DOCUMENT

WX-001-0187

Radwag

Distributed by AKRIBIS

21 CFR Part 11 Compliance Module

X2 Series Balances

USER MANUAL

IMMU-116-01-02-22-EN

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FEBRUARY 2022

CONTENTS

1. GENERAL INFORMATION 4

2. ACTIVATION OF THE MODULE 4

3. ADMINISTRATOR PANEL 5

3.1. Password Settings 6

3.2. Operator Accounts Settings 6

3.3. Permissions Management 8

3.4. Audit Trail 9

3.5. E-Signature 11

3.6. Backup 12

4. CREATING A DOCUMENT AND SIGNING IT WITH AN E-SIGNATURE 13

5. SIGNING THE DOCUMENT IN THE DATABASE 18

5.1. Saved Document Printout 21

1. GENERAL INFORMATION

Additional 21 CFR Part 11 Compliance Module

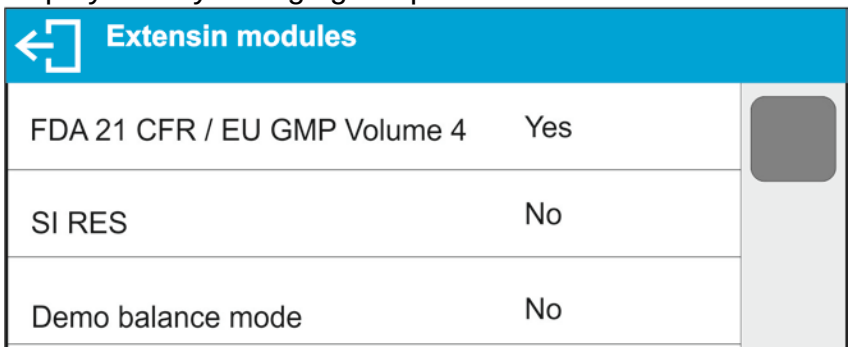
All balances of the X2 series are compliant with 21 CFR Part 11 and EU GMP Part 4, Annex 11. This means they feature an electronic signature as well as a variety of security and monitoring functions for individual operators.

Data protection is guaranteed by:

- advanced password settings
- verification of login operation correctness
- assigning operators with individual permissions
- auto logout
- electronic signature, e.g. for a series of measurements
- saving the e-signed documents in a database
- granting/denying access to data management
- database backup
- modifications saved to Audit Trail file

2. ACTIVATION OF THE MODULE

Operation of the 21 CFR compliance module is enabled by a special code, generated in RADWAG headquarters on the basis of a 12-digit license number, which can be read in the balance menu: **Setup/Balance data/Licence**.
To activate this option, send the license number to RADWAG, where an unlock code will be generated. The code will be sent back as a file. Save this file in the main directory on a USB flash drive, then plug the flash drive to the USB socket on the back of the balance and activate the option in the balance menu: **Setup/Misc/Extension modules/FDA 21 CFR / EU GMP Volume 4**. The balance program verifies the correctness of the unlocking code and the operation of this module is activated, which is signalled by an appropriate message on the balance display and by changing the parameter value to **Yes**.



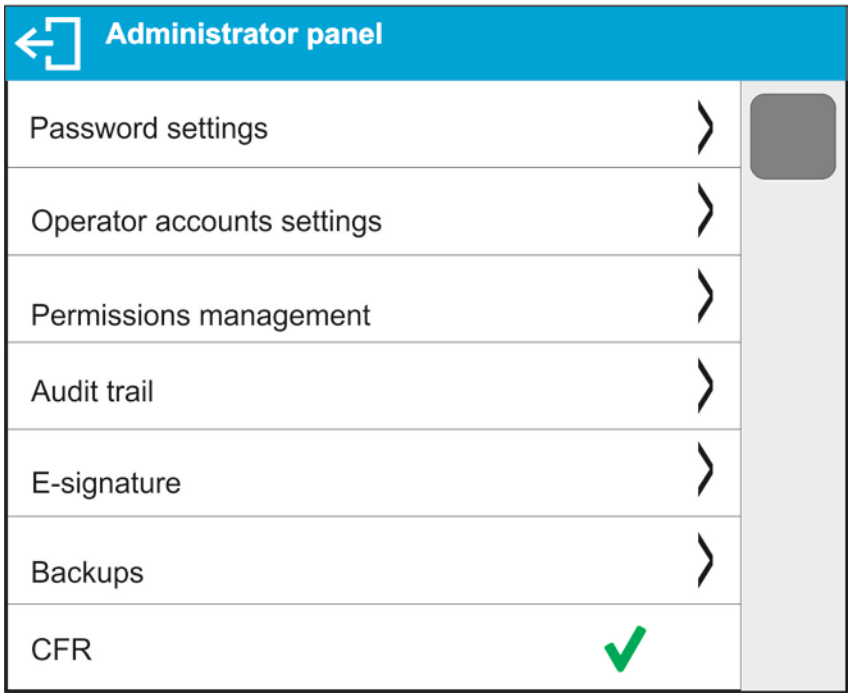
From now on, the balance program enables the full functionality of the 21 CFR Part 11 compliance module.

A new group of parameters, <**Administrator panel**>, related to the operation of the module is now available in the balance menu where the operator can set all available parameters as required by 21 CFR Part 11.

3. ADMINISTRATOR PANEL

This menu enables to determine: activities to be carried out by an operator with certain permissions, password strength and permissions for unlogged operator.

CAUTION: Only operator with Administrator permissions can modify permission-related parameters.

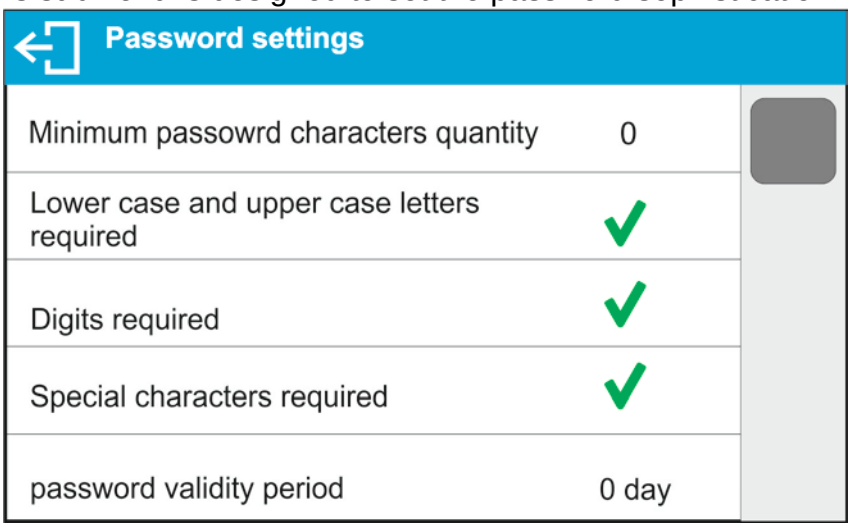


CAUTION: If the authorized operator sets the CFR parameter to disabled,

the module will be active on the balance and all settings for the module will be visible, but it will not be possible to use the module and the program will not verify the settings for this module. The balance will operate as if it does not have an active ***FDA 21 CFR / EU GMP Volume 4*** *module.*

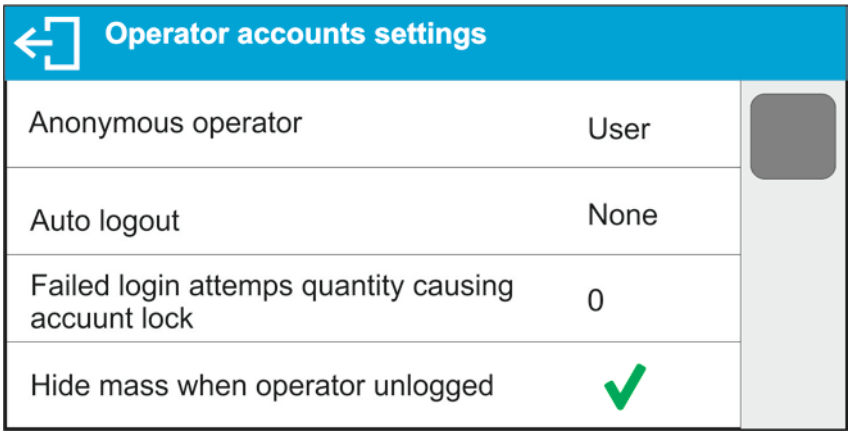
3.1. Password Settings

This submenu is designed to set the password sophistication rate.

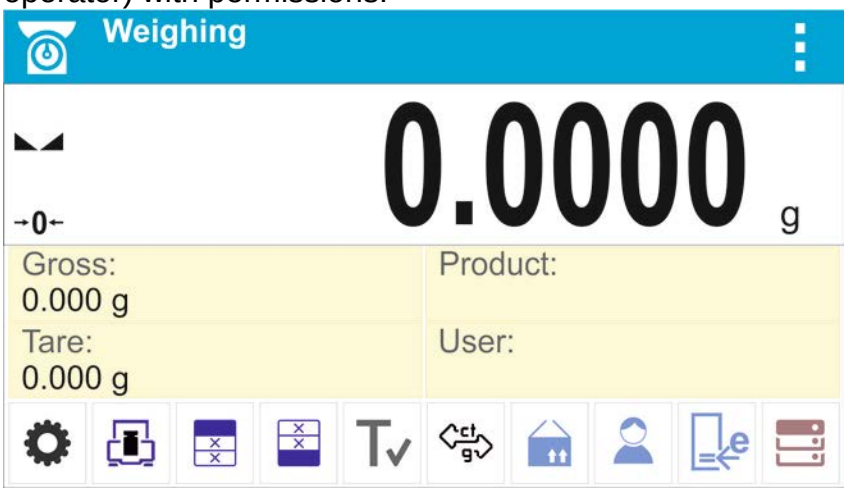


Minimum password characters quantity	Determining the quantity of characters in the operator's password. For the '0' value, set any quantity of characters.
Lower case and upper case letters required	Parameters specifying requirements regarding password characters type and format.
Digits required	
Special characters required	
Password validity period	Determining the time interval in days after which the password has to be changed. For the '0' value, password change is not required.

3.2. Operator Accounts Settings



Unlogged operator permissions
The Administrator can assign an unlogged balance operator (so-called anonymous operator) with permissions.



Procedure:
Enter <Operator accounts settings> submenu, select <Anonymous operator> option, next set respective permissions: Guest, Operator, Advanced operator, Administrator.

Caution: An operator assigned with ***<Guest>*** *permission level is not permitted to modify program settings.*

Auto logout
With Auto logout function on, the operator is logged out automatically if the balance is not operated within a specified time interval, given in minutes.
By default, the function is disabled (<None> entry set).

Procedure:
Enter <Operator accounts settings> submenu, select <Auto logout> parameter, next set respective value: none/3/5/15/30/60. The time is given in [min].

Failed login attempts quantity causing account lock
An option to set the number of incorrect logins by an operator that will result in account access being blocked.
By default, the function is disabled (<0> entry set).

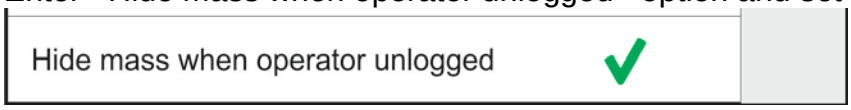
Procedure:
Enter <Operator accounts settings> submenu, select <Failed login attempts quantity causing account lock> parameter, next set respective value:

Caution: *after the occurrence of incorrect logins (mistakes when entering the password) in the number specified in this parameter, the account of the given operator gets blocked. In this case, the administrator must intervene to unblock the account.*

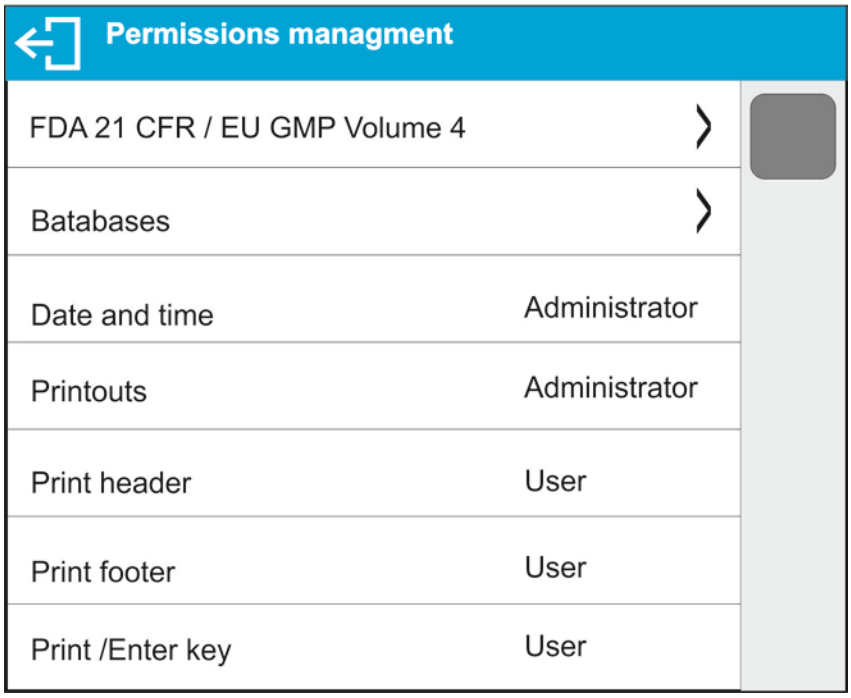
Hide mass when operator unlogged
Option to disable the mass result display if the operator is not logged in.

By default, the function is disabled (<None> entry set).

Procedure:
Enter <Hide mass when operator unlogged> option and set it to active.

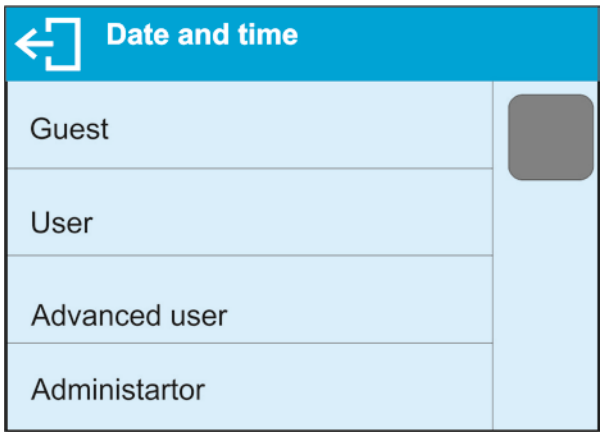


3.3. Permissions Management

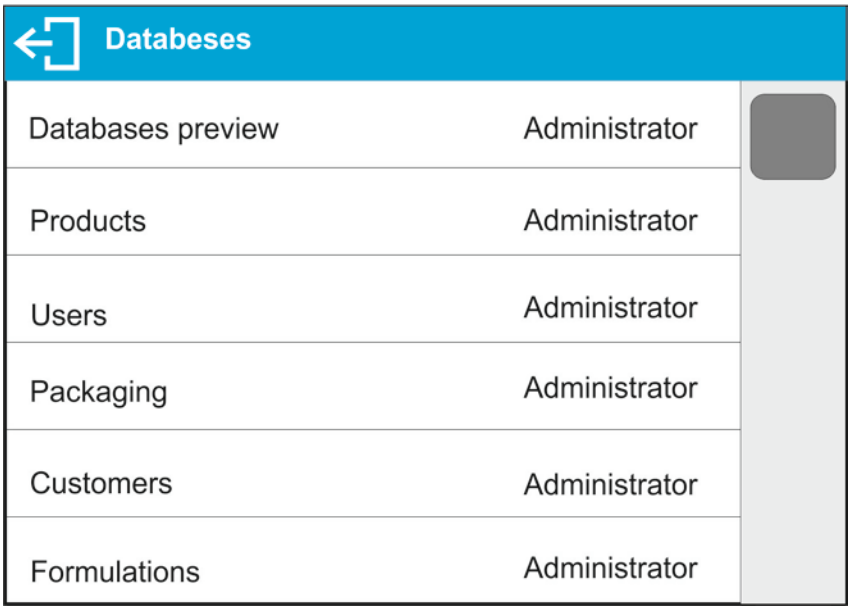


Caution: *When the* ***<Guest>*** *option is set for individual parameters, their settings can be freely accessed (there is no need to log in).*

Each option can be assigned with a permission level to edit it.
Parameter values:



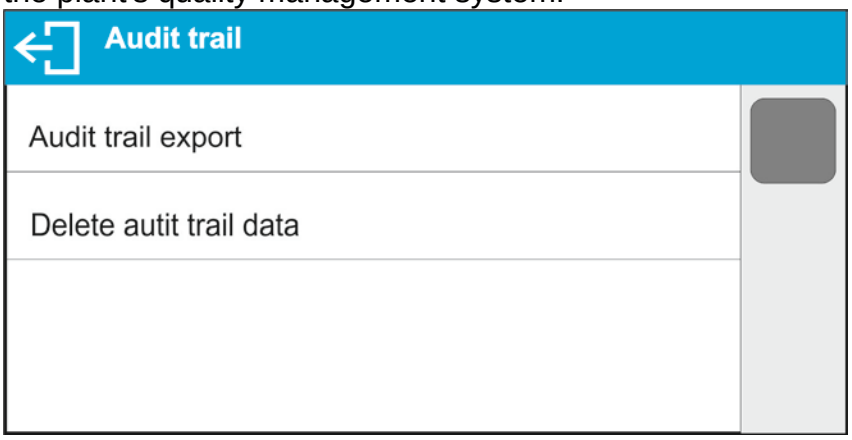
Databases



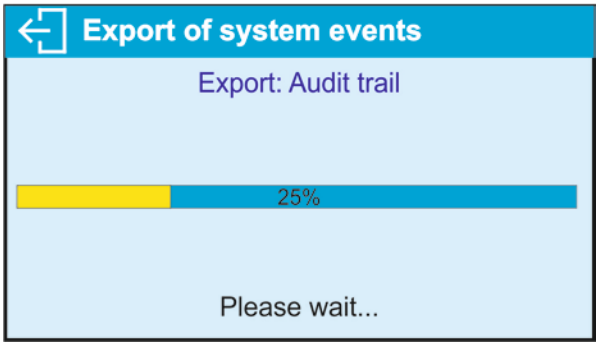
Default balance settings enable an operator who is logged as the **Administrator** to modify settings of particular databases.
The values can be changed depending on the needs.
The editing permissions for the other options available in this menu can be changed on a similar basis.

3.4. Audit Trail

The balance program records in the balance memory all actions performed on the balance since it was started that are required to be recorded by 21 CFR Part 11, such as adding, editing, or deleting an operator.
The balance memory is limited, and therefore, it is important to remember to systematically archive audit trail files in accordance with the recommendations of the plant's quality management system.



Plug the USB flash drive into the USB socket before proceeding with the function. When the function is launched, a new information window appears, displaying the status of the process.



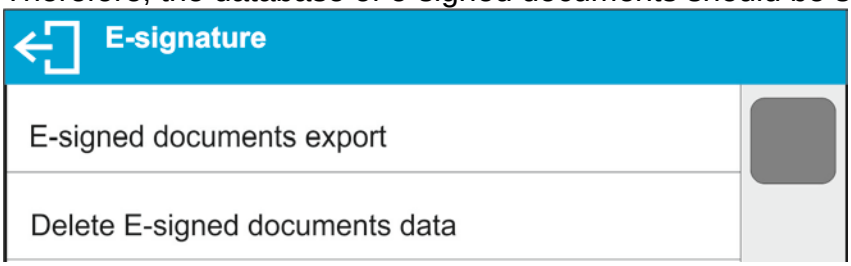
When the process is complete, the window is closed and the data is saved to the USB flash drive in the file: "*AuditTrail 589523 2022 02 08 12 15 15.txt*."

Date and time	Database name	Category	Record id	Record name	Column name	Previous value	New value	Operator id	User
06.07.2021 12:21:15		System start	0		0				
06.07.2021 12:23:02		System start	0		0				
06.07.2021 12:26:13		System start	0		0				
06.07.2021 12:26:40		System start	0		0				
06.07.2021 12:30:03		System start	0		0				
08.10.2021 13:47:59		System start	0		0				
15.10.2021 14:06:41		System start	0		0				
15.10.2021 14:11:24		System start	0		0				
22.10.2021 8:54:42		System start	0		0				
05.11.2021 13:11:46		System start	0		0				
05.11.2021 13:15:38		System start	0		0				
05.11.2021 13:16:16	Operators	Login	2147483667	Admin		2147483667	Admin		
05.11.2021 13:16:57	Operators	Update	2147483667	Admin	Język Polski	English 2147483667	Admin		
05.11.2021 13:17:08	Operators	Update	2147483667	Admin	Language	English Русский 2147483667		Admin	
05.11.2021 13:17:15	Operators	Update	2147483667	Admin	Язык Русский	Polski 2147483667	Admin		
08.11.2021 9:35:38		System start	0		0				
08.11.2021 11:46:10		System start	0		0				
08.11.2021 11:48:13		System start	0		0				
08.11.2021 11:54:48		System start	0		0				
08.11.2021 13:09:18		System start	0		0				
08.11.2021 13:12:27		System start	0		0				
09.11.2021 8:19:51		System start	0		0				
23.11.2021 14:38:07		System start	0		0				
23.11.2021 16:23:25		System start	0		0				
24.11.2021 11:14:10		System start	0		0				
24.11.2021 11:18:03		System start	0		0				
24.11.2021 11:27:54	Operators	Login	2147483667	Admin		2147483667	Admin		
24.11.2021 11:30:26		System start	0		0				
24.11.2021 11:30:46	Operators	Login	2147483667	Admin		2147483667	Admin		
24.11.2021 11:32:24	Products	Update	2147483653	1	Masa 20.000000	20.000000	2147483667	Admin	
24.11.2021 11:37:23	Operators	Update	2147483667	Admin	Język Polski	English 2147483667	Admin		
24.11.2021 12:42:19		System start	0		0				
24.11.2021 12:43:28	Operators	Login	2147483667	Admin		2147483667	Admin		
24.11.2021 13:20:02		System start	0		0				
24.11.2021 13:20:10		System start	0		0				
24.11.2021 13:23:20		System start	0		0				
24.11.2021 13:24:44	Operators	Login	2147483667	Admin		2147483667	Admin		
24.11.2021 13:47:37		System start	0		0				
24.11.2021 13:51:01		System start	0		0				
25.11.2021 10:37:52		System start	0		0				
25.11.2021 14:28:17		System start	0		0				
25.11.2021 14:28:36	Operators	Login	2147483667	Admin		2147483667	Admin		

The audit trail can be deleted once the data has been archived to make room for more data.

3.5. E-Signature

The balance program can store data about performed weighings in the balance memory in the form of documents that can be e-signed.
The balance memory is limited, and it can store up to 1000 documents of 1000 bytes each (approximately 30 lines per printout). If the documents contain a lot of data, such as SQC reports or a large series of measurements, the number of documents to save will decrease gradually. Therefore, the database of e-signed documents should be systematically archived.



Plug the USB flash drive into the USB socket before proceeding with the function. When the function is started, a new information window appears, displaying the status of the process.

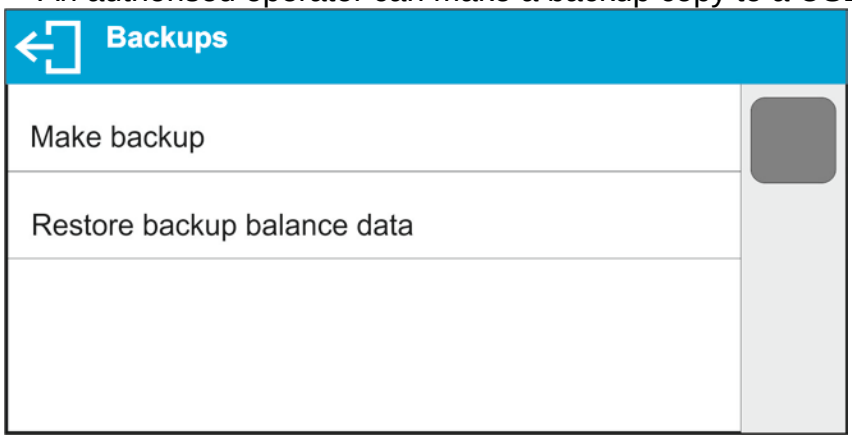
When the process is complete, the window is closed and the data is saved to the USB flash drive in the file: „*SignedReports_589523 2022_02_08 11_44_58.txt*."

```
Record id        2147483662
Working mode     Weighing
----------------------------------------
----------------------------------------
Date                            10.02.2022
Time                               7:02:50
Balance type                   WLC X2 PLUS
Balance S/N                       58952365
User                                 Admin
Name and Surname
Net                                50.07 g
Tare                                0.00 g
Gross                              50.07 g
----------------------------------------


Signature

.........................................
--------------E-signatures--------------
Date and time          10.02.2022 7:03:39
User                                 Admin
Name and Surname
Action                             Signed
Ok
----------------------------------------
```

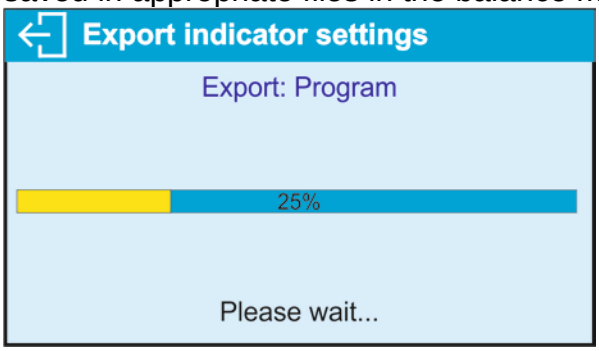
The e-signed documents can be deleted once the data has been archived to make room for more data.

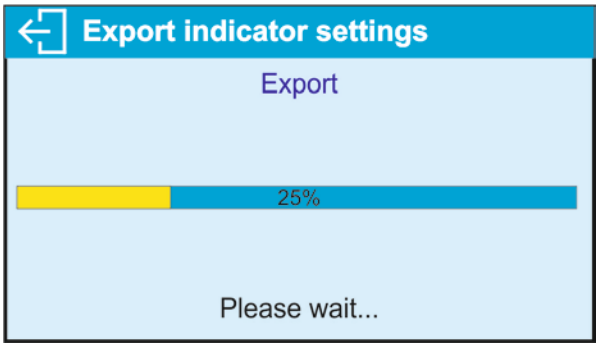
3.6. Backup

The balance program allows you to create a backup copy of the settings and data stored in the balance memory, as well as import the stored settings and data to a new balance in the event of an emergency, such as a balance failure and the need for a replacement. For the data restoration procedure to work, the new balance must be identical to the previous balance in terms of software and metrological settings.
An authorised operator can make a backup copy to a USB flash drive at any time.



Plug the USB flash drive into the USB socket before proceeding with the function. When the function is started, a new information window appears, displaying the status of the process. During the process, the balance settings and stored data are saved in appropriate files in the balance memory.





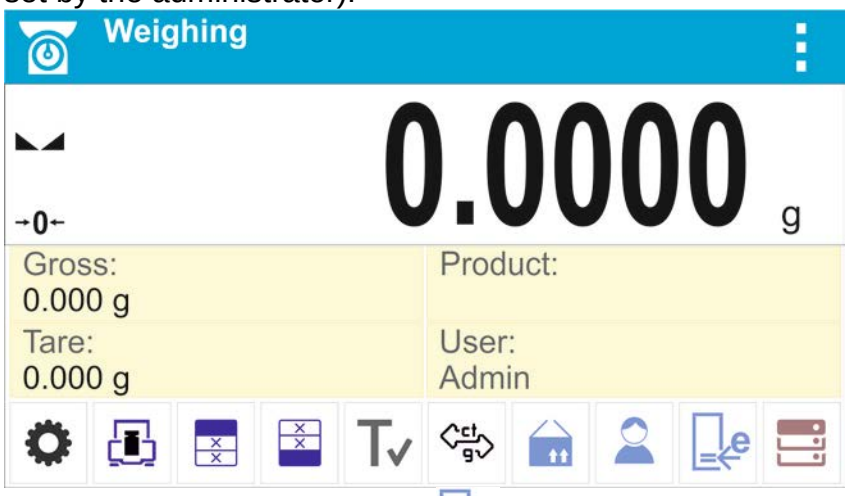
When the process is complete, the window closes and the file is saved on the USB flash drive as: „*update589523_220208_1227.x3prg*" – file with balance settings, „*Backup589523_220208_1227.x3cfg*" – file with balance data.

To restore data, plug the USB flash drive with the backup files stored on it into the USB port and run the option: <Restore backup balance data>.

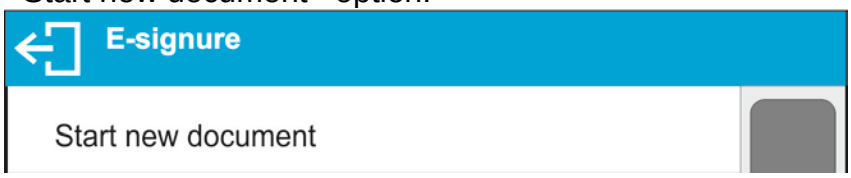
The balance program checks the correctness of the data and determines whether or not it can be copied to the balance memory. If the procedure is feasible, the copy is restored automatically, and the operator informed of the progress via appropriate messages displayed on the home screen. When the restoration is finished, information about it is saved in the Audit Trail file.

4. CREATING A DOCUMENT AND SIGNING IT WITH AN E-SIGNATURE

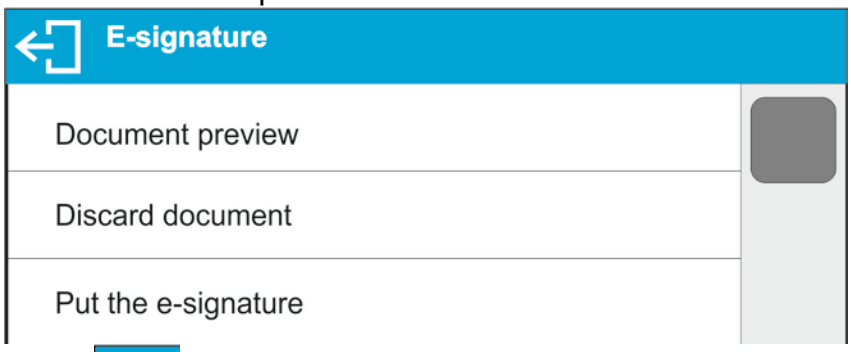
All operations on the balance should be performed by the logged-in operator. The operator will be able to carry out the operations that are available to him/her based on his/her permission level (the scope of operations for a given permission level is set by the administrator).



To start the document, press . The communication window gets open. Run the <Start new document> option.

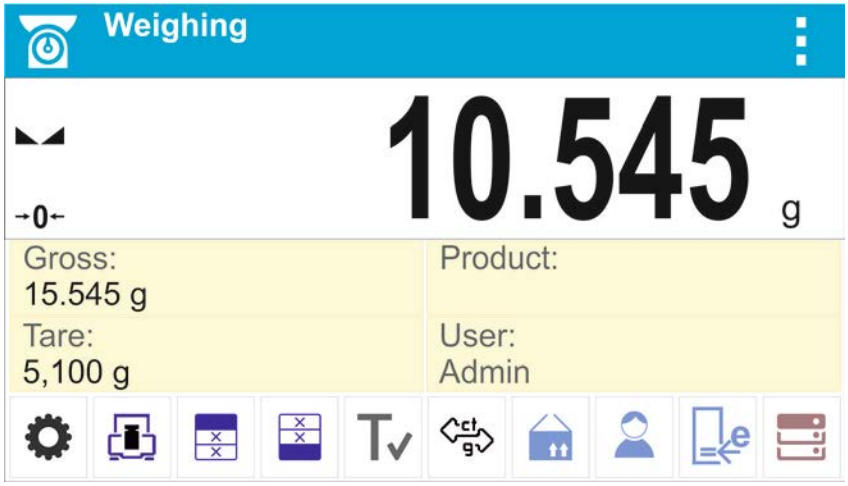


Another window opens.

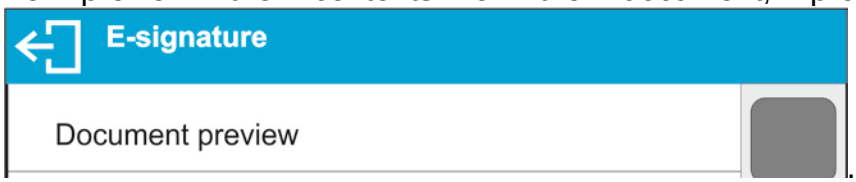


Press to return to the home screen.

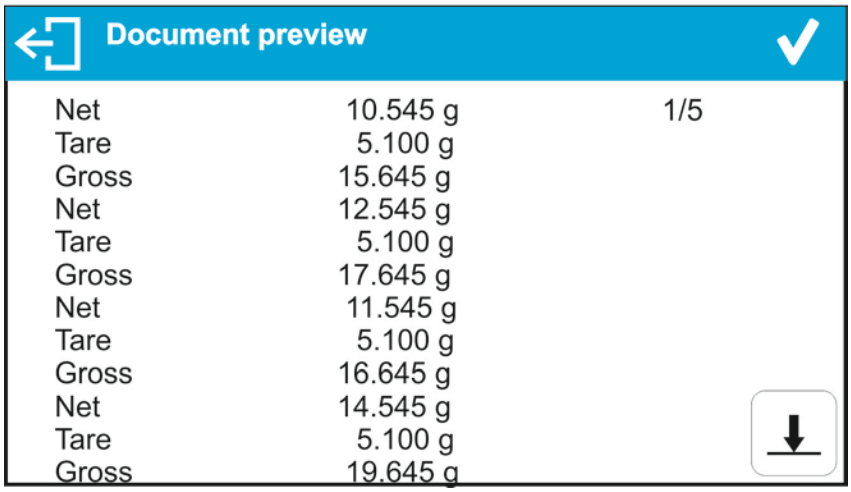
From now on, each confirmed measurement (the PRINT button on the operation panel) is saved in the open document.



To preview the contents of the document, press and select:



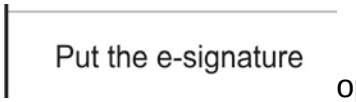
When selected, the contents of the data stored in the document are displayed on the home screen.



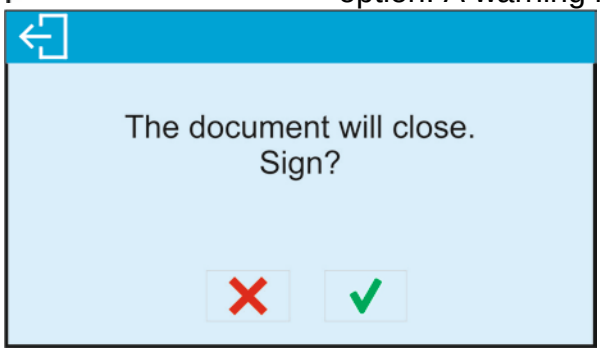
1/5 means that the first of the five pages the document contains is displayed. Press to display next pages.

You can stop saving data in the document at any time. To do so, press and select Discard document option. When selected, the following message is displayed: <Discard document?>. Press to confirm. The document is completed without saving it in the database.

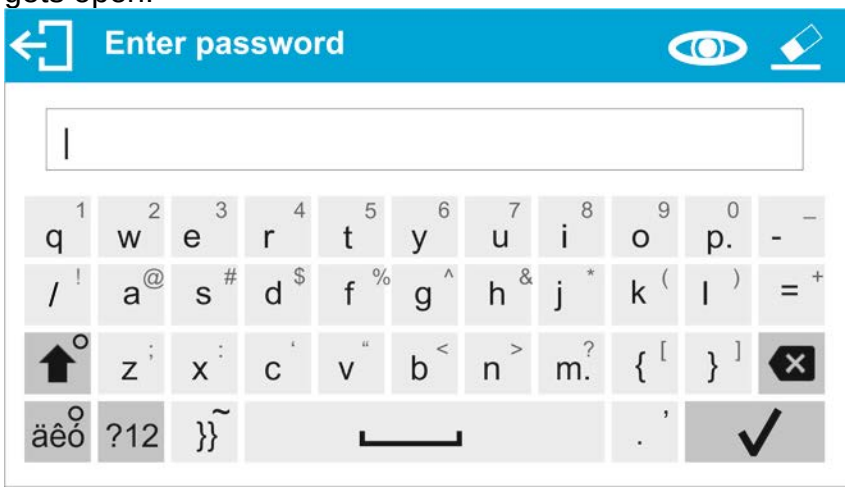
To save the document in the database, press and select



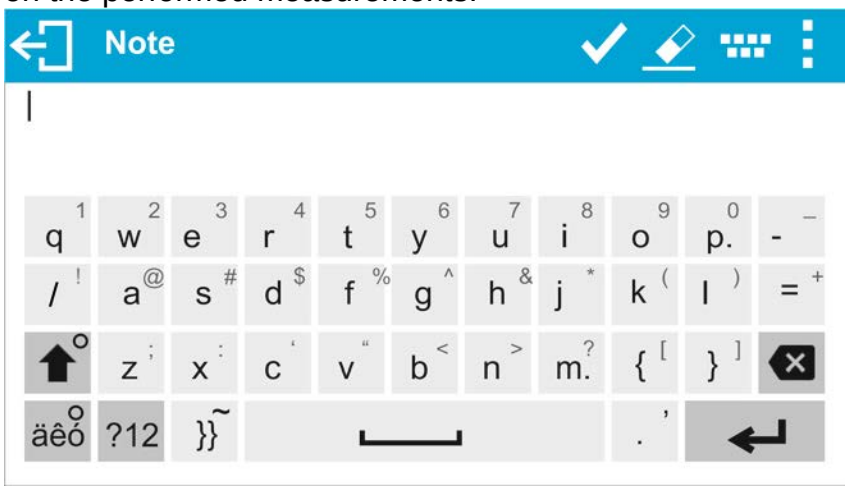
option. A warning message is displayed:



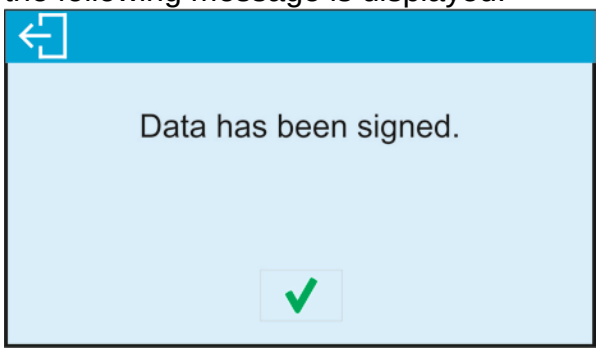
Please note that signing the document results in its being closed. Following confirmation of the operation, a window displaying a preview of the document is displayed. To continue signing the document, press , and a keyboard window gets open.



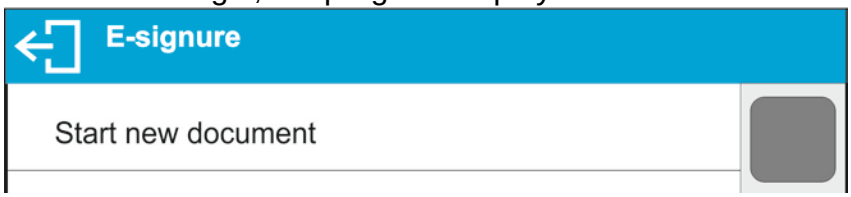
Enter the correct password of the logged-in operator and press to confirm. Another window with a keyboard is displayed, where the operator can add comments on the performed measurements.



Once a comment has been entered and saved in the document with the button , the following message is displayed:

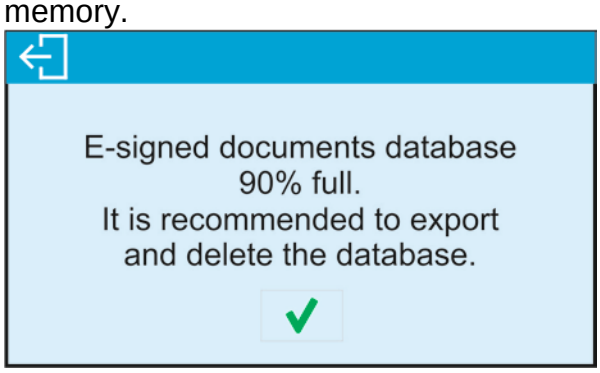


After confirming it, the program displays a window:

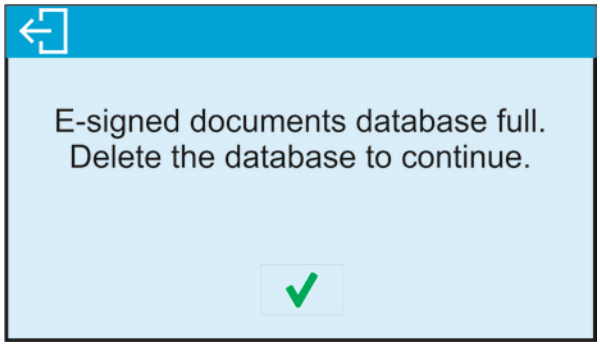


You can start another document or return to the home screen.

The balance memory is limited, and it can store up to 1000 documents of 1000 bytes each (approximately 30 lines per printout). If the documents contain a lot of data, such as SQC reports or a large series of measurements, the number of documents to save will decrease gradually. Therefore, the database of e-signed documents should be systematically archived.
The balance program continuously controls the amount of free storage space for documents. If it detects that 90% of the memory is already occupied, it displays a message reminding the operator to archive the data and delete it from the balance memory.

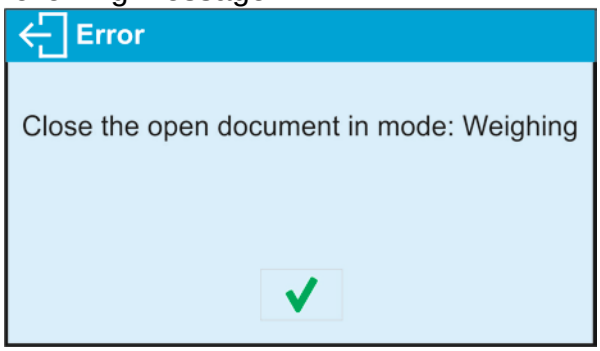


When this message is displayed, the operator has the option to continue saving documents.
If data is still being saved and the program detects that all memory is being used, the following message is displayed:



In this case, it is no longer possible to save additional measurements, and you must complete the document by signing it. Then archive the data and delete the memory contents.

The documents are related to the current working mode of the balance. If the operator switches to a different working mode before closing the document and wants to start a new document in a different mode, the balance program displays the following message:

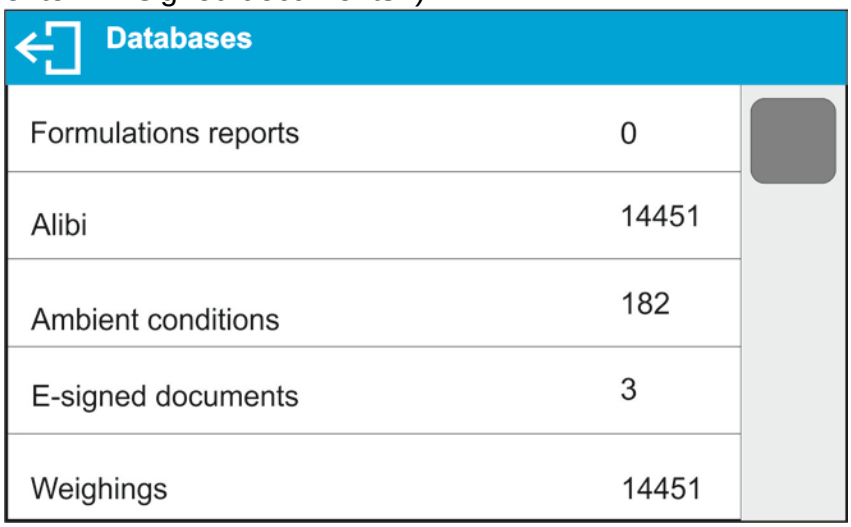


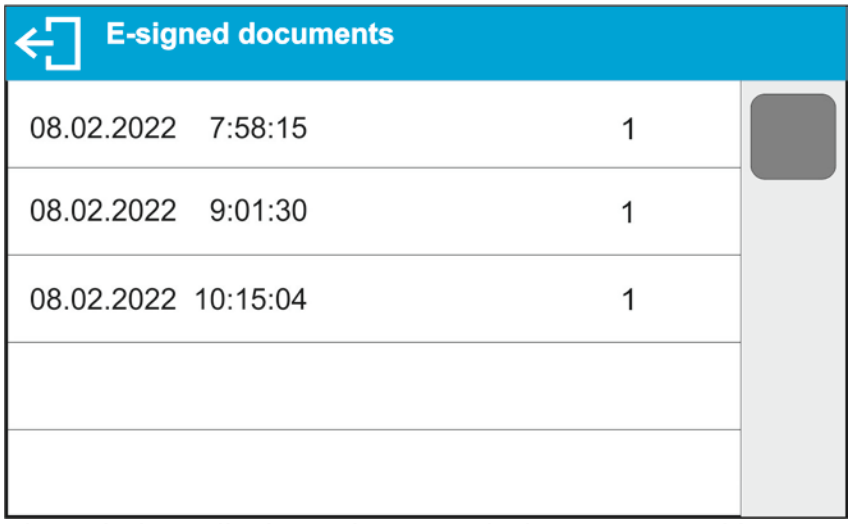
In this case, return to the previous working mode and close the document you started.

5. SIGNING THE DOCUMENT IN THE DATABASE

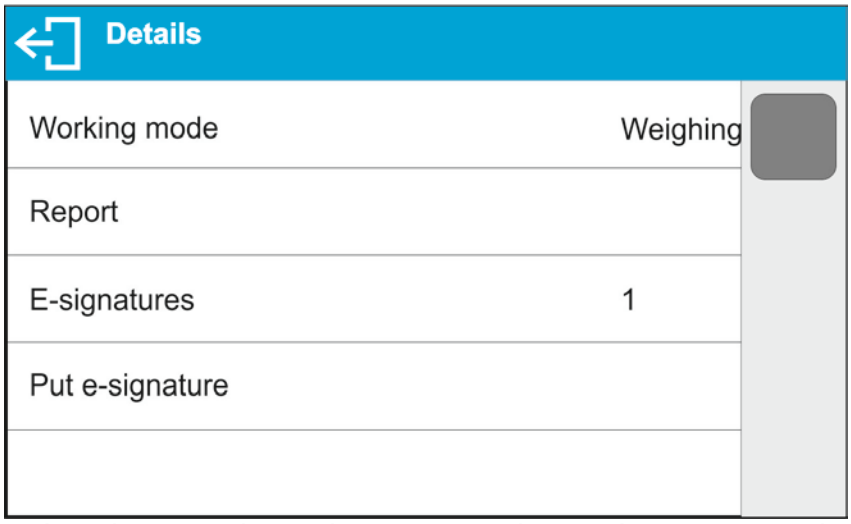
Signing the document is only possible from within the working mode. Signing automatically completes the document and saves it in the database in the <E-signed documents> parameter group.

To re-sign, approve or authorise a document, enter the database (press and enter <E-signed documents>).

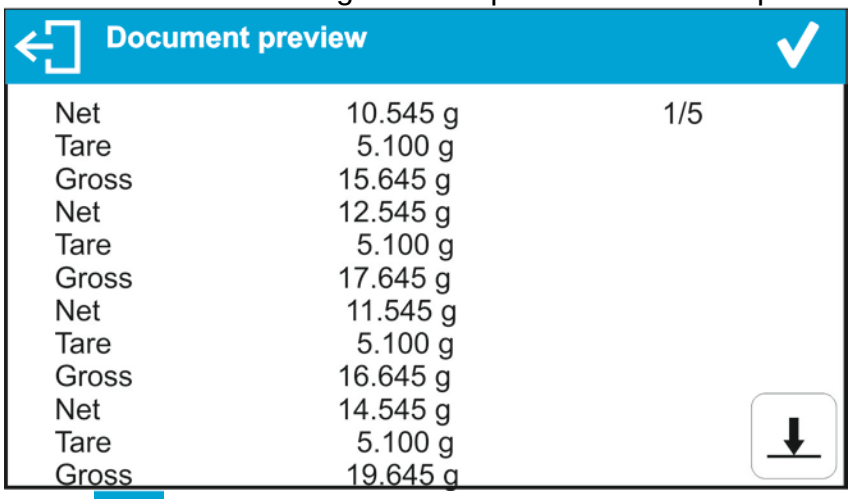




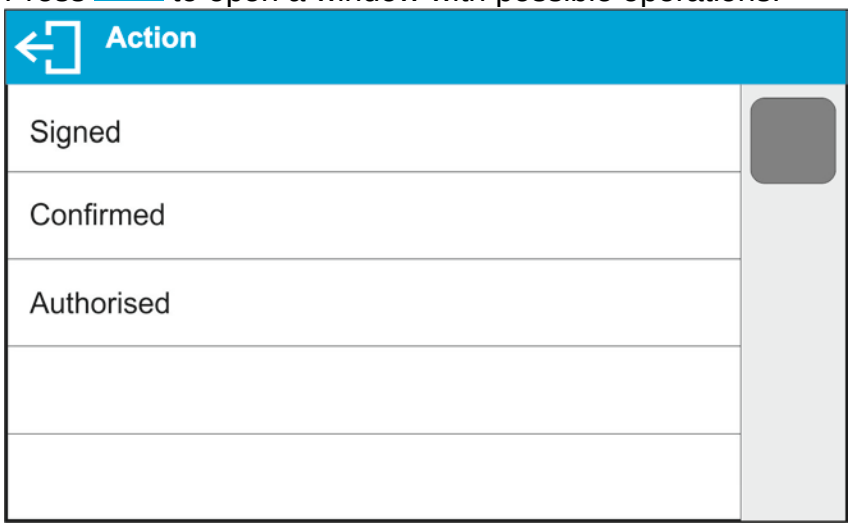
The window displays the saved documents, with a number next to each one indicating the number of e-signatures the document contains.
To add another e-signature, click in the document field. Details are displayed:



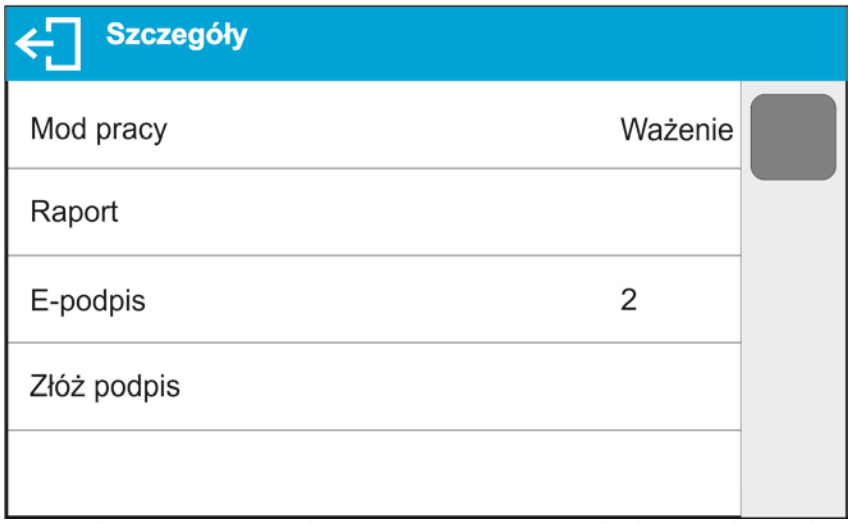
Select the <Put the e-signature> option. A document preview window is displayed:



Press to open a window with possible operations:



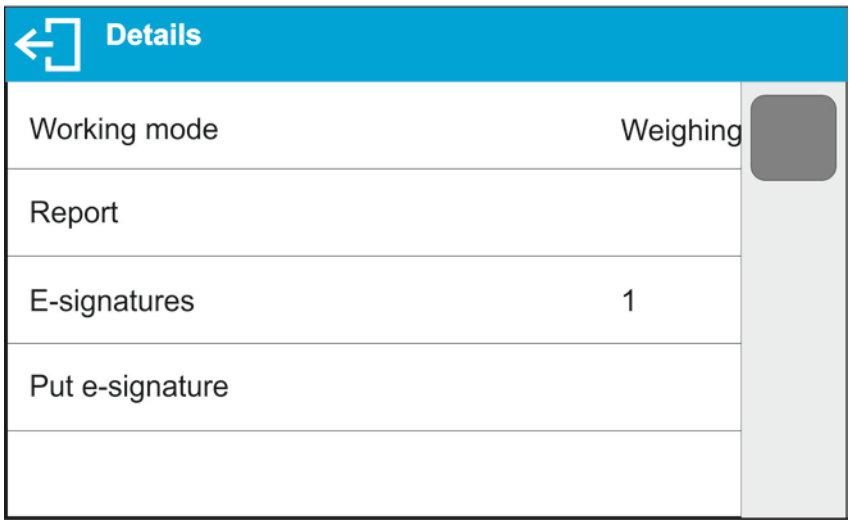
Select one of the options, e.g. <Confirmed> and, as described above, sign the document with a password and add a comment if necessary. Once confirmed, a window with details is displayed and the <E-signature> field increases the number of signatures by one.



A maximum of 10 e-signatures can be added to a given document.

5.1. Saved Document Printout

To print a document on a connected printer, go to the <Details> window and press .



The document is printed out automatically. The printout contains the e-signature data.

```
Working mode                    Weighing
----------------------------------------
----------------------------------------
Date                          10.02.2022
Time                             7:02:50
Balance type                 WLC X2 PLUS
Balance S/N                    58952365
User                              Admin
Name and Surname
Net                              50.07 g
Tare                              0.00 g
Gross                            50.07 g
----------------------------------------


Signature

........................................
--------------E-signatures--------------
Date and time         10.02.2022 7:03:39
User                              Admin
Name and Surname
Action                           Signed
Ok
----------------------------------------
```

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