# **Protos**° 3400(X)

# **Additional Functions**





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# **Additional Functions**

for the Protos 3400(X) modular measuring system

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# **How to Order an Additional Function**

Device-specific TAN (transaction number)

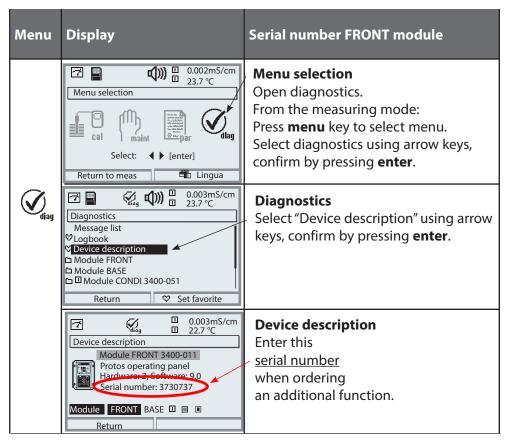
Additional functions expand the device capabilities.

The additional functions are device-specific. When ordering an additional function, you therefore have to specify the serial number of your FRONT module in addition to the respective order number.

(The FRONT module contains the Protos system control).

The manufacturer then supplies a TAN (transaction number) to release the additional function.

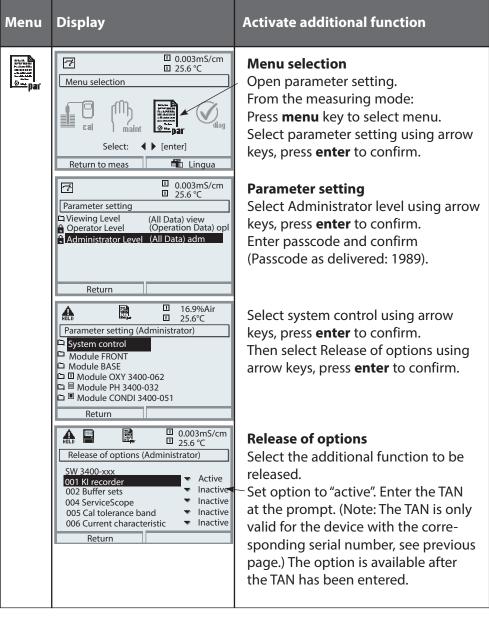
### Serial number of FRONT module



# **Activating an Additional Function**

Select menu: Parameter setting/System control/Release of options

Note: The TAN for releasing an additional function is only valid for the device with the corresponding serial number (see previous page).



Select menu: Parameter setting/Module FRONT/KI recorder Additional function SW 3400-001

The KI recorder follows the course of the process and releases a messages in the event of a deviation. It is called from the measuring mode: **meas** 

### **Continuous processes**

The measured signal is surrounded by a dynamically tracked, process-controlled tolerance band. Slight fluctuations are tolerated. If the measured value leaves the tolerance range, a message is released (Fig.). The recording interval can be set from 10 s to 60 h.

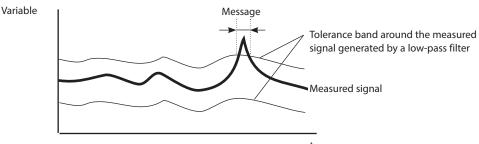


Fig.: KI recorder, continuous process

# **Batch processes**

The KI recorder provides an automatic self-learning function. This allows checking whether regularly recurring processes keep the preset tolerances. Deviations from the normal course of process (plus preset tolerances) generate a message (Fig.). Maximum process duration can be set from 1 to 60 h.

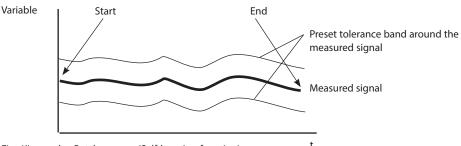
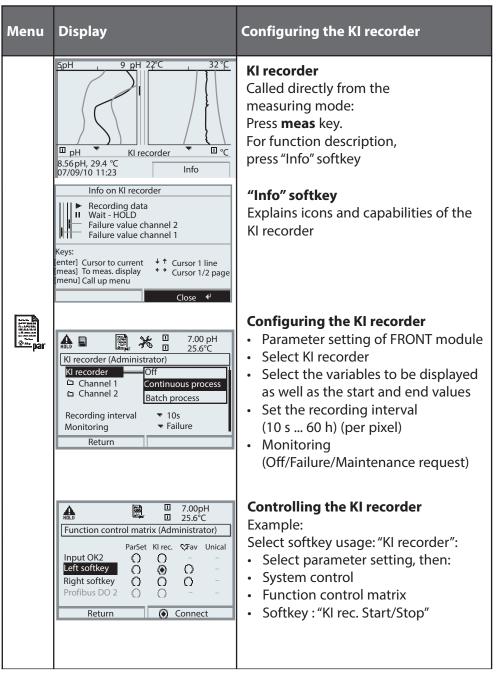
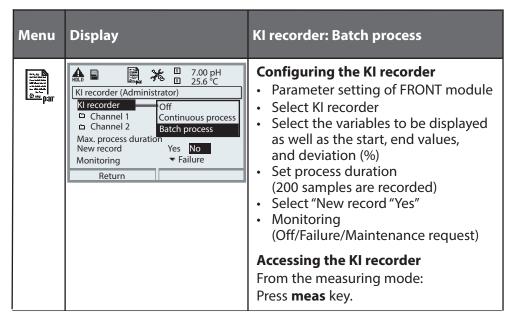
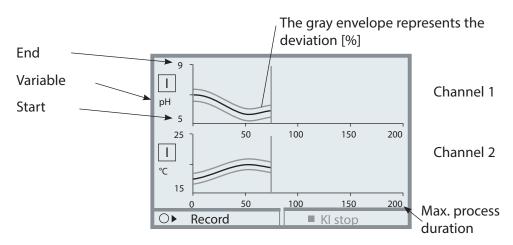


Fig.: KI recorder, Batch process (Self-learning function)





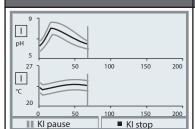
### Parameters adjustable for batch operation

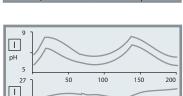


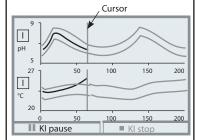
When the parameters are edited once more, the reference curve is automatically re-adjusted to start, end and deviation.

When variable or process duration are changed, the curve will be deleted!

# Display







KI start

# KI recorder: Batch process

# Recording a reference curve

Start "Record" with left softkey.
Reference value and envelope are displayed during the recording process. At the end of recording or after "KI stop" the KI recorder switches to control mode.

In control mode only the envelope is visible.

### **Batch control**

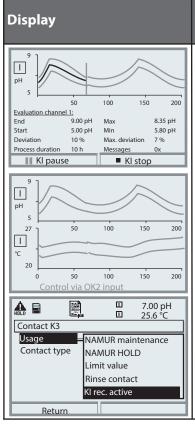
After a synchronous start the recorder monitors whether the currently measured values remain within the envelope.

Every deviation can trigger a message.

KI pause: Stops the recorder. KI stop: Terminates control.

Pressing "Continue" restarts a stopped recorder.

**Note:** In HOLD mode (e.g. during calibration) neither recording nor checking of a batch are interrupted. The last measured value continues to be used.



### KI recorder: Batch process

### **Evaluation**

Within the "KI recorder" function you can evaluate a reference curve directly on the device. To do so, use the arrow keys (up/down). The reference curves and the most important parameters are displayed one after the other.

### External control

A Start/Stop function can be remote-controlled via the OK2 input (BASE module) or via the COMPA 3400(X)-081 PROFIBUS module (To set the control element, call: Parameter setting / System control / Function control matrix). The softkeys will then be deactivated.

The K1, K2, and K3 contacts of the BASE module can be assigned to the "KI rec active" signal.



# Saving / loading reference curves

Up to 5 batch reference curves can be stored on and retrieved from a SmartMedia card:

<u>Parameter setting / System control / KI batch recording</u>
The reference curve, envelope, time response and KI settings are saved.

# Archiving of completed batch processes

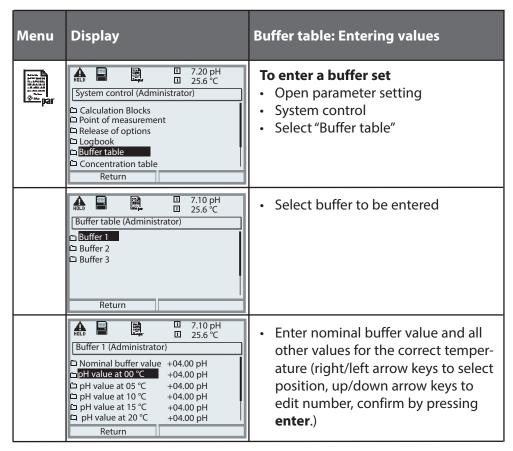
Complete batch results can be archived on the SmartMedia card. All reference values and current batch data are stored in the archive.

# SW 3400-002: Specifiable Buffer Set

Select menu: Parameter setting/System control/Buffer table Individual buffer set (with 3 buffer solutions) for pH measurement

### **Buffer table**

You can enter an individual buffer set (with 3 buffer solutions). To do so, you enter the nominal buffer values for the correct temperature (range 0 ... 95  $^{\circ}$ C / 5 $^{\circ}$ C steps). Then this buffer set is available in addition to the permanently set standard buffer solutions in the "Calimatic buffer" menu (select "Table").



The special buffer set is selected as follows:

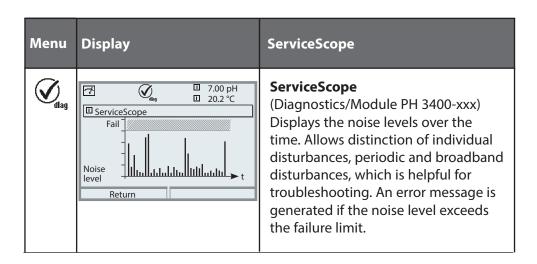
Parameter setting/Module PH/Cal preset values/Calimatic buffer/Table.

# SW 3400-004: ServiceScope (pH)

Select menu: Diagnostics/Module PH/ServiceScope

# ServiceScope

ServiceScope monitors the pH input signal and checks whether it remains in the control range. An error message is generated if the input signal exceeds the failure limit.



# SW 3400-005: Tolerance Adjustment (pH)

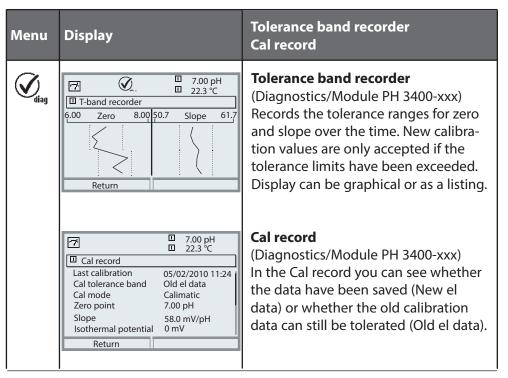
Select menu: Diagnostics/Module PH/Tolerance band recorder

# Tolerance band recorder (For adjusting the tolerance band, see next page.)

During manual calibration this function checks the zero and slope values and automatically performs an adjustment when the tolerance band is exceeded. The parameters are stored in the tolerance band recorder (Diagnostics menu). If the zero and slope values determined during calibration remain within their tolerance bands, the new data are not saved.

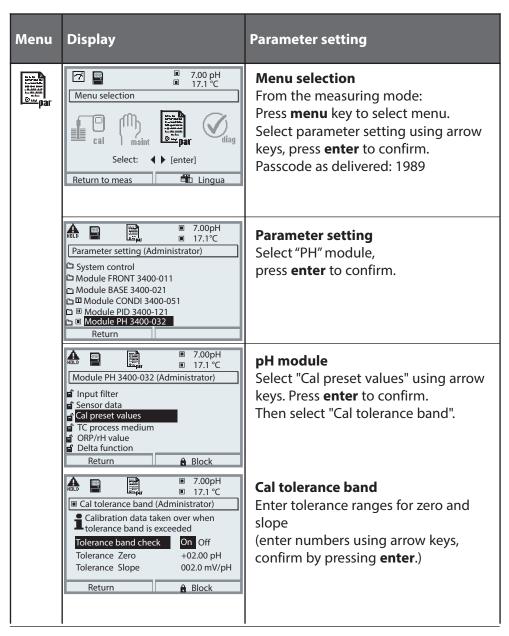
Drift due to aging or calibration scatter can be identified at a glance, thus allowing to draw conclusions as to electrode life and the required calibration interval.

In the **Calibration record** you see whether the data have been saved or whether the old data can still be tolerated.



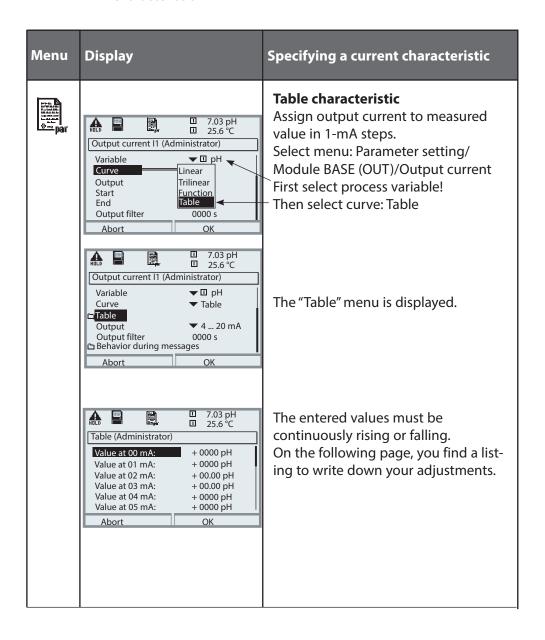
# SW 3400-005: Tolerance Adjustment (pH)

Adjustment of tolerance band. Select menu: Parameter setting/Module PH/Cal preset values/Cal tolerance band



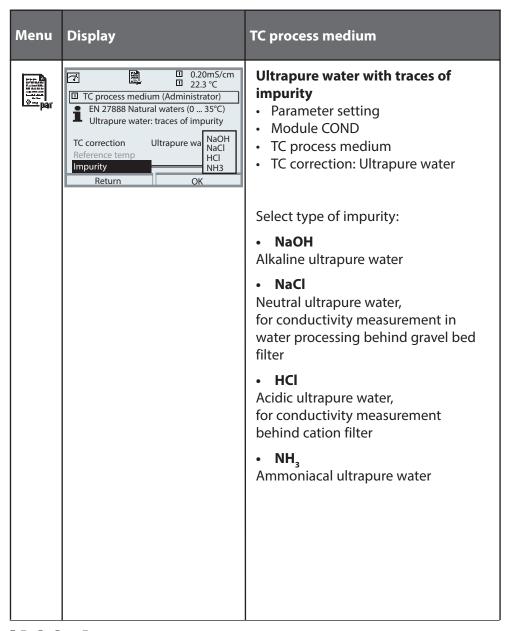
# SW 3400-006: Current Characteristic Definable

Select menu: Parameter setting/Module BASE (OUT)/Output current/ Characteristic



# **SW 3400-008: TC Ultrapure Water (COND)**

Select menu: Parameter setting/Module COND/TC process medium/ Ultrapure water



# **Current Curve Adjustments – Original for Copy**

Parameter setting/Module BASE (OUT)/Output current/ Characteristic "Table", own adjustments

# Value at measured variable

00	mA
01	mA
02	mA
03	mA
04	mA
	mA
	mA
	mA
	mA
09	mA
	mA
	mA
	mA
13	mA
	mA

# SW 3400-009: Concentration Determination

Select menu: Parameter setting/System control/Module COND/Concentration Default settings and selection range

### **Concentration determination**

The substance concentration in percent by weight (% by wt) is determined for  $H_2SO_4$ ,  $HNO_3$ , HCI, NaOH, NaCI from the measured conductivity and temperature values.

### Conditions for concentration determination

Below you find tables with the concentration ranges of the preset substances. These tables show the conductivity of the substances versus substance concentration and process temperature.

The following conditions must be met for a reliable concentration determination:

- For calculation of concentration, the medium to be measured must be
  a purely binary mixture (e.g. water-hydrochloric acid). Presence of other
  dissolved substances (e.g. salts) leads to incorrect concentration values.
- In the region of small slopes (e.g. at the range limits) small conductivity changes can correspond to great concentration changes.
   This may lead to an unsteady display of the concentration value.
- As the concentration value is calculated from the measured conductivity and temperature values, accurate temperature measurement is very important. Therefore, you should make sure that sensor and process medium are in thermal equilibrium.

# Messages

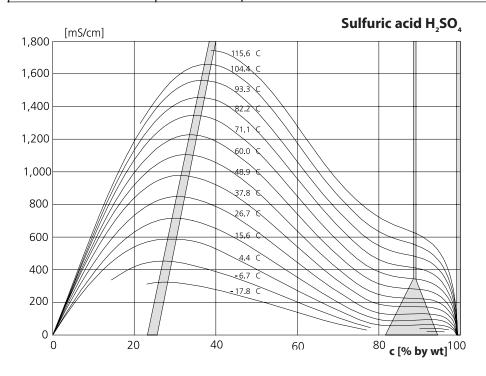
You can define limits for warning and failure messages for the concentration value:

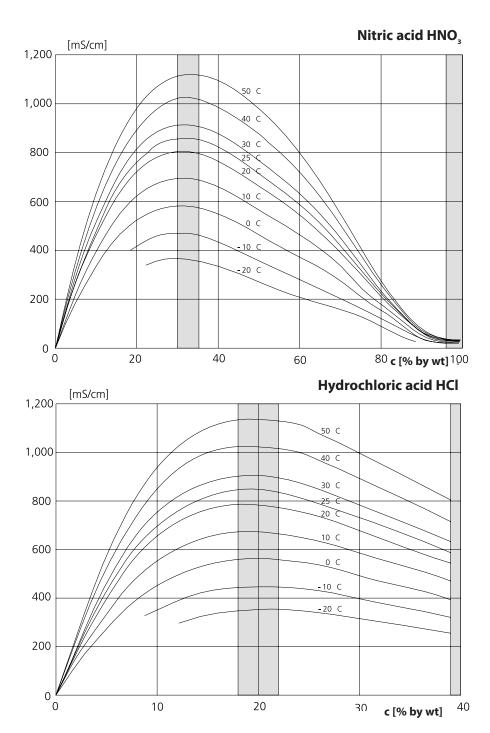
Select menu: Parameter setting/System control/Module COND/Messages

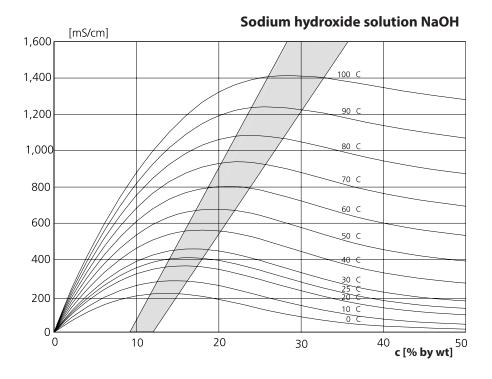
# **Parameter Setting: Concentration Curves**

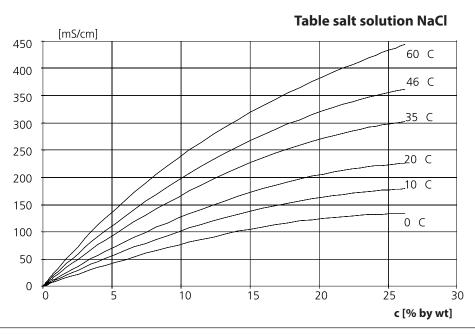
(Additional function SW 3400-009) Default settings and selection range Note: HOLD mode active

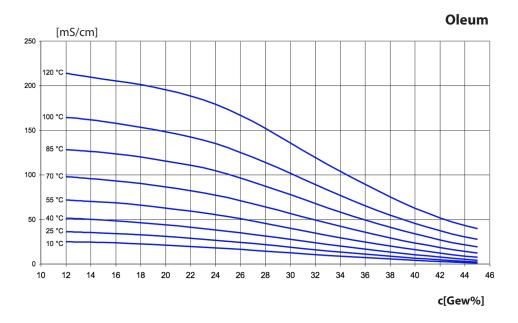
Parameter	Default	Selection / Range
Concentration • Medium ("Yes" selected)	Off H <sub>2</sub> SO <sub>4</sub> (0-30%)	On, Off  H <sub>2</sub> SO <sub>4</sub> (0-30 %), H <sub>2</sub> SO <sub>4</sub> (32-84 %), H <sub>2</sub> SO <sub>4</sub> (92-99 %),  HNO <sub>3</sub> (0-30 %), HNO <sub>3</sub> (35-96 %),  HCI (0-18 %), HCI (22-39 %),  NaOH (0-14 %), NaOH (18-50 %),  NaCI (0-26 %),  Table
USP function Reduced limit value Monitoring	Off 100 % Off	On, Off 10 % 100% Off, Failure, Maint. request











# SW 3400-009: Concentration Table

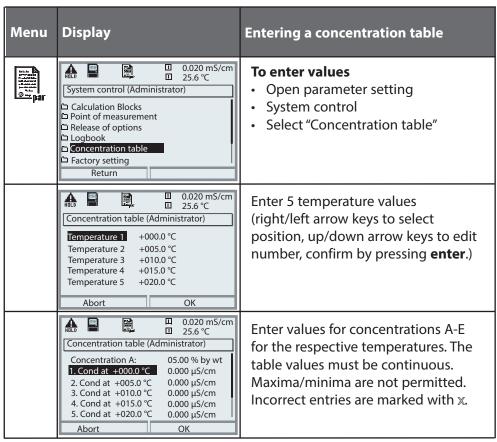
Select menu: Parameter setting/System control/Concentration table Specifying a concentration solution for conductivity measurement

### **Concentration table**

To specify the customer-specific solution, 5 concentration values A-E are entered in a matrix together with 5 temperature values 1-5.

To do so, first enter the 5 temperature values, then enter the respective conductivity values for each concentration A-E.

These solutions will then be available in addition to the permanently stored standard solutions (select "Table").



The concentration table is selected as follows:

Parameter setting/Module COND/Cal preset values/Automatic/Table.

The table is built up as 5 x 5 matrix:

	Conc. A	Conc. B	Conc. C	Conc. D	Conc. E
Temp 1	A1	B1	C1	D1	E1
Temp 2	A2	B2	C2	D2	E2
Temp 3	А3	В3	C3	D3	E3
Temp 4	A4	B4	C4	D4	E4
Temp 5	A5	B5	C5	D5	E5

### Conditions for the table:

- The temperature values must be rising (Temp 1 is the lowest, Temp 5 the highest temperature).
- The concentration values must be rising (Conc. A is the lowest, Conc. E the highest concentration).
- The table values A1 ... E1, A2 ... E2, etc. must all be rising within the table or all falling. Points of inflection are not allowed!

The analyzer automatically checks the table values. Incorrect entries are marked.

# SW 3400-011: Dissolved Oxygen Measurement ...

Application-specific additional function for breweries

This additional function simplifies parameter setting since all steps not required for dissolved oxygen measurement in carbonated beverages are omitted. It simultaneously acts on all installed OXY modules (module software version 2.2 and higher).

# **Function principle:**

The following processes are automated by the additional function, i.e. all parameters required for the respective program step are set automatically.

During the beer filling process, for example, it must be ensured that as little oxygen as possible is dissolved in the beer to extent its shelf life. During oxygen trace measurement the sensor is operated with a very low polarization voltage (-500 mV). This results in low cross-sensitivity to CO<sub>2</sub>.

For a calibration in air, this polarization voltage is too low. It must be set to -675 mV and afterwards be reduced again to -500 mV for measuring in the trace range. Be sure to wait long enough for the sensor to stabilize.

Opening and closing of valves causes pressure variations in the beer pipes which momentarily falsify the  $O_2$  signal. Therefore the input signal must be attenuated correspondingly to suppress transient interferences.

When the additional function has been activated, the parameter setting steps are displayed as follows:

Parameter	Default	Selection / Range
Input filter • Pulse suppression	Weak	Off, Weak, Medium, Strong, On (000 sec 999 sec)
Sensor data • Measure in • Sensor type  • Temperature probe " • Sensor " • Reference electrode " • Membrane correction • Polarization voltage • Sensocheck	Liquids A Standard NTC 22 kohms Without guard Off 1.00 0500 / 0675 mV Off	A Standard, B Trace sensor (with guard) *, C Trace sensor (without guard), Others NTC 30 kohms, NTC 22 kohms With guard, Without guard On, Off Entry required for Hamilton OXYGOLD: 1.23 for sensor type A, B, C fix Off, Failure, Maint. request
Cal preset values	%AIR mg/l 0000 h	%Air μg/l, mg/l, ppb, ppm xxxx h (entry)
Pressure correction  Pressure during meas  Pressure during cal	Auto Auto	Auto, Manual (default value 1013 mbars) Auto, Manual (default value 1013 mbars)
Salinity correction Input	Salinity	Salinity, Chlorinity, Conductivity (00.00 g/kg or 0.000 μS/cm, depending on selection)

<sup>\*</sup> Sensocheck not possible for trace sensor with guard, therefore disabled

# **Membrane correction (with Hamilton OXYGOLD sensor)**

The sensor is selected in the Parameter setting / Sensor data menu: Sensor type: Other

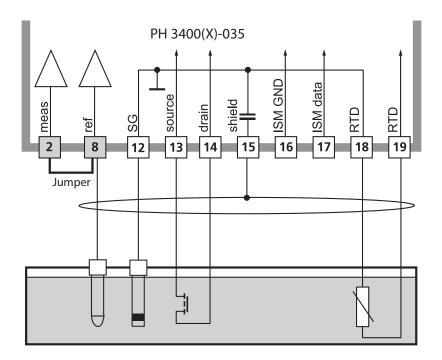
When using the Hamilton OXYGOLD oxygen sensor, you must specify a membrane correction factor of 1.23.

<sup>\*\*</sup> Can only be set with "Sensor type Others" selected

# SW 3400-012: ISFET for PH 3400(X)-035 ISM Module



Connection for ISM sensor (e.g. Mettler-Toledo InPro 3300)

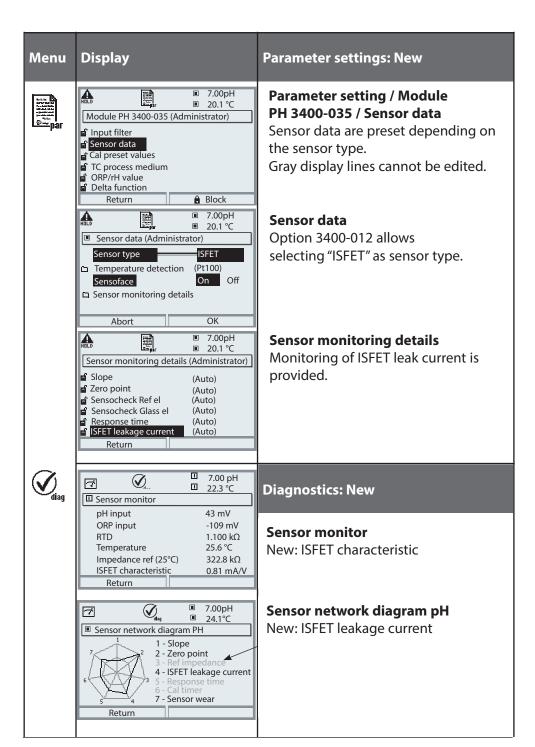


### Note:

Each time a new sensor is connected, you must perform an ISFET zero adjustment to adjust the operating point.

After that, you should perform one of the following calibration methods:

- · Calimatic: automatic calibration
- · Manual entry of buffer values
- Data entry: premeasured electrodes



# SW 3400-014: 2nd Channel for FIU 3400-141 / FIU 3400X-140 Module

### FIU 3400-141 module

Channel1 (Memosens, radio transmission or probe control)

Channel 2 (Memosens or radio transmission, activation via TAN) The 2nd channel for connecting a Memosens sensor or enabling radio transmission allows you to make use of the full range of functions of the FIU module – it can then be used like two separate measuring modules.

# SW 3400-015:

# **OXY Measurement for Memosens Modules**

MS 3400(X)-160, FIU 3400-141, FIU 3400X-140

# SW 3400-016:

# **OXY Trace Measurement for Memosens Modules**

MS 3400(X)-160, FIU 3400-141, FIU 3400X-140

# Memosens PH or Memosens COND, FIU modules including: radio transmission or probe control TAN required: OXY: SW 3400-015 OXY traces: SW 3400-016

# Inserting the SmartMedia Card

To release an additional function via TAN, see Pg 6: Release of options

# Inserting and replacing the SmartMedia card

The SmartMedia card may be inserted or replaced with the power supply switched on. Protect against electrostatic discharge!

When closing the device, make sure that the sealing is properly seated and clean.

### Warning!

# Do not touch the terminal compartment, there may be dangerous contact voltages!



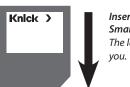
### 1. Opening the analyzer

- · Loosen the 4 front screws
- Open the FRONT module at its right side (pivot hinge inside at the left)
- The slit for inserting the SmartMedia card is located at the inner side of the FRONT module

# 2. Inserting the SmartMedia card

- Remove SmartMedia card from its package without touching the contact surface
- Insert card in the slit at the inner side of the FRONT module





Inserting the SmartMedia card: The label must be facing you.

# 3. Removing the SmartMedia card

- To avoid data loss, please first open the Maintenance menu.
- Select "<u>Close memory card</u>" to terminate software access to the SmartMedia card. Now the card can be taken out.

# **SMARTMEDIA Card: Usage**

Use as memory card in combination with additional functions. Additional functions must be ordered separately (activation via TAN).

# A SmartMedia card is provided with the following additional functions:

- Software update (SW 3400-106, see Pg 45)
- Memory card (SW 3400-102 ... 1xx (see Pg 36 and the following)

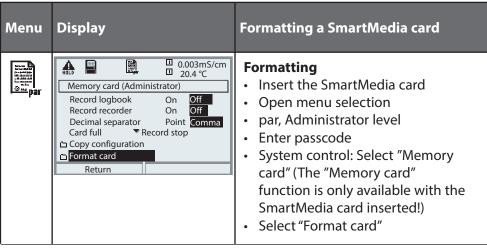
# Using commercially available SmartMedia cards

Commercially available SmartMedia cards can be used as additional memory card.

The following types of cards are supported: 8 MB, 16 MB, 32 MB, 64 MB and 128 MB. Externally produced files, such as from a digital camera, are tolerated. Long file names can be read. Protos generates file names in the 8.3 format (8 characters file name, 3 characters program-specific file name extension).

### Formatting a commercial SmartMedia card

Some devices (e.g. digital cameras, scanners) cause a formatting of the SmartMedia card which does not correspond to the SSFDC specification or the SmartMedia Interface Library (SMIL). The manufacturer therefore recommends to format a commercial SmartMedia card as Protos memory card prior to first use.



# Saving / Loading Device Configuration

System control/Memory card/Copy configuration.

# Saving / loading the complete device configuration

System control/Memory card/Copy configuration.

"Save" configuration means that the complete device configuration (except the passcodes) is written on the memory card.

"Load" configuration means that the complete device configuration is read from the memory card and pogrammed.

BACKUP file generated on SmartMedia card: \BACKUP\BACKUP01.PAR

# Transferring the complete device configuration from one device to further devices

Prerequisite: The devices have the same hardware equipment, the modules are placed in the same slots (e.g. PH 3400-032 in slot 1, OXY 3400-062 in slot 2 etc.)

- 1) Write device configuration of configured device on SmartMedia card: <u>Parameter setting/System control/Memory card/Copy configuration/Save.</u>
- 2) Change to maintenance menu. Select "Close memory card".
- 3) Remove the SmartMedia card.

Now you can transfer the device configuration to further identically equipped devices.

To do so, insert the SmartMedia card containing the configuration in the next device to be configured.

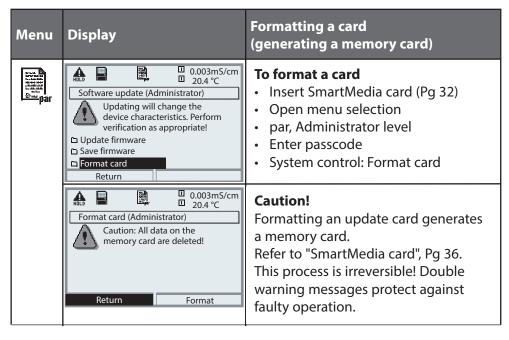
Select

Parameter setting/System control/Memory card/Copy configuration/Load.

- 4) Change to maintenance menu. Select "Close memory card".
- 5) Remove the SmartMedia card.

# **SMARTMEDIA Card: Formatting a Card**

Parameter setting/System control/Format card



### Note:

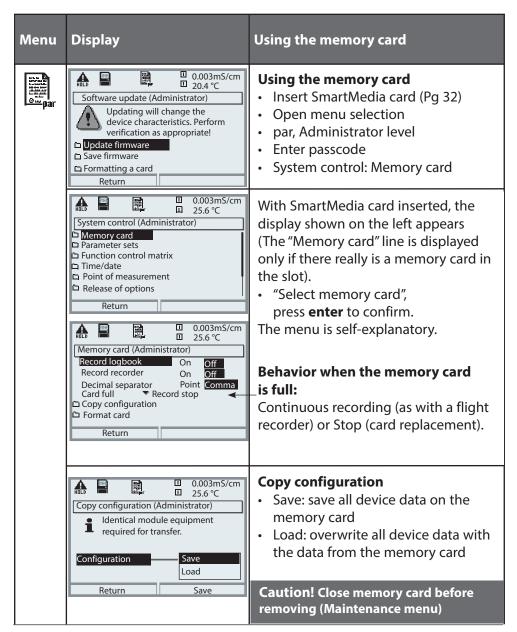
The SmartMedia card must always be formatted in the Protos. Correct functioning of a SmartMedia card with different formatting cannot be guaranteed.

# File structure of a memory card (example):

Folder	Typ. file name	Remark
BACKUP	BACKUP01.PAR	Parameter set (Backup)
LOGBOOK	L_YYMM00.TXT	Logbook file
		YY=year, MM=month
PARASET	1.SET	Parameter set
RECORDER	R_YYMMDD.TXT	Recorder entry
		YY=year, MM=month, DD=day

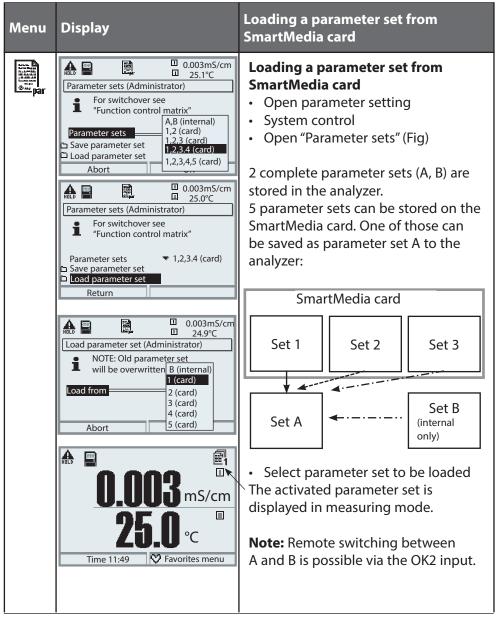
# SMARTMEDIA Card: Memory Card

Parameter setting/System control/Memory card



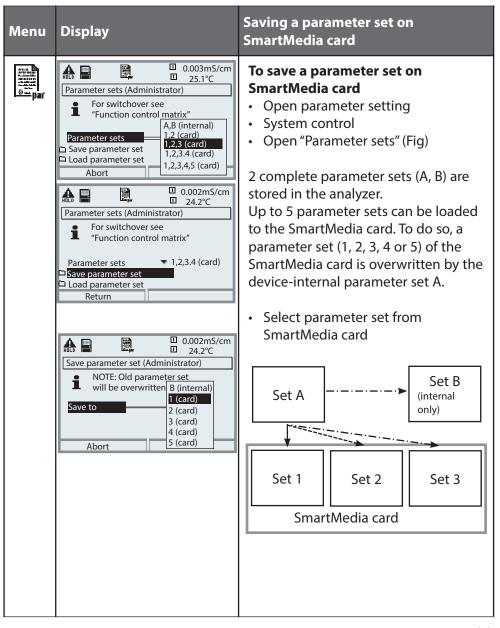
## SW 3400-102: Loadable Parameter Sets

Parameter setting/System control/Parameter sets



## SW 3400-102: Loadable Parameter Sets

Parameter setting/System control/Parameter sets



## SW 3400-103: Measurement Recorder

Select menu: Parameter setting/Module FRONT/Measurement recorder

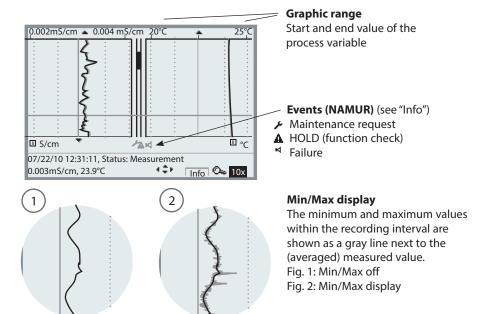
The last 200 data records are stored in the analyzer and are represented graphically – like on a recorder. All further data can be stored on the SmartMedia card and be evaluated by a computer.

2 process variables are represented. You can configure:

- · The process variable to be displayed
- · Start and end value for the variable to be recorded
- Time base (recording interval, selectable from 10 s to 10 h)

In addition, the time axis can be stretched by factor 10 using the "zoom" function. In the event of quick changes, the zoom function is automatically activated. It always starts several pixels before the event. This allows detailed investigation of signal instabilities.

With "Min/Max displays" activated, the respectively measured peak values (gray) are shown in addition to the measured value (average).



## SW 3400-103: Measurement Recorder

Select menu: Parameter setting/Module FRONT/Measurement recorder

#### Additional function SW 3400-103: Measurement recorder

The measurement recorder saves all entries in a file. The last 200 entries can be displayed on the Protos. A new file is generated for each day. The date is encoded in the file name.

Example for a file generated on SmartMedia card:

### \RECORDER\R\_YYMMDD.TXT

Recorder data of YYMMDD (YY = year, MM = month, DD = day)

The data is recorded as ASCII file with the extension .TXT.

The individual columns are separated by tabs. This makes the file readable with word processing or spreadsheet programs (e.g. Microsoft Excel).

Each time the memory card is inserted in the slot, a "Device Info" consisting of Model number, BASE serial number and tag number is written.

Thus, a memory card can also be used to collect the measurement recorder data of several devices.

### Example:

Protos 3400 - Measurement recorder								
Time stamp	CH Left	t	CH Ri	ght	M-req	Fct.	Fail	Slow
<< PROTOS 3400 - Serial 000815 [DSE KL_007] >>								
21.10.05 07:09:15	1015	mbar	2,8	°C	0	0	0	0
21.10.05 07:19:15	1015	mbar	2,9	°C	0	0	0	0
21.10.05 07:29:15	1015	mbar	2,8	°C	0	0	Н	0
21.10.05 07:39:15	1015	mbar	2,9	°C	0	0	0	0
21.10.05 07:49:15	1015	mbar	2,9	°C	0	Н	0	0
21.10.05 07:59:15	1015	mbar	3,0	°C	0	0	0	0

## SW 3400-103: Measurement Recorder

Select menu: Parameter setting/Module FRONT/Measurement recorder

Meaning of the entries in the recorder file:

Time stamp of recorder entry

CH Left Left channel of recorder with measured value and unit CH Right Right channel of recorder with measured value and unit

M-req. NAMUR signal\* "Maintenance request"

Fct. NAMUR signal\* "Function check"

Fail NAMUR signal\* "Failure"

Slow Zoom function active (Slow motion)

#### \* Definition:

NAMUR = German committee for measurement and control standards in the chemical industry

# SW 3400-104: Extended Logbook

Parameter setting/System control/Logbook

### Additional function SW 3400-104: Extended logbook

The extended logbook saves all entries in a file. The last 50 entries can be displayed on the Protos. A new file is generated for each month. The date is encoded in the file name.

Example for a file generated on SmartMedia card:

```
\LOGBOOK\L_YYMM00.TXT Recorder data of YYMM
(YY = year, MM = month)
```

The data is recorded as ASCII file with the extension .TXT.

The individual columns are separated by tabs. This makes the file readable with word processing or spreadsheet programs (e.g. Microsoft Excel).

Each time the memory card is inserted in the slot, a "Device Info" consisting of Model number, BASE serial number and tag number is written.

Thus, a memory card can also be used to collect the logbook data of several devices.

### Example:

```
PROTOS 3400 - Logbook
Time Stamp
                   Status Message
<< PROTOS 3400 - Serial 0001760
                                 [DSE KL 001] >>
11/21/09 19:08:43
                          Power supply Off
11/22/09
          06:02:01
                          Power supply On
11/22/09 06:09:27
                          Diagnostics active
11/22/09 06:09:36
                          Measurement active
11/23/09 16:45:07
                   (x)
                          Fail current I2 > 20 mA
11/23/09 18:43:11
                          Parameter setting active
11/23/09 18:47:38
                          Measurement active
11/23/09 18:47:39 (x)
                          Fail current I2 > 20 mA
    :
```

Time stamp of logbook entry
Status (x) - Message activated
( ) - Message deactivated
Message Message text (in selected operator language)

# SW 3400-106: Software Update

For a software update (additional function SW3400-106), the manufacturer supplies a specially formatted SmartMedia card. The analyzer replaces its own firmware (operating program) by the new version ("Update").

#### Caution!

During a software update the analyzer is not operable! After a software update you should check the configuration.



This icon indicates that a SmartMedia card is inserted in the slot. The card allows storing of current device software on the card as well as loading of new software into the analyzer.

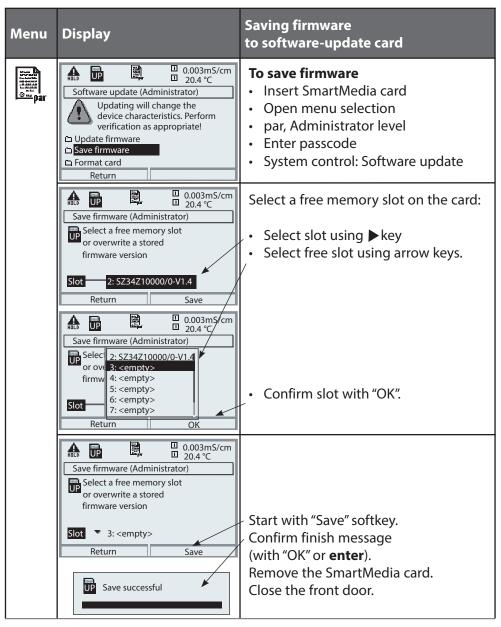
- 1. Save the firmware currently installed in your analyzer (Pg. 44).
- 2. Load the software update as described on Pg 45.

#### Note:

A memory card can be generated by formatting an update card (irreversible!). See Page 33.

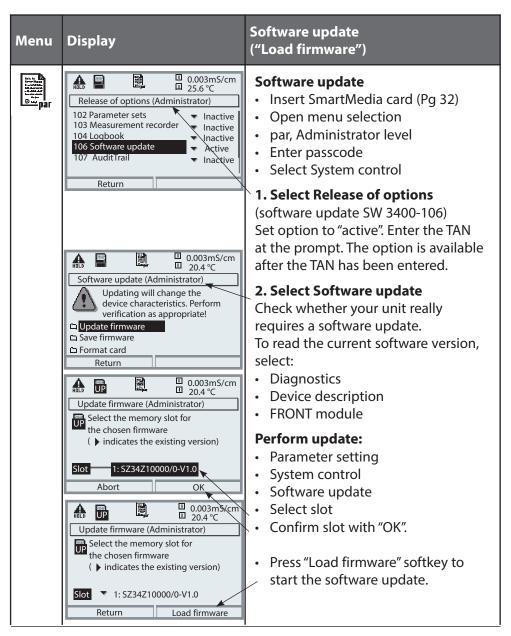
# **SMARTMEDIA Card: Saving Firmware**

Parameter setting/System control/Software update/Save firmware



# **SMARTMEDIA Card: Loading Firmware**

Parameter setting/System control/Software update/Load firmware



# **AuditTrail and Signature**

Electronic data recording and backup according to FDA 21 CFR Part 11 Additional function SW 3400-107

## Provided by: TAN and AuditTrail card

#### **Contents**

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## **AuditTrail**

**Function description** 

## Electronic data recording and backup according to FDA 21 CFR Part 11

Pharmaceutical applications not only require a hygienic design, but also the protection and complete recording of data (FDA regulation: 21 CFR Part 11). The PROTOS with stainless steel enclosure and SmartMedia card meets these demands. The FDA regulation basically consists of two parts: "Audit Trail" and "Electronic Signature". For every change of parameters, the device records what has been changed and who has changed it.

Functions like calibration (adjustment) often may only be performed after written approval! This approval is given by an electronic signature.

#### AuditTrail card

The AuditTrail card is a specially prepared SmartMedia card. The Protos records the audit trail log on an audit trail card only. Readability from PC is not affected.

#### Note:

Only specially coded SmartMedia cards supplied from Knick can be used as AuditTrail cards.

As delivered, the AuditTrail card includes a PC program which makes the recorded AuditTrail data readable. When log encryption has been activated, it also allows decrypting of the data. The program supports the data export to other programs, e.g. Microsoft Excel.

# Signature

**Function description** 

## **Signature**

A signature consists of two entries, the user name and the corresponding pass-code. Each change at the device (calibration/adjustment, parameter setting, maintenance, if required also diagnostics) is recorded in the "AuditTrail Log" and the respective records together with the name of the user who has performed the change. For that purpose, access authorizations are introduced.

#### **Access authorization**

Every access authorization consists of a signature:

- User name and
- Passcode.

The administrator and the user enter the access data in the user management menu. The administrator enters the user name (short name) and the user adds his/her personal passcode.

Each time he/she calls a protected menu, the user must enter his/her name and passcode. The analyzer only gives access to the function if the access codes are valid. The recordings (AuditTrail log, records) on the AuditTrail card include the user names so that all actions can clearly be traced back.

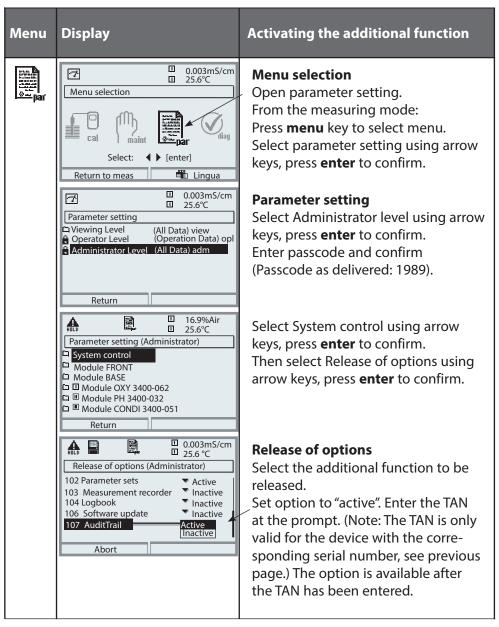
### **Encrypted storage**

The entries in the audit trail log can be encrypted using an algorithm and protected with checksums so that a special evaluation program can prove the authenticity of the data records on a PC.

# Activating the AuditTrail

Select menu: Parameter setting/System control/Release of options

**Note:** The TAN for releasing an additional function is only valid for the device with the corresponding serial number!



# **Entering a Signature**

(User name, passcode)

### Entering a signature (user name, passcode) to open a menu

To protect the data against unauthorized query or modification, access data must be entered before a main menu from the menu selection is opened. Two-stage security is provided by input of user name and passcode.



The passcode is not visible. It is only displayed as 4 dots. The administrator can delete each user's passcode (with entry in audit trail log). The user is identified by his/her access data.

After entry of the valid signature all menus are available with the defined user rights. Only in measuring mode, the rights will be erased again. This allows accessing several menus without having to enter the access data each time. When an invalid combination of user name and passcode is entered, access is denied with the text "Wrong passcode". The entry "Wrong passcode" with the entered (wrong) user ID is recorded in the AuditTrail log.

### **Default setting for signature**

Signature

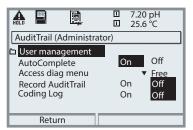
User: ADMIN Passcode: 1989

# AuditTrail: Parameter Setting

Adapt function: Parameter setting/System control/AuditTrail

### **Parameter setting**

In the System control menu the Administrator can adjust the audit trail system to the requirements of his company. For example, he/she can select the protection against unauthorized query and the encrypting of the data in the audit trail log.



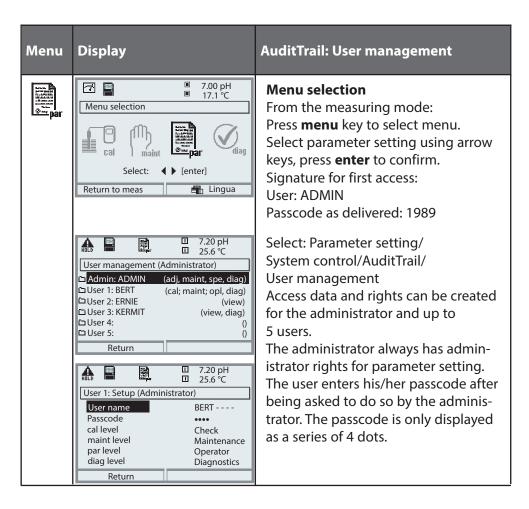
- "AutoComplete" is an input assistance for the user name as known from some Windows programs.
- Access to the Diagnostics menu can be "free" or require input of a "Signature" according to the access authorization granted the User Management menu.
- For the recording on SmartMedia card, an encryption can be activated so that the data cannot be read or queried without corresponding programs.

### **User management**

An administrator and up to 5 users can be entered in the Protos 3400. Each user has a user name (max. 8 characters) and a passcode (4 characters). Each user can be granted access and usage rights for each main menu level. The combination of user name and passcode is the user's "Electronic Signature". Every logged modification is signed and can clearly be traced back. Different access rights for each menu can be defined for each user.

# AuditTrail: User Management

Create, edit, erase user data



### Access rights for the main menu levels:

Calibration: [No access | Check | Adjustment ]

Maintenance: [ No access | Maintenance ]

• Parameter setting: [No access | Viewing | Operator | Administrator ]

• Diagnostics: [No access | Diagnostics]

# AuditTrail Log

**Function** 

### **AutoComplete**

The "AutoComplete" function facilitates the input of the user name. You only have to enter so many letters as the analyzer requires to identify the name. This function can be switched off in the AuditTrail menu because the automatic display of the user name reduces system security, which then might not be sufficient for FDA documentation.

### Accessing the diag menu

To protect all data against unauthorized query, it is also possible to protect the diagnostics level with a passcode (this will also affect the Favorites menu). As delivered, access to the diagnostics level is free.

## AuditTrail log

The AuditTrail log is an additional – protected if required – recording of all data on the AuditTrail card (SmartMedia card). The log is recorded in the currently selected language.

The data can be encrypted (to protect against unauthorized query) and secured with a checksum (to prove the authenticity of the data). The encryption can be switched on or off in the AuditTrail menu of the Administrator level. A four-digit line numbering (0000 ... 9999 P 0000 ..., cyclic) ensures uninterrupted recording. The audit trail log cannot be deleted by the Protos. A buffer storage is provided to store the recorded data while the AuditTrail card is being replaced, for example. An error message "Fail AuditTrail card" is generated when the buffer is full. The oldest entries in the buffer will be recorded. They are then missing in the log (the corresponding line numbers will be missing).

When an empty AuditTrail card is inserted, the buffer storage and the current entries are transferred to the empty card.

# AuditTrail Log

**Parameter** 

The audit trail log cannot be queried by the Protos. It can only be evaluated using the suitable PC program. According to FDA 21 CFR Part 11 the user must ensure the transport of the data from the PROTOS to evaluation and further processing or archiving. Furthermore, the user must ensure that the log data cannot be deleted from the memory card. The PC evaluation program is able to decrypt the data and verify the security parameters and thus to prove the authenticity of the data on the card. It allows printing the encrypted data and exporting them to other PC applications.

## Logbook

The logbook is provided in addition. In AuditTrail systems it runs simultaneously with the audit trail log in contrast to which it can be queried provided that the diagnostics menu is accessible. The administrator is permitted to delete the logbook data since all security-relevant data are stored in the AuditTrail log.

## Recordings in the AuditTrail log

#### Caution!

Data loss (even total destruction) might occur if the card is not closed before it is pulled out (Maintenance menu, "Close memory card").

The following entries and messages are recorded:

- Measuring point, device description, module equipment and serial numbers
- · Menu system log-ins
- Movements within menus (menu headlines)
- Modified parameters at the press of enter
- Calibration record at the end of a calibration or adjustment incl. user name, sensor type and serial number
- · Messages such as failure and maintenance request

Point of	0-110	t Tank UF08 0006123 0006458 0007221 0006045	B15	nick >
6653	07/06/09	10:43:02	Login: Admin (ADMIN)	OK
6654	07/06/09	10:43:02	Login: > Parameter setting (Administrator)	OK
6655	07/06/09	10:43:02	Login: > [1] Module PHU 3400-110 (Admin.)	OK
6656	07/06/09	10:43:02	Login: > Parameter setting (Administrator)	OK
6657	07/06/09	10:43:02	Login: < Menu selection	OK
6658	07/06/09	10:43:02	Login: Admin (ADMIN)	OK
6659	07/06/09	10:43:02	Login: > Calibration	OK
6660	07/06/09	10:43:02	Login: > [1] Module PHU 3400-110	OK
6661	07/06/09	10:43:02	Login: > [1] Calimatic	OK
6662	07/06/09	10:43:02	Login: Warn Identical Buf	OK
6663	07/06/09	10:43:02	Login: > [1] Calimatic	OK
6664	07/06/09	10:43:02	Login: [1] Cal record	OK
6665			Last calibration: 05/31/09 10:04	OK
6666			User: ADMIN	OK
6667			Sensor type: El 204	OK
6668			Serial number: 0815	OK
6669			Cal mode: Calimatic	OK
6670			Zero point 7.02 pH	OK
6671			Slope: 58.0 mV/pH	OK
6672			Impedance glass (25°C): 825.9 Mohms	OK
6673			Impedance ref (25°C): 119.4 kohms	OK
6674	0		1st nominal buffer value: 7.00 pH	OK
6675			Setpoint: 6.97 pH	OK
6676			Actual value: 7.10 pH	OK
6677			Delta value: 0.13 pH	OK
6678	0		Electrode potential: 1 mV	OK
6679	0		Cal temperature: 25.0 °C	OK
6680	0		Response time: 19 s	OK
6681	07/06/09	10:43:02	Login: > [1] Module PHU 3400-110	OK
6682	07/06/09	10:43:02	Login: > Calibration	OK

Typical AuditTrail log (gray: logged measurement deviations)

Protos 3400

## **Additional Functions**

## Provided by: device-specific TAN

To release: Parameter setting / System control / Release of options

Passcode: Administrator level 1989 (new: .....)



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# **Additional Functions**

## Provided by: device-specific TAN + SMARTMEDIA card



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