to the channel identifier **Divert Set-point**. This value will be displayed as draw line.



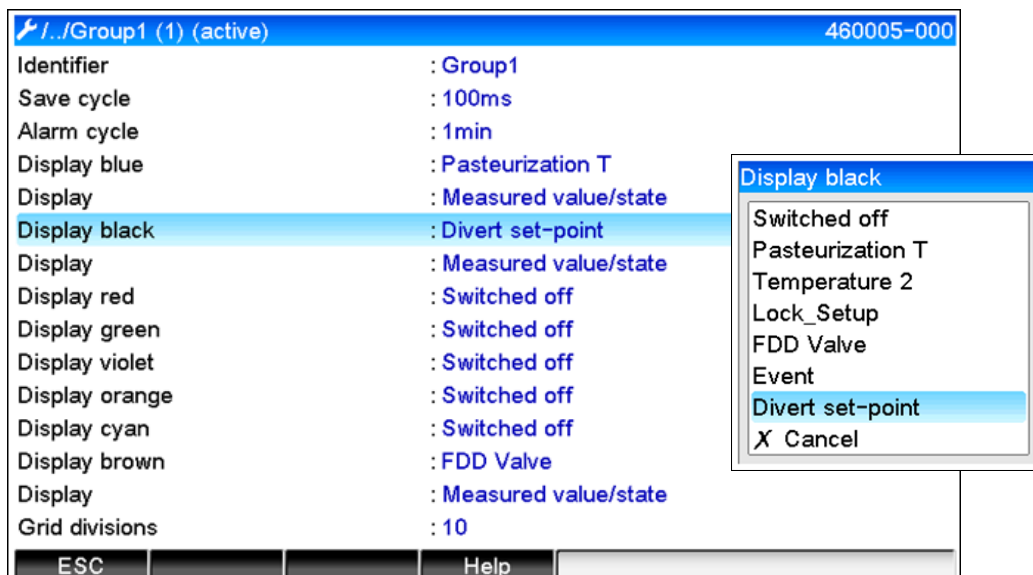


The draw line will be displayed in the analysis software “FDM Field Data Manager” in the same way. The example above shows a divert set-point change from 172°F to actual 178°F. Any selection of a set-point (e.g. for a new batch) executed by an operator is documented tamper-proof with ID, user name and timestamp according to FDA 21 CFR Part 11 in the audit-trail.

2.2.5. Visualization

To visualize the measured temperature, divert set-point temperature, and FDD valve state, proceed as follows and assign the measures to the colors as shown in the screenshot below.

Menu -> Setup -> Advanced setup -> Application -> Signal groups -> Group 1

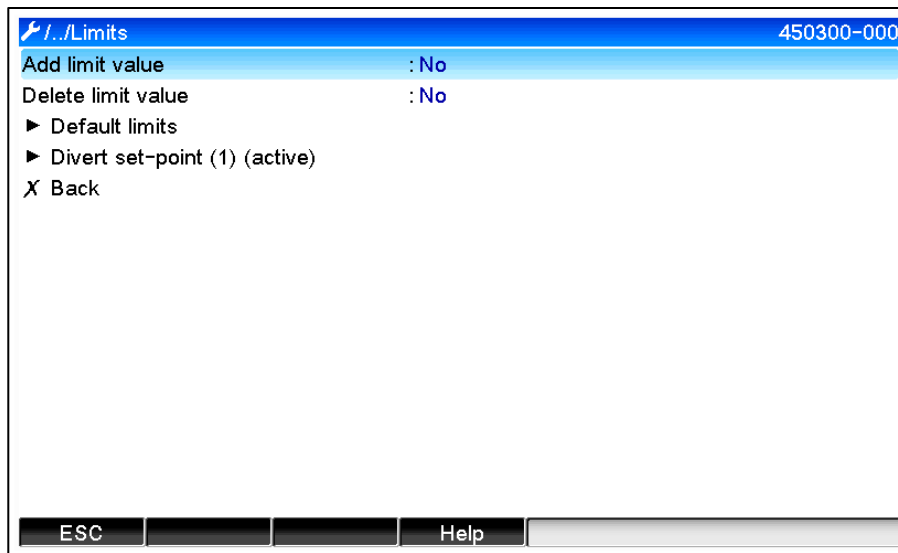


2.2.6. Predefined divert set-point temperatures (Default limits)

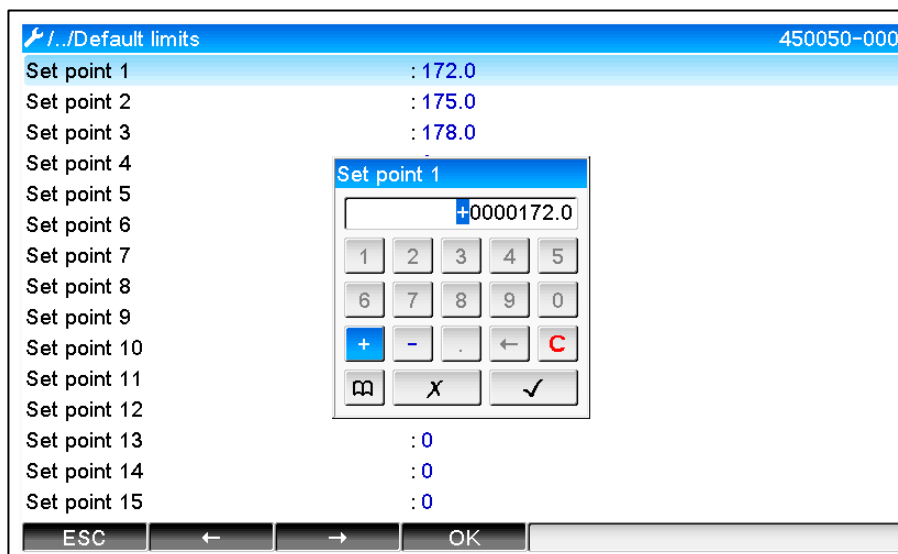
The divert set-point temperature witch can be selected by a “main user” during operation of a batch must be predefined by the plant administrator during set-up and prior to sealing unit. This prevents the main user from entering impermissible values for the divert set-point temperature.

The system administrator can enter up to 20 standard limit values in a list. To edit the list, the administrator must be logged in and edit the values according to the following path:

Menu -> Setup -> Advanced setup -> Application -> Limits -> Default limits



A temperature value can be assigned to each of the 20 list entries



2.2.7. FDD (flow diversion valve) status indication

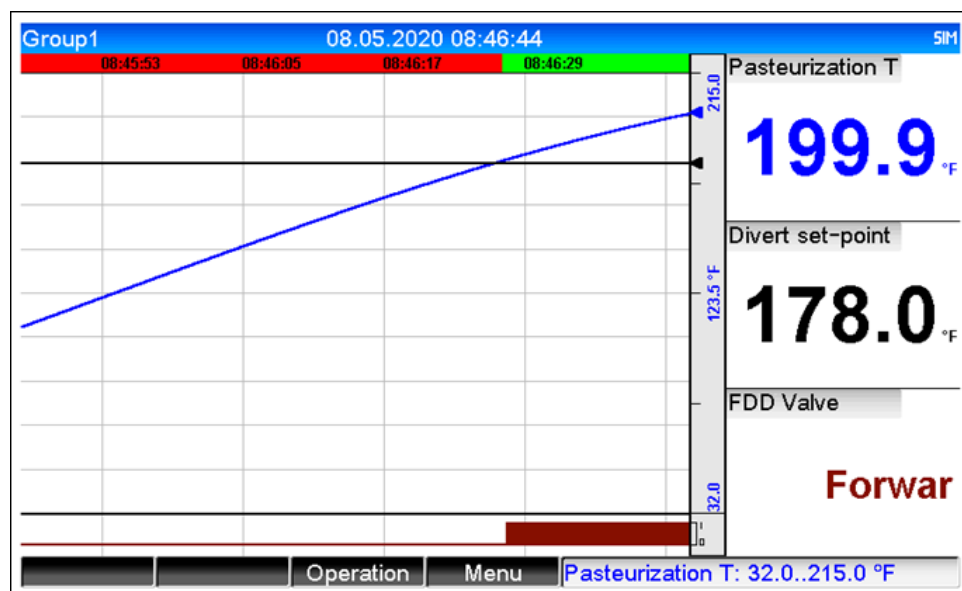
To indicate the FDD valve status configure a digital input (where the FDD valve status signal is wired) as a control input like shown below.

Menu -> Setup -> Advanced setup -> Inputs -> Digital inputs -> Add input

/.../FDD Valve (2) (active)		250000-001
Function	: Control input	
Channel ident.	: FDD Valve	
Action	: Switched off	
Switches relay	: Not used	
Description `H`	: Forwar	
Description `L`	: Divert	
Save event	: Yes	
Event Message	: Do not acknowledge	
Event text L->H	: Forward	
Event text H->L	: Divert	
Record duration	: No	
Copy settings	: No	
X Back		

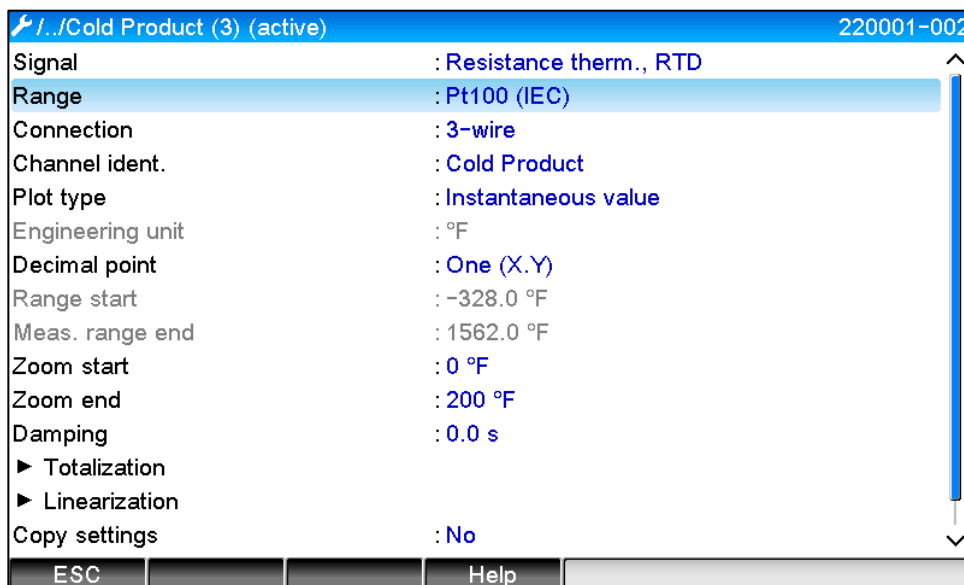
ESC Help

Visualize the status in the signal group. Display will be like shown below.



2.2.8. Display of cold product temperature (optional)

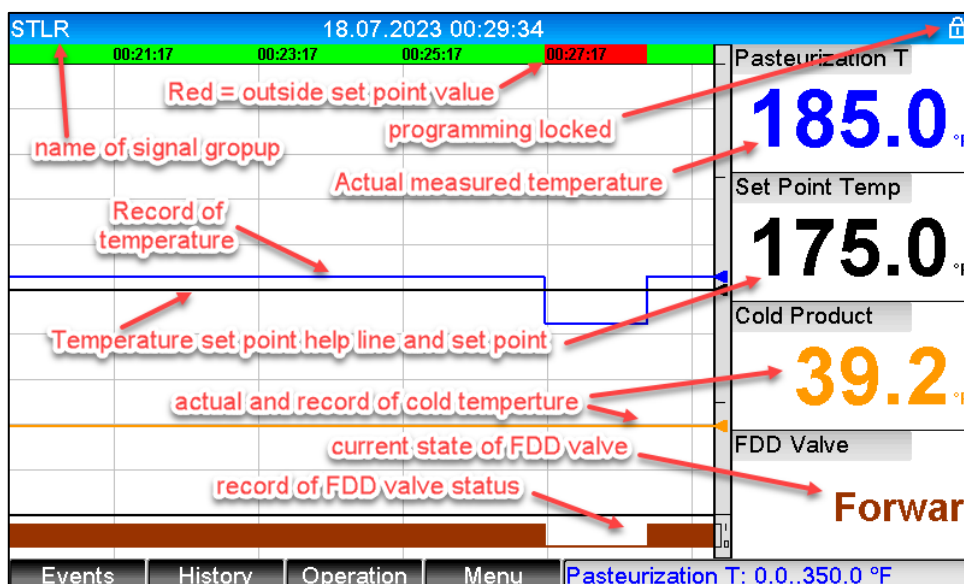
An optional temperature sensor can be connected and set up to display the cold product temperature.



Example: parameter setting of an optional cold product temperature sensor.

2.2.9. STLR visualization

After completing the set up the visualization will display the information as shown below:



2.3. Safety Flow Limit Recorder (SFLR)

In addition to monitor the temperature signal as a Safety Thermal Limit Recorder (STLR), the RSG45 data manager can take over the functionality of the Safety Flow Limit Recorder (SFLR) in the same device. The basic task is to monitor and record the (product) flow rate and to output and document the "High flow alarm" and the alarm for low flow (Loss of Signal).

2.3.1. Configuration of flow monitoring

To record and monitor the flow value, please proceed as follows:

Menu -> Setup -> Advanced setup -> Inputs -> Universal inputs -> Add input

Select physical input by number, set up channel name (e.g. Flow), select unit GPM and measurement range 0 to XXX GPM. The maximum value XXX for the flow corresponds to the 20mA signal which equals to the calibrated signal of the flow sensor. In the example for the screenshots a maximum flowrate of 300 GPM was chosen.

/.../FLOW (3) (active)		400000-002
Function	: Formula editor	
Channel ident.	: FLOW	
Formula	: AI(1;2)	
The result is	: Instantaneous value	
Plot type	: Instantaneous value	
Engineering unit	: GPM	
Decimal point	: One (X.Y)	
Zoom start	: 0 GPM	
Zoom end	: 300 GPM	
► Totalization		
Copy settings	: No	
X Back		

ESC			Help	
-----	--	--	------	--

The measured flow value can be monitored with two limit switches regarding a high flow alarm and low flow (Loss of Signal). These limit value violations are logged in the audit trail and displayed in the recording. The limit values switch two relays to give a signal to a PLC or to switch warning lights

2.3.2. Setting up the alarm for “Loss of Signal”

Setting up the limit switch for “Low” Flow please proceed as follows:

Menu -> Setup -> Advanced setup -> Application -> Limits -> Add limit value

/.../FlowLossOfSignal (2) (active)		450000-001
Channel/value	: FLOW	
Type	: Lower set point	
Identifier	: FlowLossOfSignal	
Set point	: 8 GPM	
Hysteresis (abs.)	: 0 GPM	
Time delay	: 0 s	
Switches	: Relay 3	
LV messages	: Do not acknowledge	
Save event	: Yes	
Event text LV on	: Flow loss of signal	
Event text LV off	: Flow loss of signal OK	
Record duration of LV on	: No	
Save cycle	: Normal	
Draw help line	: Yes	
Copy settings	: No	
ESC Help		

Relay no. 3 – assigned to indicate Loss of Signal (Low Flow) alarm

2.3.3. Setting up the “High Flow Alarm”

Setting up the limit switch for “High” Flow please proceed as follows:

Menu -> Setup -> Advanced setup -> Application -> Limits -> Add limit value

/.../Flow_High_Alarm (3) (active)		450000-002
Channel/value	: FLOW	
Type	: Upper set point	
Identifier	: Flow_High_Alarm	
Set point	: 155.0 GPM	
Hysteresis (abs.)	: 0 GPM	
Time delay	: 0 s	
Switches	: Relay 4	
LV messages	: Do not acknowledge	
Save event	: Yes	
Event text LV on	: Flow High Alarm	
Event text LV off	: Flow High Alarm OK	
Record duration of LV on	: No	
Save cycle	: Normal	
Draw help line	: Yes	
Copy settings	: No	
ESC Help		

Relay no. 4 – assigned to indicate flow high alarm

2.3.4. SFLR Status indication

With a mathematic formula the flow signal can be checked if it is within the defined borders (low flow, high flow). The resulting status “GOOD” or “BAD” can be indicated.

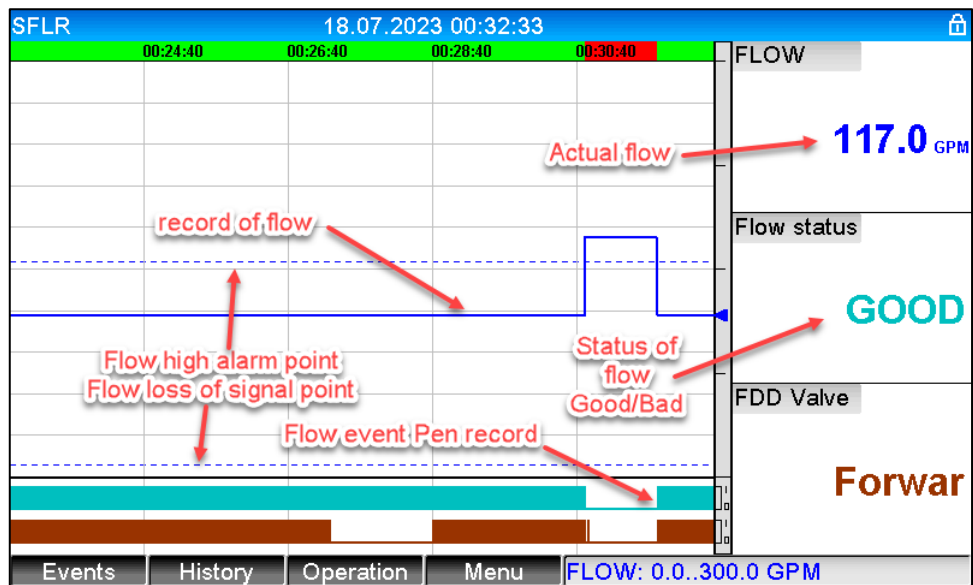
/.../Flow Status (4) (active)		400000-003
Function	: Formula editor	
Channel ident.	: Flow Status	
Formula	: if(or(Al(5;2)=0;or(LMT(2;2);LMT(2;3)))=1;0;1)	
The result is	: State	
Switches relay	: Not used	
Description `H`	: GOOD	
Description `L`	: BAD	
Save event	: Yes	
Event Message	: Do not acknowledge	
Event text L->H	: flow inside limits	
Event text H->L	: flow outside limits	
Record duration	: No	
Copy settings	: No	
X Back		
ESC		
Help		

2.3.5. SFLR Visualization

To visualize the flow signal, the “High flow” limit and the “Loss of Signal” limit it is recommended to use a new display group. According to chapter 2.2.5. define a new group “SFLR” and visualize the flow measurement. The graph will show all needed information including measured flow signal, flow signal status (green/red) and draw lines of the “High flow” and the “Loss of Signal” limits.

/.../SFLR (3) (active)		460000-002
Identifier	: SFLR	
Save cycle	: 1s	
Alarm cycle	: 1min	
Display blue	: Switched off	
Display black	: Switched off	
Display red	: Switched off	
Display green	: FLOW	
Display	: Measured value/state	
Display violet	: Switched off	
Display orange	: Switched off	
Display cyan	: Flow Status	
Display	: Measured value/state	
Display brown	: FDD Valve	
Display	: Measured value/state	
Grid divisions	: 10	
ESC		
Help		

After completing the set up the visualization will display the information as shown below:

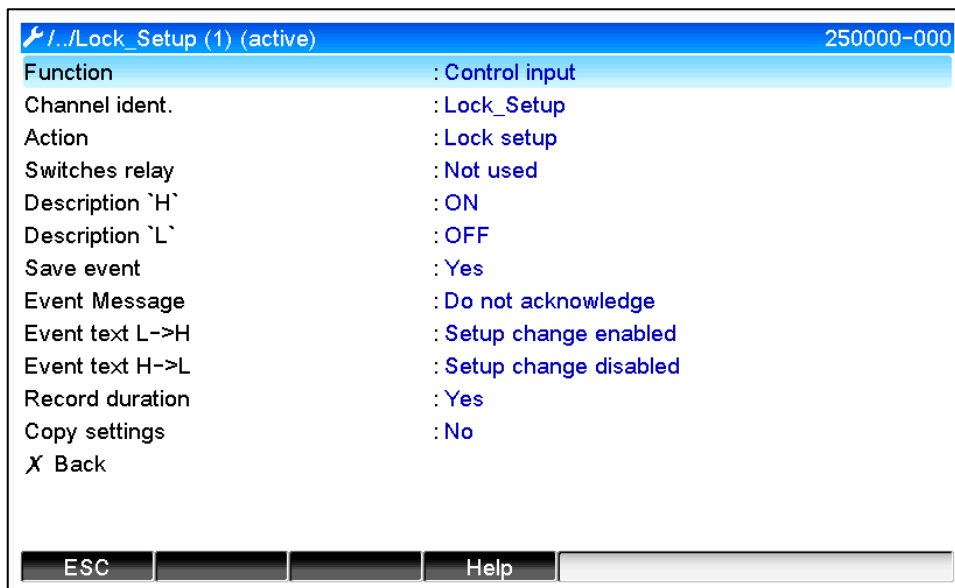


2.4. Setup protection

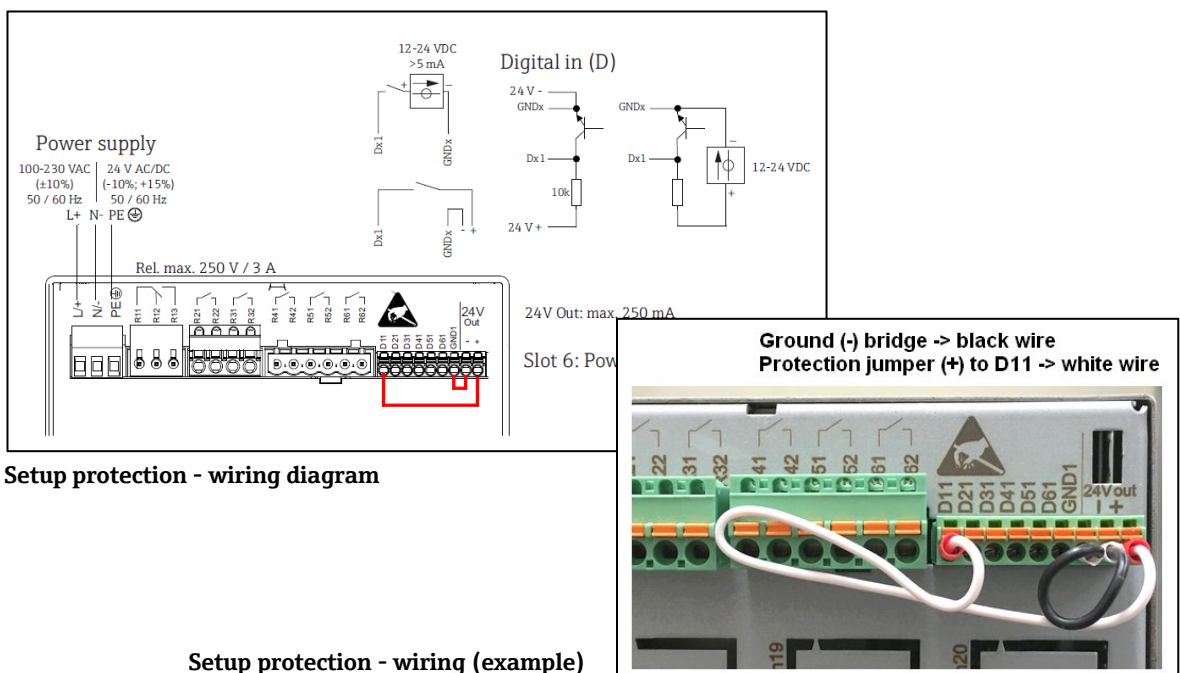
For PMO applications the changing of the setup (all parameters) need to be secured against accidental or intentional modification by configuring a digital input as a “setup lock”.

Activation of the setup lock in RSG45 settings:

Menu -> Setup -> Advanced setup -> Inputs -> Digital inputs -> Add input



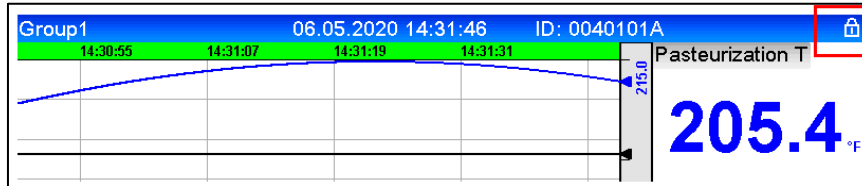
The digital input is connected to +24V/DC by a jumper (wire bridge) or e.g. a key switch according to the wiring diagram below for digital input D11.



Setup protection - wiring diagram

Setup protection - wiring (example)

During operation the setup lock is indicated on the top right corner of the display.

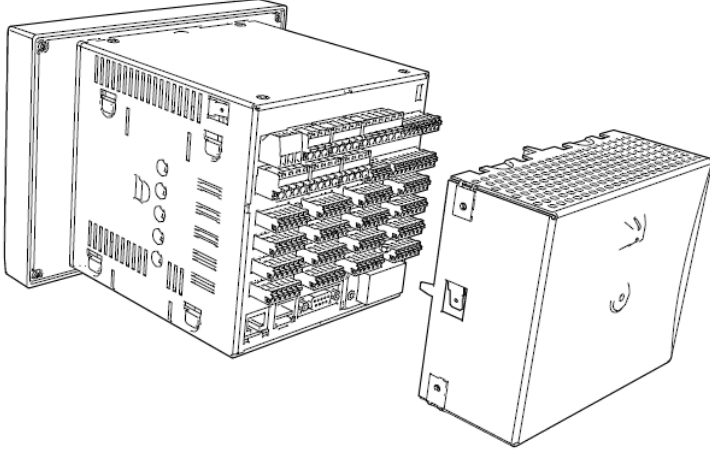


Configure event messages (the messages will appear in the audit-trail when the jumper is closed/opened) according your needs.

In addition to this hardware protection, only a user with access rights as administrator can change the setup (FDA user administration needs to be enabled, see chapter 2.1.1ff). **Exception:** the divert set-point of the temperature monitoring can be changed during operation by a user of the role "main user", see chapter 3.2.).

2.5. Terminal cover

After commissioning the device and wiring and all setup settings are finished, the hardware protection jumper (see above) can be set and the complete terminal block of the device can be covered by the RSG45 terminal cover for panel mount devices (stainless steel or zinc diecast versions). The cover fits on both housing versions and can be sealed with a regulatory seal like shown in picture below.

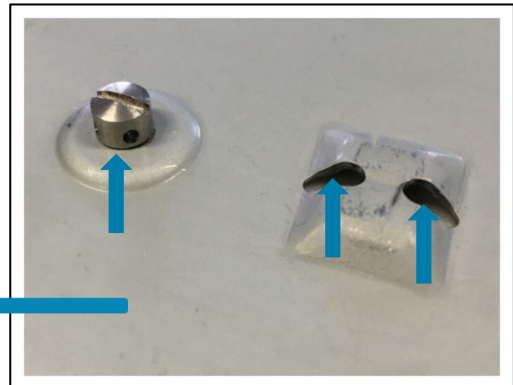
Description	Order No.
Terminal cover can be sealed (for panel-mounted device) An optional terminal cover is available to prevent tampering at the device terminals and terminal temperature measurement. 	XPR0011-A5

RSG45 Terminal cover

Terminal cover mounted on RSG45 (stainless steel version)



Terminal cover on RSG45 (zinc diecast version)

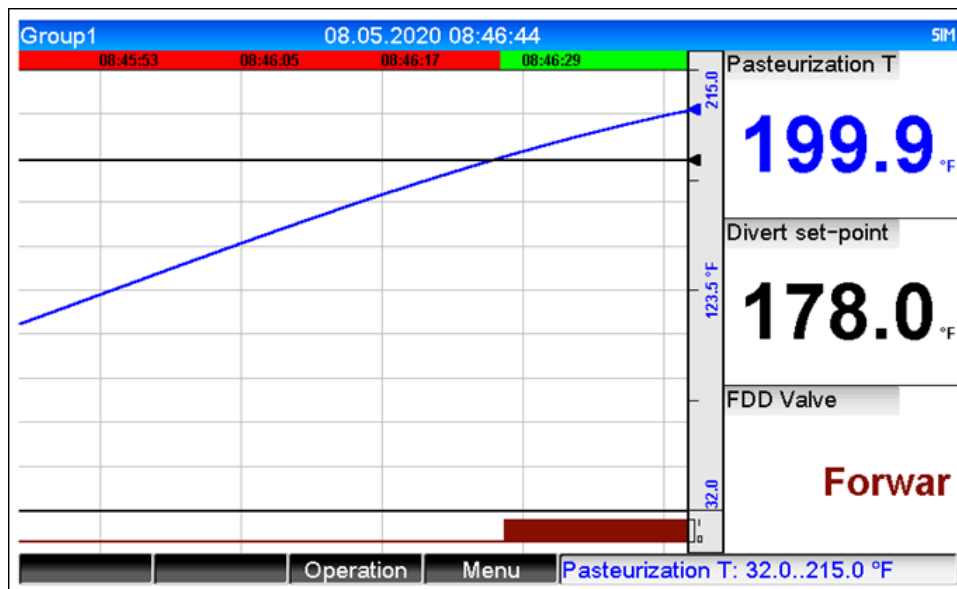


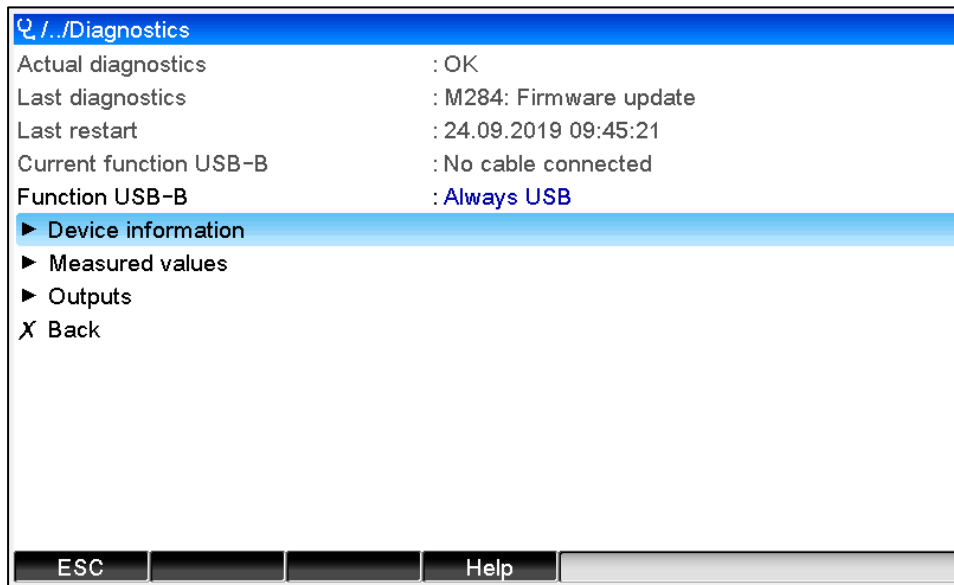
Fixing screw with hole for regulatory seals

3. Operation

3.1. User Log In

During operation when no user is logged in only basic display function is available like display of the measured values, device information and diagnostics. No further input options or interactivity is available. Screen examples see below.

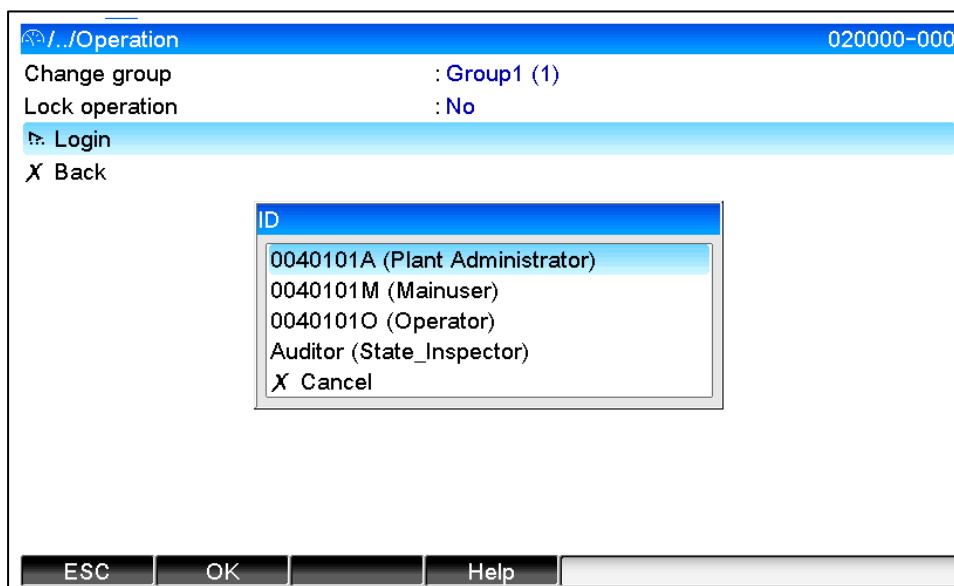




To get access to the operation levels like described under chapter 2.1 the user has to log in with his ID and password

Menu -> Operation -> Log in

A selection list of all created users appear for log in. For logging in, the operator can choose name, enters password and gets access according to his assigned level. The logged in user is indicated in the display header (alternating ID/user name). All user log ins and log outs are traced tamper-proof in the audit trail as shown below.

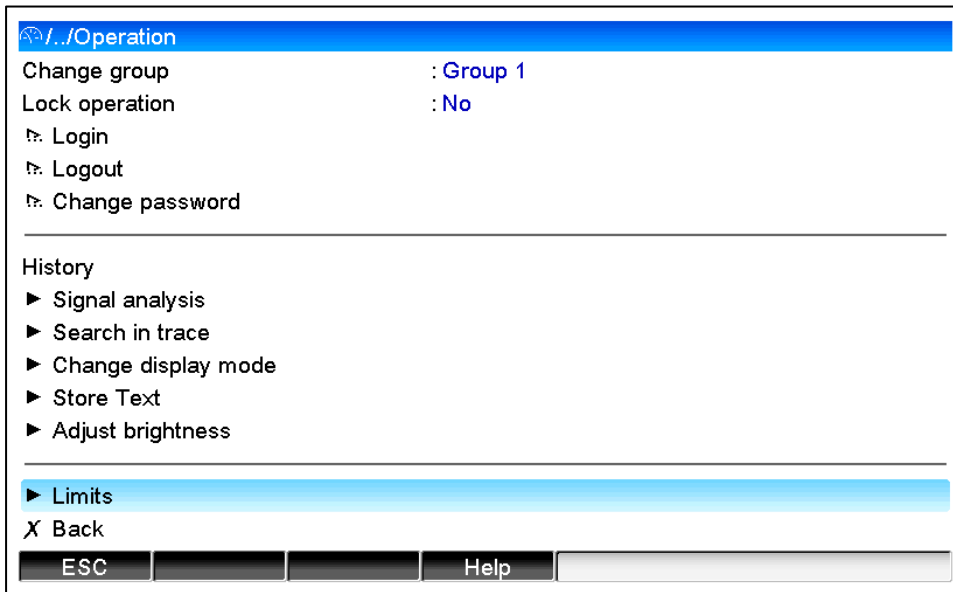


To log out the user has to select ***Menu -> Operation -> Log out*** and enters his password again

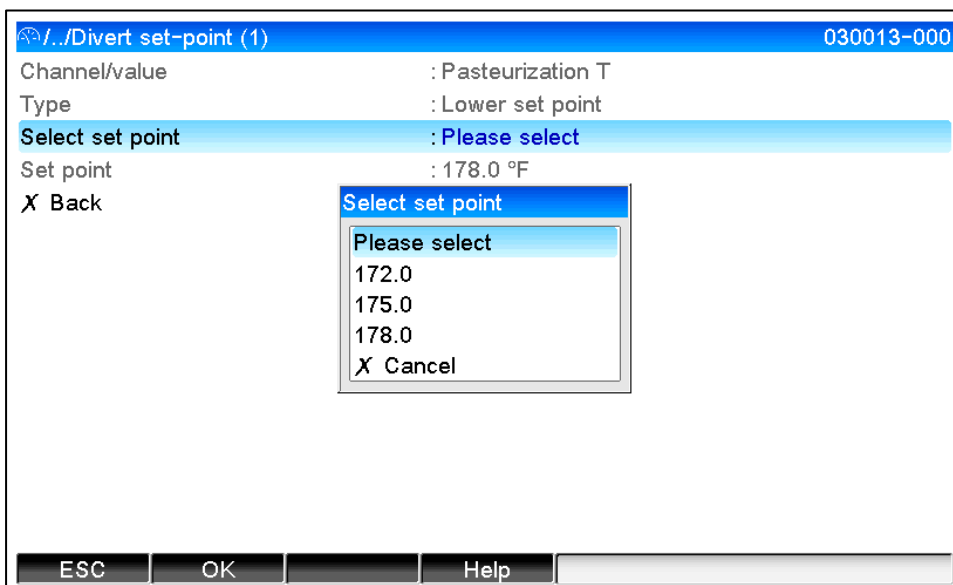
3.2. Select a divert set-point (limit)

According to FDA user administration a user with access rights “main user” can select the divert set-point of a production batch. The user has to log in like described above.

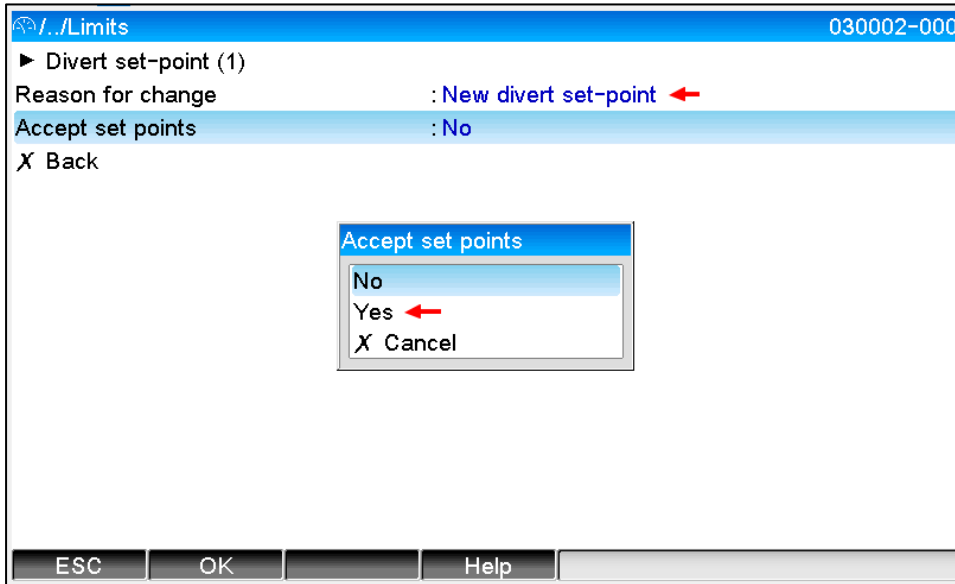
Menu -> Operation -> Limits -> Select set-point



The new limit value can be selected from the predefined default limits (see chapter 2.2.5).



In the next step the user is asked to enter a text for the reason of the change,
The change is valid after selecting **“Accept set point -> yes”**



The screenshot shows a configuration window titled 'Limits' with the identifier '030002-000'. It contains a section 'Divert set-point (1)' with two fields: 'Reason for change' set to 'New divert set-point' and 'Accept set points' set to 'No'. A red arrow points to the 'Accept set points' field. Below this is a 'Back' button. A modal dialog box titled 'Accept set points' is open, showing a list with 'No', 'Yes' (highlighted with a red arrow), and 'Cancel'.

The complete sequence is documented tamper-proof in the audit trail as shown below.

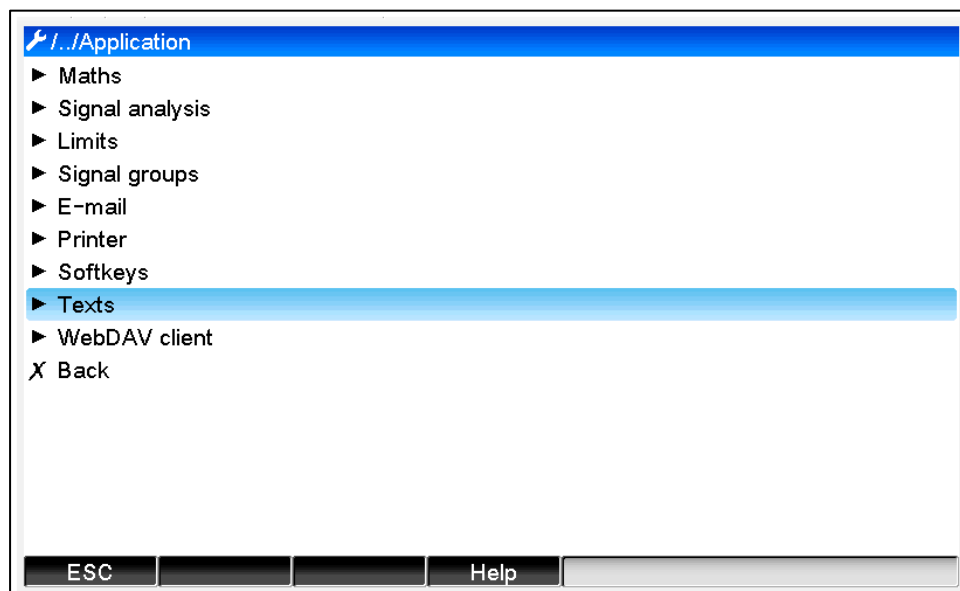
Event logbook		08.05.2020 09:26:52	ID: 0040101M	
	Reason: New divert set-point: 0040101M (Mainuser)	08.05.2020 09:26:37		
	450003-000 Set point: '172.0 °F', old: '175.0 °F': 0040101M..	08.05.2020 09:26:37		
1	Divert: 0040101M (Mainuser)	08.05.2020 09:25:37		
0	Forward 00h39:09: 0040101M (Mainuser)	08.05.2020 09:25:36		
1	Setup change enabled: 0040101M (Mainuser)	08.05.2020 09:25:28		
	Pasteurization T < 175.0 °F: 0040101M (Mainuser)	08.05.2020 09:25:23		
	Pasteurization T > 175.0 °F: 0040101M (Mainuser)	08.05.2020 09:23:45		
	Pasteurization T < 175.0 °F: 0040101M (Mainuser)	08.05.2020 09:20:03		
	Pasteurization T > 175.0 °F: 0040101M (Mainuser)	08.05.2020 09:18:25		
	Pasteurization T < 175.0 °F: 0040101M (Mainuser)	08.05.2020 09:14:43		
	Pasteurization T > 175.0 °F: 0040101M (Mainuser)	08.05.2020 09:13:05		
	Pasteurization T < 175.0 °F: 0040101M (Mainuser)	08.05.2020 09:09:23		
▶	Search more recent events			
▶	Search older events			
X	Back			

3.3. Post protocol

Administrators, main users have the rights to enter subsequent texts at any time of the production batch. The text will be stored in the audit trail and appear e.g. in the printout of the production batch printout.

For easy operation, texts can be stored for selection from a text pool. This has to be done by the administrator in the setup.

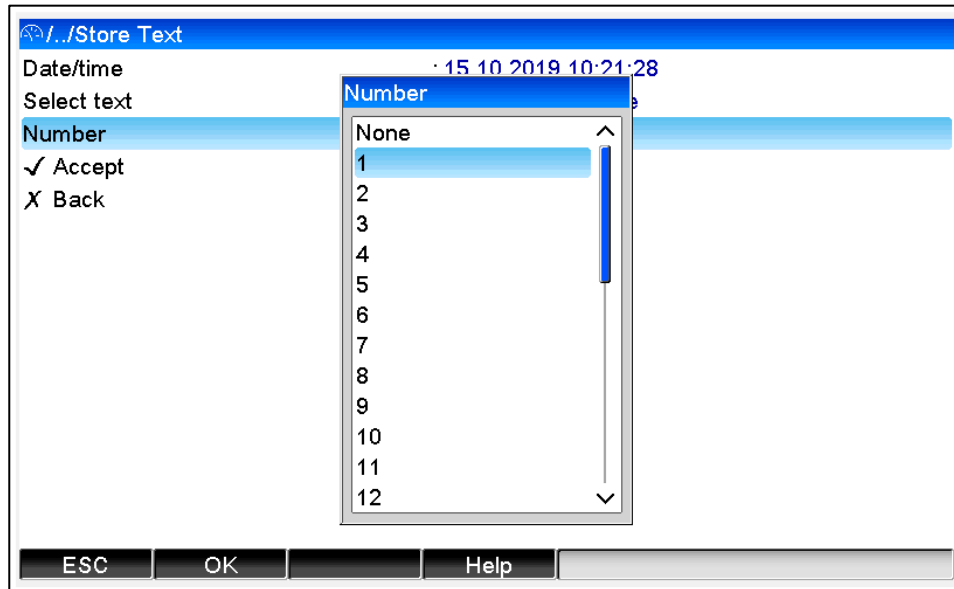
Menu -> Setup -> Advanced setup -> Application -> Texts



Menu -> Operation -> Store text -> Select text



A new or in the setup predefined text can be entered. An additional order number can be selected and entered.



After pressing “Accept text”, the text is entered with time stamp in the audit trail.

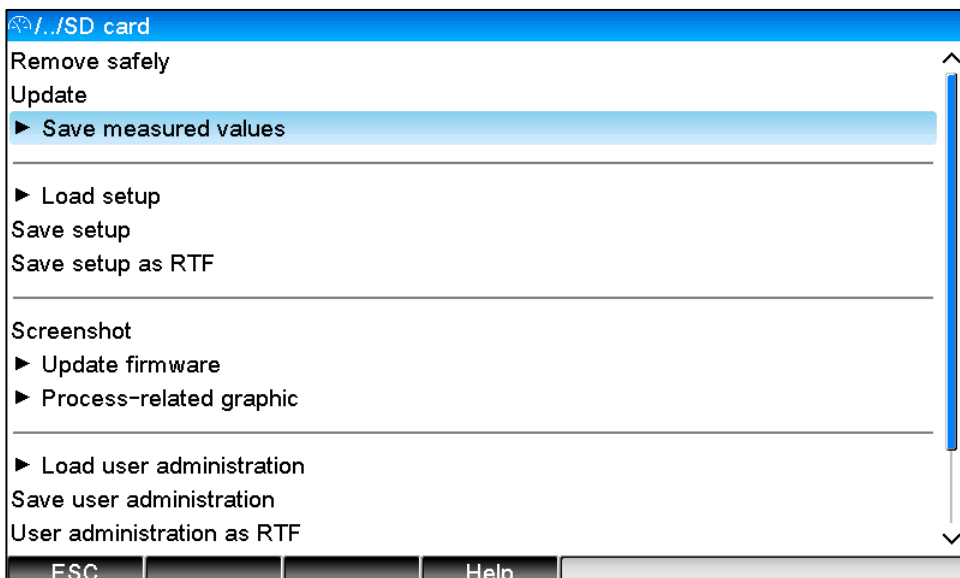
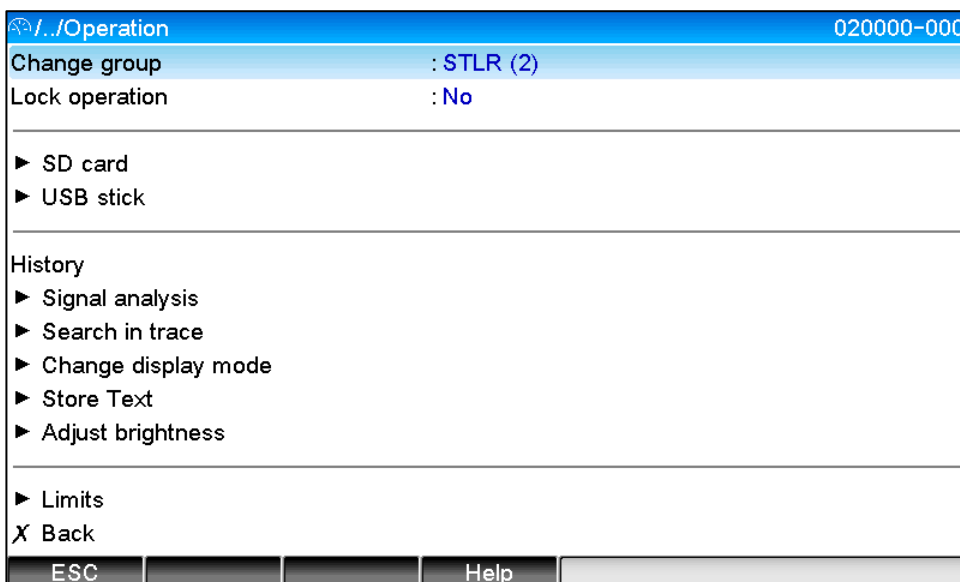
3.4. Secondary data backup via SD card or USB-stick

Note: Primary method for data storage is via continuous connection to FDM software via EthernetTCP/IP. However if desired a secondary method is to utilize removable SD card or USB stick.

Without affecting the internal memory, data packets are copied automatically block by block (min. 1 x per day, midnight) to the SD card. Tests are also made to determine whether the data have been written without any errors.

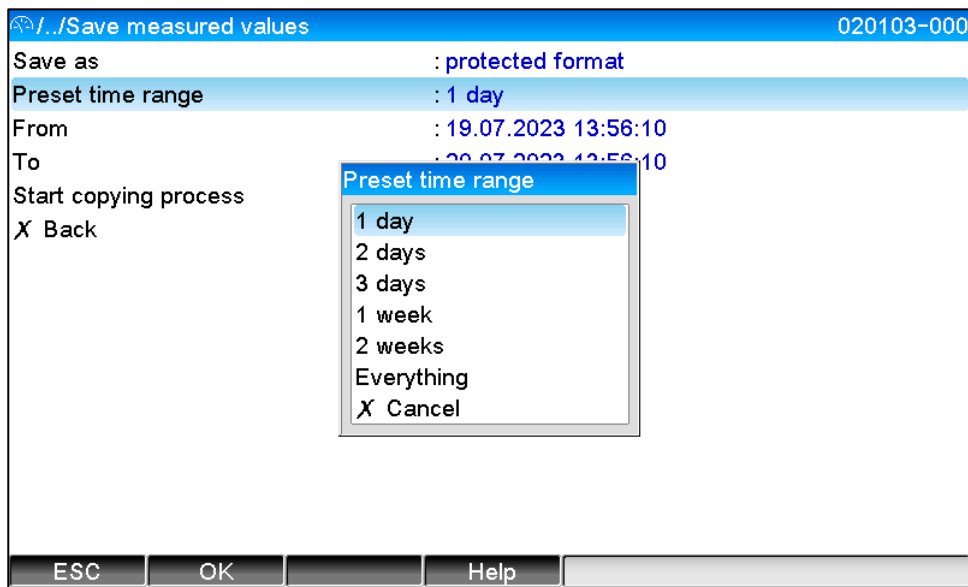
If needed a manual copy process can be executed e.g. when a SD card or USB stick is used only temporarily:

Menu -> Operation -> SD card (or USB stick) -> Save measured values



Select the time range you want to store -> press “Start copying process”

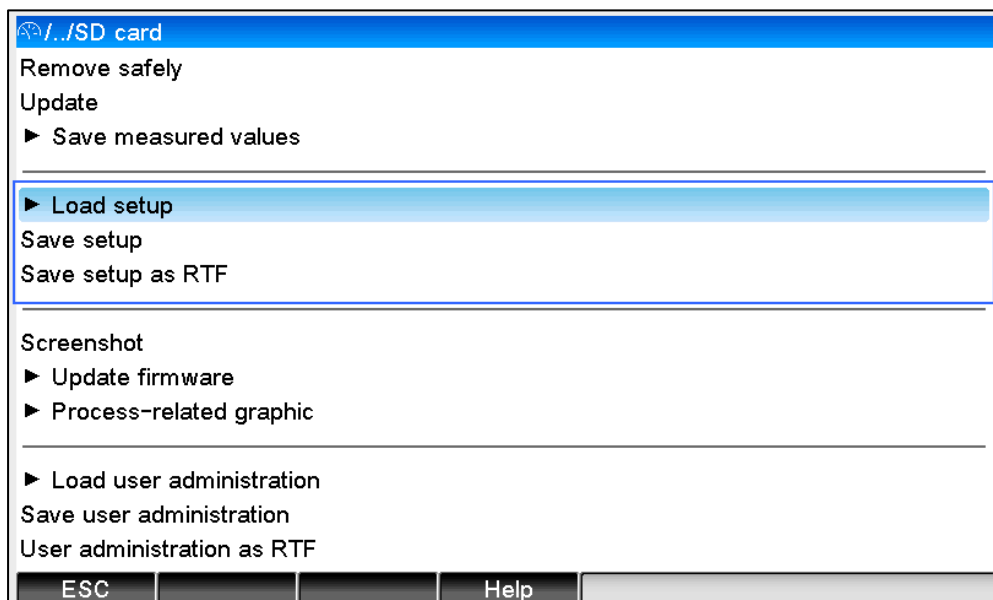
➔ The selected data is copied to the storage medium

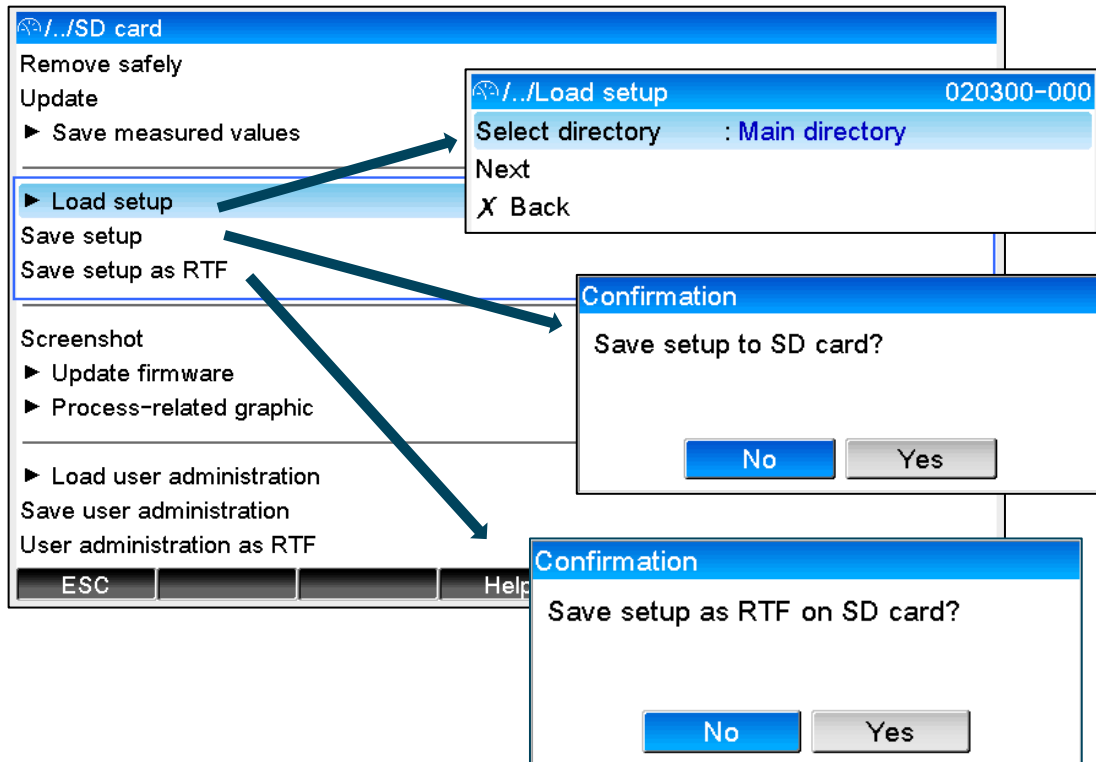


3.5 Setup management via SD card or USB-stick

RSG45 supports the management of all settings (e.g. after commissioning or to clone a device with identical setup). A setup file is saved to the storage medium or load from the storage medium.

Menu -> Operation -> SD card (or USB stick) -> Load setup / Save setup





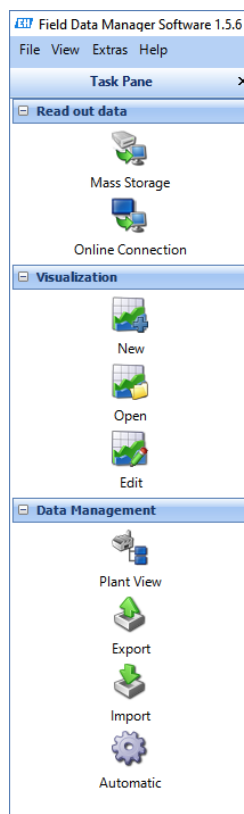
To document the completed commissioning, a text file can also be created in *.RTF format where all parameter settings are listed. This file can be saved on an SD card or USB stick and used for archiving (e.g. on the company server).

4. Data analyzing and storing with FDM Field Data Manager software

Field Data Manager is the software to read out recorded data from the RSG45, generate customer specific reports (e.g. for batch documentation) and manage recorded data. The data can be stored in databases and shared for validation purposes. With FDM, the customer receives a software tool that makes it easy for him to meet his legal obligations to provide evidence. This chapter gives an overview of the FDM main functions, for details refer to the FDM user manual. All settings, operation, reporting and printout are documented there. The following chapter gives a quick start and data access overview.

4.1. Overview

Field Data Manager (FDM) software offers a modern user interface which makes it easy to organize connected devices, connect to them, read out data and set up automatic jobs to create reports, export data, etc.



Description of the main menu:

Mass storage – functions to handle data on a disc or card drive

Online connection – connect to a device (RSG45) and read out data

New – create a new visualization

Open – open a (stored) visualization

Edit – edit a (stored) visualization

Plant view – manage and organize all devices in your plant

Export – export recorded data as CSV or XLS file

Import – import data from another resource

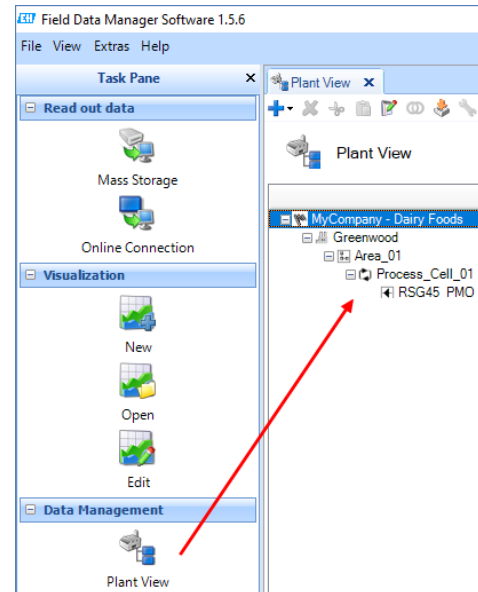
Automatic – setup automatic jobs (e.g. read out, report, etc.)

4.2. Organize your plant

With the “Plant View” tool you can organize the devices in your plant. Built up the structure with the elements:

Company
Site
Aera
Cell
Unit (RSG45 device)

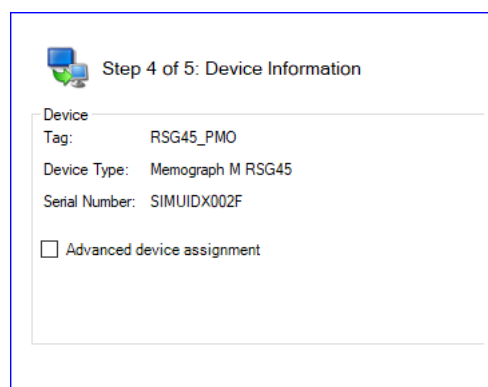
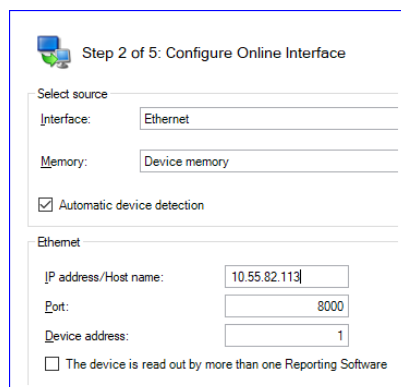
You can use and rename all elements on your demands



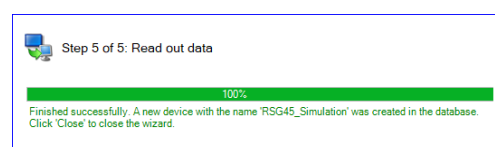
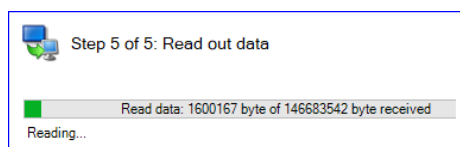
4.3. Set up a connection to RSG45 in a PMO application

To get connected to a RSG45 in a PMO application it is recommended to use the Ethernet interface. This will provide fast and convenient data transmission. Connect the Ethernet RJ45 jack on the back of the RSG with your company network or with your laptop by a point-to-point connection.

Select “Online connection” and you will see the plant as defined. Click on “New unit” (resp. how you named the RSG) and follow the connectivity wizard step by step. You have to enter the IP-address of the device, port (8000) and Device address (1) remain on the presets.

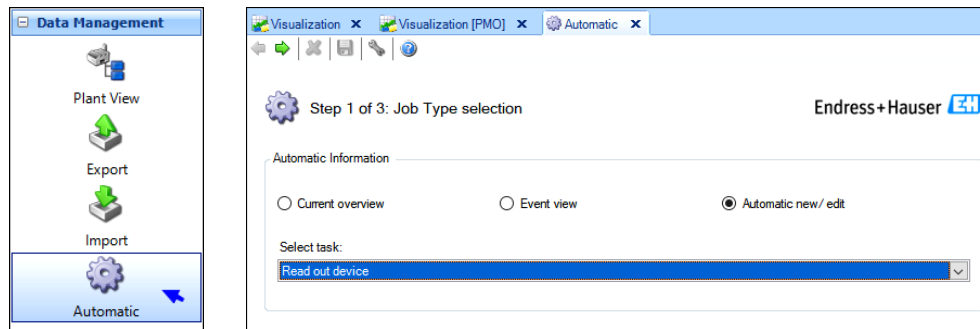


FDM will start to read out recorded data and indicates the result.

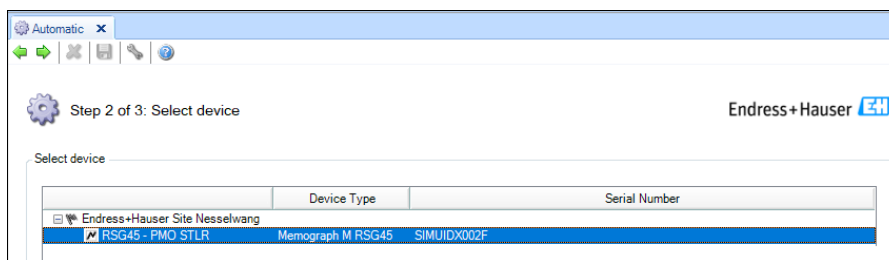


A cyclic automatic read out function of all recorded data can be activated with the following steps. The FDM software can be closed and the read out is executed in the background.

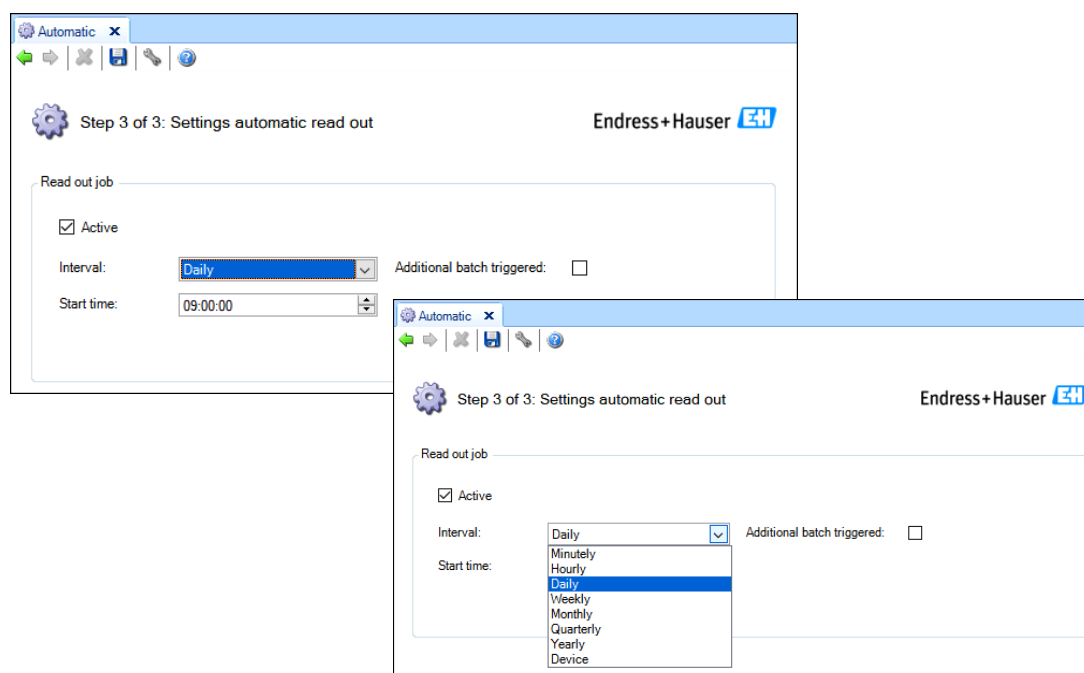
Select “Data Management ***Automatic***” and set up the automatic read out



Select the target device you want to read out

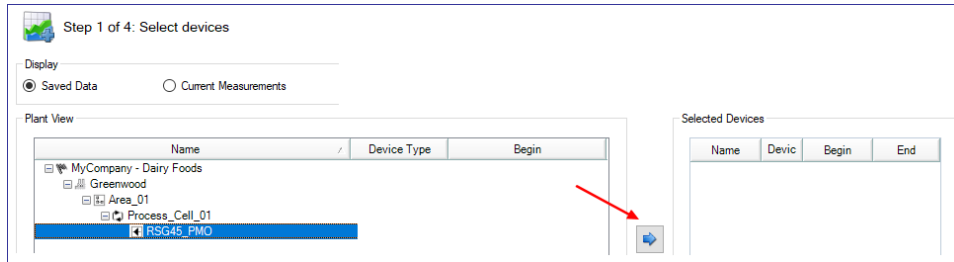


Set the desired read out rate with the time details

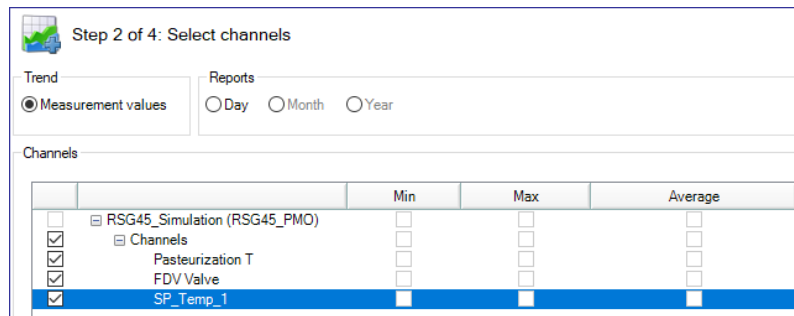


4.4. Visualize recorded data and events

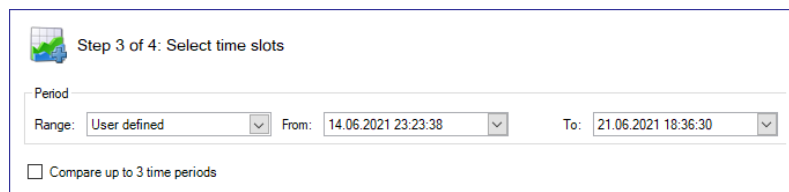
To visualize the recorded data and events (failures, logbook entries, etc.) generate a new visualization or open an already existing one. If you use FDM the first time click on “New visualization”, select the device, press the select button and follow the step-by-step wizard.



Select the measured values you want to visualize



Select a time slot e.g. a production batch



The result is the visualization of the recorded data, event log, etc.

The data visualization and data printout can be customized to the requirements defined for PMO applications. For user defined chart settings click on the measured value.

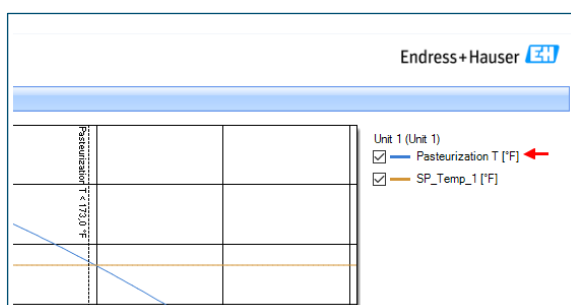


Chart settings for each measurement channel like display color, pen width can be set. To set up the grid and scaling for each channel please proceed as follows: Deselect **Automatic scaling**, enter minimum and maximum display value (example 120°F to 220°F). Deselect **Scale spacing automatic generation** and enter 2.0°F for the scale spacing. For the **Grid spacing** choose “**User defined**” and enter 1.0°F.

Pasteurization T [°F]

Chart

☒ Line chart ☐ Bar Chart

59; 125; 211

Pen width: 3

Style: Solid

Display stored/measured value marks

☐ Visible

Size: 1

Style: Circle

Scale/y-Axis

☐ Scale y-Axis to max value ☐ Inverted

☐ Logarithmic scale ☒ Exponential notation

☐ Automatic scaling

Minimum: 120,0 °F

Maximum: 220,0 °F

☐ Scale spacing automatic generation

Scale spacing: 2,0 °F

y-Axis: Default

☐ Help line 1: 0,0 °F

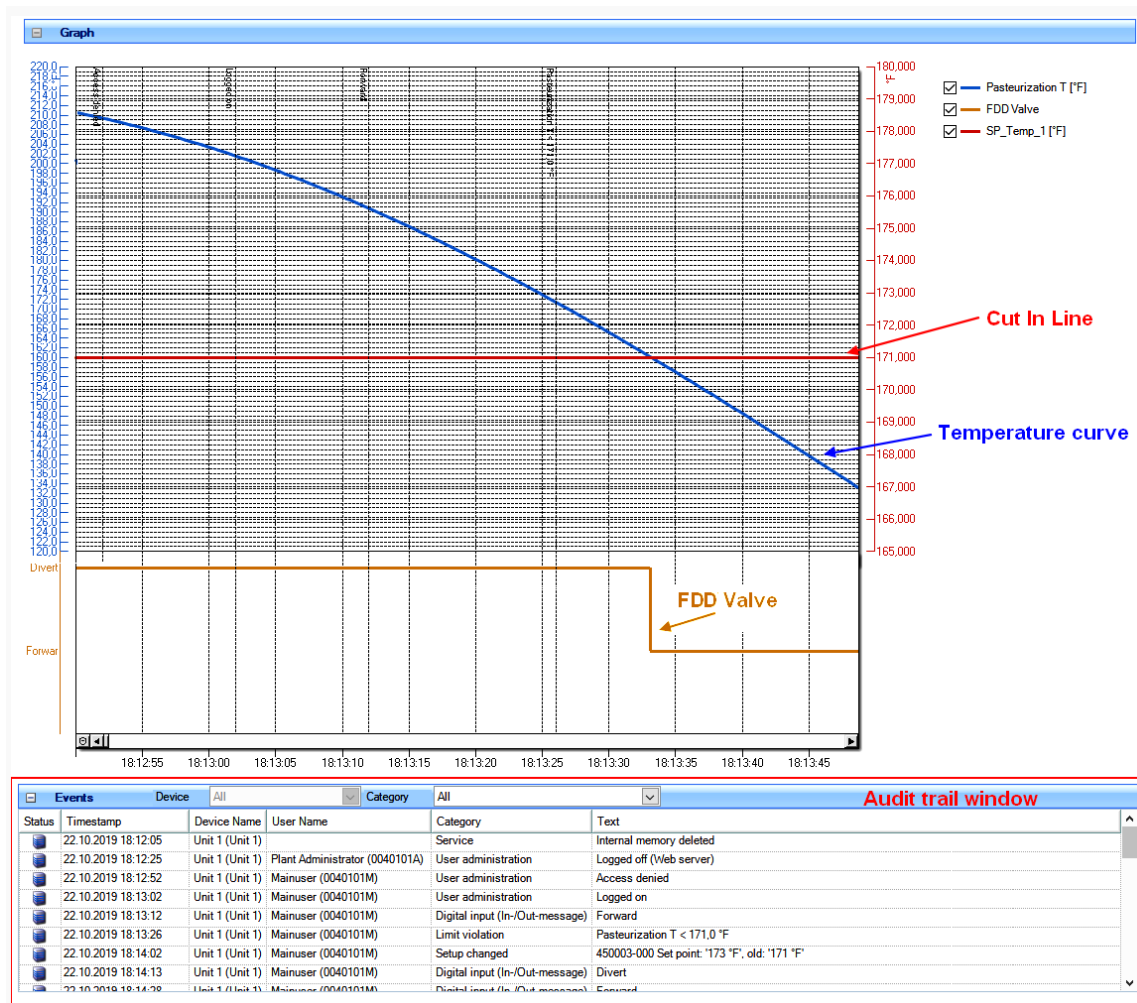
☐ Help line 2: 0,0 °F

☐ Help line 3: 0,0 °F

Grid: User defined

Grid spacing: 1,0 °F

OK Cancel



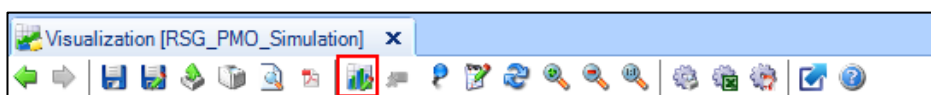
Example: FDM view of temperature measurement recording incl. audit trail and divert set-point

4.5. Creating printouts

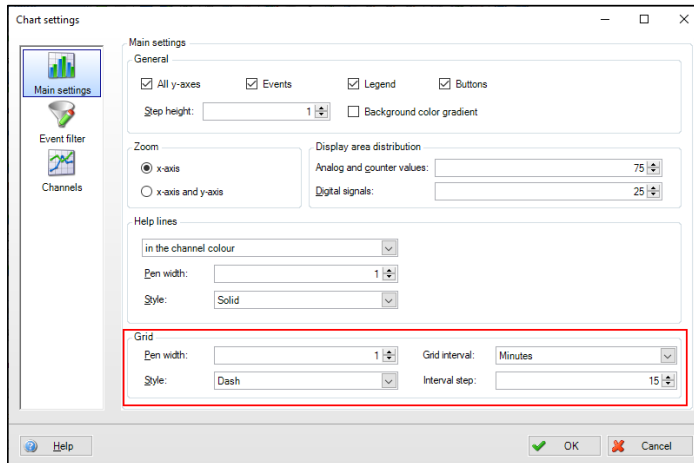
Printouts of production batches or customer-specific time ranges (daily logs, 6h logs, 12h logs, etc.) can be easily generated for documentation purposes.

In dairy industry it is quite common to generate 12h log printouts with an 15min chart grid. Please follow steps below for a one page chart printout.

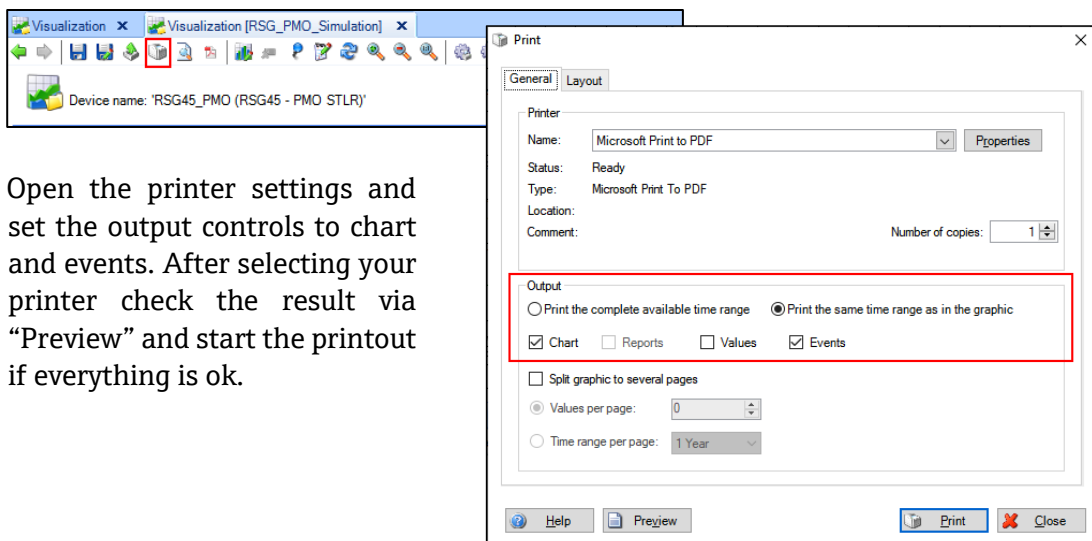
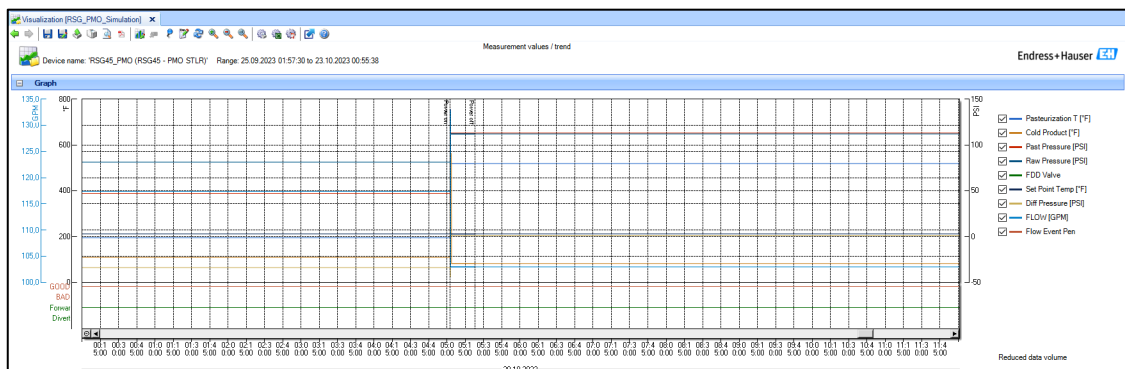
Open the visualization for the device you want to execute the printout and click on the chart configuration button.



Set the x-axis (time-axis) to grid interval “Minutes” and interval step to “15”



Mark the 12h time range in the chart you want to print out, the view will be zoomed to the selected time range. If desired, deselect unnecessary measured values in the control section on the right side.



Open the printer settings and set the output controls to chart and events. After selecting your printer check the result via “Preview” and start the printout if everything is ok.

5. Supplementary documents

For additional information please refer to the following supplementary documents

- Whitepaper: *Memograph M RSG45 and FDM FDA 21 CFR part 11 (WP01028L)*
- User manual: *Memograph M RSG45*
- User manual: *FDM (Field Device Manager) software*

All listed documents are available on www.endress.com in the download area:
<https://www.endress.com/en/downloads>