

Electronic data recording and protection according to
FDA 21 CFR Part 11

(Additional function SW 700-107 for M 700 modular process analysis system)



- **AuditTrail**
- **Signature**

Latest product information: www.mtpro.com

Order number: 52 121 241

METTLER TOLEDO



Warranty

Defects occurring within 1 year from delivery date shall be remedied free of charge at our plant (carriage and insurance paid by sender). Sensors, fittings and accessories: 1 year

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Return of products under warranty

Please contact your local METTLER TOLEDO representative before returning a defective device. Ship the cleaned device to the address you have been given. If the device has been in contact with process fluids, it must be decontaminated/disinfected before shipment. In that case, please attach a corresponding certificate, for the health and safety of our service personnel.



Disposal (Directive 2002/96/EC of January 27, 2003)

Please observe the applicable local or national regulations concerning the disposal of "waste electrical and electronic equipment".

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Mettler-Toledo GmbH, Process Analytics, Industrie Nord,
CH-8902 Urdorf, Tel. +41 (01) 736 22 11 Fax +41 (01) 736 26 36

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AuditTrail and signature

Electronic data recording and protection according to FDA 21 CFR Part 11
Additional function SW 700-107

Provided by: TAN and AuditTrail card

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Latest product information

Additional functions

The M 700 is an expandable modular process analysis system.
For latest product information, please refer to:

www.mtpro.com

Additional functions

A current version of the respective function description is available as pdf for download.

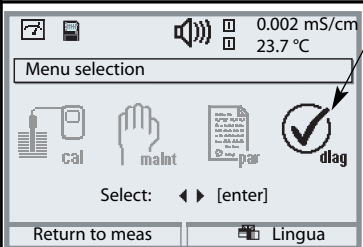

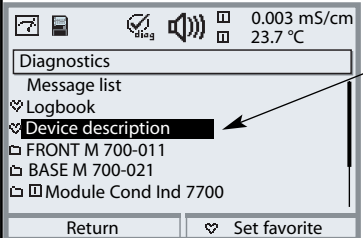
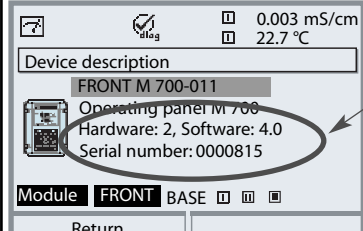
How to order an additional function

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 and hardware version of your M 700 FRONT in addition to the respective order number. The manufacturer then supplies a TAN (transaction number) to release the additional function.

Serial number of FRONT module

Menu	Display	Serial number FRONT module
		<p>Menu selection</p> <p>Call up diagnostics. From the measuring mode: Press menu key to select menu. Select diagnostics using arrow keys, confirm with enter.</p>
		<p>Diagnostics</p> <p>Select Device description using arrow keys, confirm with enter.</p>
		<p>Device description</p> <p>Please specify the <u>serial number/hardware version</u> when ordering an additional function.</p>

AuditTrail

Function description

Electronic data recording and protection 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 M 700 with stainless steel enclosure and SmartMedia card meets these demands. The FDA regulation basically consists of two parts: "Audit Trail" and "Electronic Signature". Both parts interact directly: 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 M 700 records the AuditTrail log on an "AuditTrail card" only. Readability from PC is not affected.

Note:

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

As delivered, the AuditTrail card includes a PC program which makes the recorded AuditTrail data readable. When log coding has been activated, it also allows decoding 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 passcode. For each change at the device (calibration/adjustment, parameter setting, maintenance, if required also diagnostics), the M 700 records in the "AuditTrail Log" and in addition in the logbook 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 up a protected menu, the user must enter his/her name and passcode. The M 700 only gives access to the function if the access codes are valid. The recordings (AuditTrail log, logbook) on the AuditTrail card include the user names so that all actions can be clearly traced back.


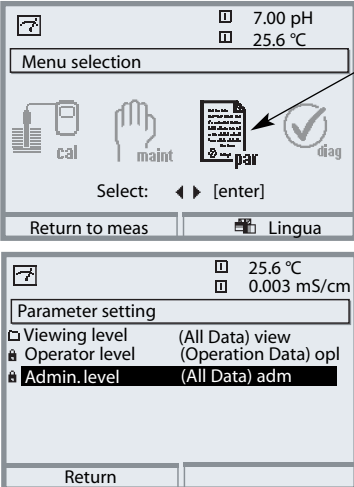
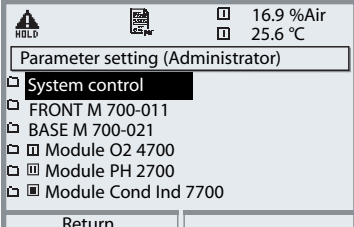
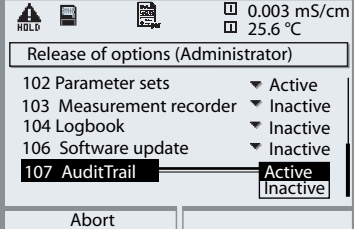
Coded storage

The entries in the AuditTrail log can be coded 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

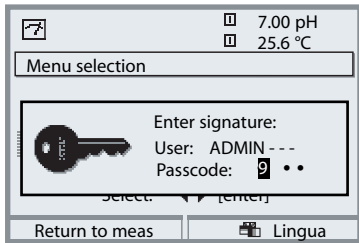
Menu	Display	Activate additional function
		<p>Menu selection</p> <p>Call up parameter setting. From the measuring mode: Press menu key to select menu. Select parameter setting using arrow keys, confirm with enter.</p> <p>Parameter setting</p> <p>Select Administrator level using arrow keys, confirm with enter. Enter passcode and confirm (Passcode as delivered: 1989).</p> <p>Select System control using arrow keys, confirm with enter. Then select Release of options using arrow keys, confirm with enter.</p> <p>Release of options</p> <p>Select the additional function to be released. Set option to "active". Enter the TAN at the prompt. (Note: The TAN is only valid for the device with the corresponding serial number, see previous page.) The option is available after the TAN has been entered.</p>
		
		

Signature entry

(User name, passcode)

Signature entry (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 AuditTrail 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

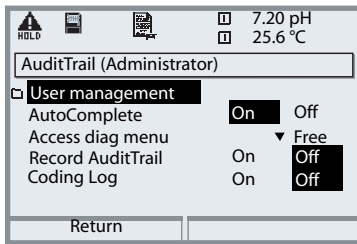
Passcode: 1989

AuditTrail: Parameter setting

Adapt function: Parameter setting/System control/AuditTrail

Parameter setting

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




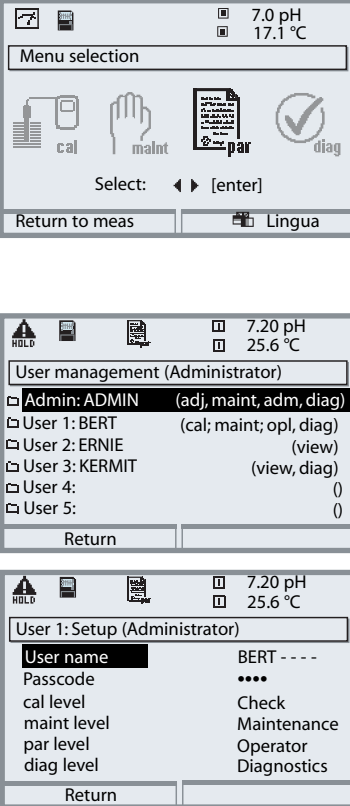
- “AutoComplete” is an input assistance for the user name as known from some Windows programs.
- Access to the Diagnostics menu can be “free” or require input of a “Signature” according to the access authorization granted the User Management menu.
- For the recording on SmartMedia card, a coding can 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 M 700. 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 be clearly traced back. Different access rights for each menu can be defined for each user.

AuditTrail: User management

Create, edit, erase user data

Menu	Display	AuditTrail: User management
		<p>Menu selection</p> <p>From the measuring mode: Press menu key to select menu. Select parameter setting using arrow keys, confirm with enter. Signature for first access: User: ADMIN Passcode as delivered: 1989</p> <p>Select: Parameter setting/System control/ AuditTrail/User management. Access data and rights can be created for the administrator and up to 5 users. The administrator has always administrator rights for parameter setting. The user enters his/her passcode after being asked to do so by the administrator. The passcode is only displayed as a series of 4 dots.</p>

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]

Record AuditTrail

Functions

AutoComplete

The "AutoComplete" function facilitates the input of the user name. You only have to enter as many letters as the M 700 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.

Access to 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.

Record AuditTrail

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 coded (to protect against unauthorized query) and secured with a checksum (to prove the authenticity of the data). The coding 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 AuditTrail log cannot be deleted by the M 700. 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.

Record AuditTrail

Parameters

The AuditTrail log cannot be queried by the M 700. 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 M 700 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 decode the data and verify the security parameters and thus to prove the authenticity of the data on the card. It allows printing the encoded 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) if the card is not closed before it is pulled out. (Maintenance menu, "Close 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

AuditTrail log**METTLER TOLEDO**

Measurement point	BIGBLUE vessel
FRONT M 700-011	0006123
BASE M 700-021	0006458
pH 2700	0007221
O2 4700	0006045

6653	07/01/04	10:43:02	Login: Admin (ADMIN)	OK
6654	07.01.04	10:43:02	Login: > Parameter setting (Administrator)	OK
6655	07.01.04	10:43:02	Login: > [1] Module pH 2700 (Administrator)	OK
6656	07.01.04	10:43:02	Login: < Parameter setting (Administrator)	OK
6657	07.01.04	10:43:02	Login: < Menu selection	OK
6658	07.01.04	10:43:02	Login: Admin (ADMIN)	OK
6659	07.01.04	10:43:02	Login: > Calibration	OK
6660	07.01.04	10:43:02	Login: > [1] Module pH 2700	OK
6661	07.01.04	10:43:02	Login: > [1] Calimatic	OK
6662	07.01.04	10:43:02	Login: Warn Identical Buf	OK
6663	07.01.04	10:43:02	Login: > [1] Calimatic	OK
6664	07.01.04	10:43:02	Login: [1] Cal record	OK
6665			Last calibration: 20.11.03 10:44	OK
6666			User: ADMIN	OK
6667			Sensor type: El 204	OK
6668			Serial number: 0815	OK
6669			Cal mode: Calimatic	OK
6670			Zero: 7.02 pH	OK
6671			Slope: 58.0 mV/pH	OK
6672			Impedance glass (25°C): 825.9 MOhm	OK
6673			Impedance ref (25°C): 119.4 kOhm	OK
6674	0		1st nominal buffer value: 7.00 pH	OK
6675	0		Electrode potential: 1 mV	OK
6676	0		Cal temperature: 25.0 °C	OK
6677	0		Response time: 19 s	OK
6678	07/01/04	10:43:02	Login: < [1] Module pH 2700	OK
6679	07.01.04	10:43:02	Login: < Calibration	OK

Typical AuditTrail log