USER GUIDE

5Y.35.PM

Radwag

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User manual

IMMU-1161-01-04-23-EN

21 CFR Part 11 Compliance module

5Y Balances
CY10 Balances

radwag.com
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OCTOBER 2023

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1. GENERAL INFORMATION

Additional 21 CFR part 11 compliance module

All 5Y-series balances comply with the 21 CFR part 11 regulation and EU GMP part 4 regulation, annex 11. This means that they hold an electronic signature and a series of functions that protect and monitor operations of particular operators.

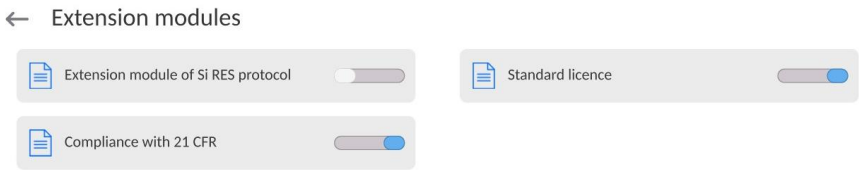
The data are fully protected through the following:

- advanced password settings
- correct login check
- assignment of unique permission levels to operators
- automatic logout
- electronic signature, e.g. for a series of measurements
- saving signed documents in the database
- data management access settings
- data backup
- saving modifications in the Audit Trail file

2. ACTIVATION OF THE MODULE

The 21 CFR compliance module can be activated through a special code generated in the RADWAG's head office on the basis of a 12-digit license number that can be read in the balance menu: **Setup / System info / License ID**.

To enable this option, send the license number to RADWAG for generation of an unlocking code. The code will be returned to the client as a file. Save the file in the main directory on the Pendrive (external storage device) and then put the Pendrive into the USB port on the side of the balance, and activate the option in the menu: **Setup / Miscellaneous / Extension modules / Compliance with FDA 21 CFR / EU GMP Volume 4**. The balance software will check if the unlocking code is correct and the module will be activated. A relevant message will be displayed on the balance screen and the parameter value will turn into **Enabled** to signal the above-stated operation.



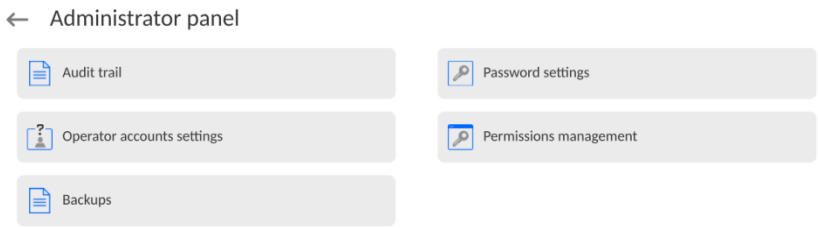
From now on, the balance software assures full functionality of the 21 CFR part 11 compliance module.

New settings related to operation of the module will show up in the **<Administrator panel>** parameters group in the balance menu. The operator can set all available parameters in accordance with 21 CFR part 11 requirements.

3. ADMINISTRATOR PANEL

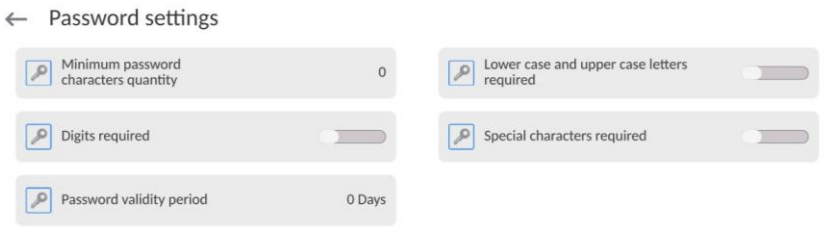
In this menu group, you can declare the scope of actions that the operator with a specific permission level can take, password protection level and the unlogged operator's permission.

NOTE: Only the operator with the <Administrator> permission level can modify this menu.



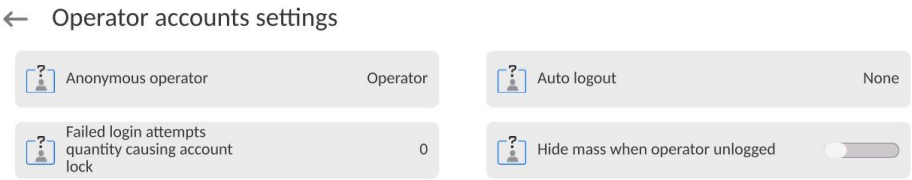
3.1. Password settings

The menu group that allows you to specify the password complexity for balance operators.



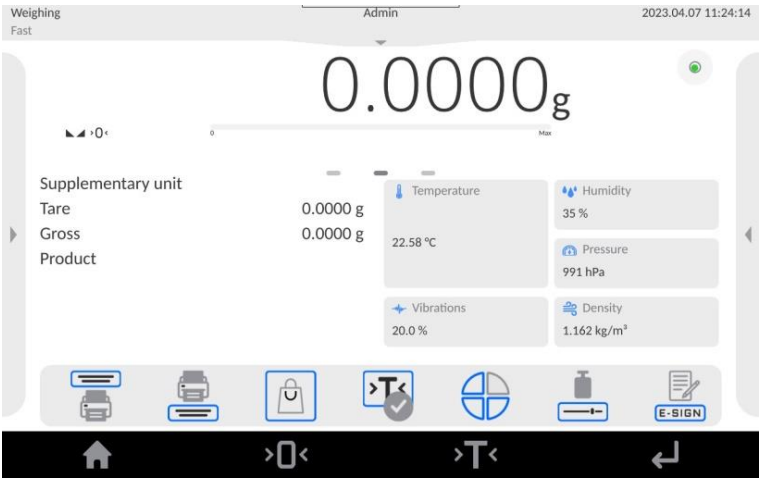
Minimum password characters quantity	Specify the minimum number of characters in the operator's password. For '0" value, you can set any number of characters.
Lower- and upper- case letters required	Specify requirements regarding characters in operators' passwords.
Digits required	
Special characters required	
Password validity period	Specify the period of time, in days, after which you need to change the password. For '0' value, the balance software does not require you to change the password.

3.2. Operator accounts settings



Unlogged operator's permission

The administrator can assign permission levels to the balance operator who has failed to log in (the so-called anonymous operator).



Procedure:
Enter the <Operator accounts settings> parameters group, select <Unlogged operator permission levels> and then choose one of the following variants: Guest, Operator, Advanced Operator, Administrator.

Note: *If you set <Guest>, the unlogged operator will not be authorised to change any software settings.*

Automatic logout
This option allows you to activate the automatic logout after a specific period of time, given in minutes, if the balance is not used.
By default this option (<None>) is inactive in the balance.

Procedure:
Enter the <Operator accounts settings> parameters group, select <Automatic logout> and then choose one of the following variants: none/3 minutes/5 minutes/15 minutes/30 minutes/60 minutes.

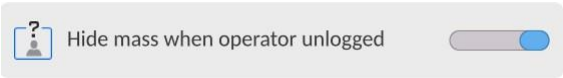
Number of account-blocking login errors
The option allows you to set the number of unsuccessful logging attempts taken by the operator. When the limit is exceeded, the access to the account will be blocked.
By default this option is disabled in the balance (<0> setting).

Procedure:
Go to the <Operator accounts settings> parameters group, select <Number of account-blocking login errors> and then enter the desired value.

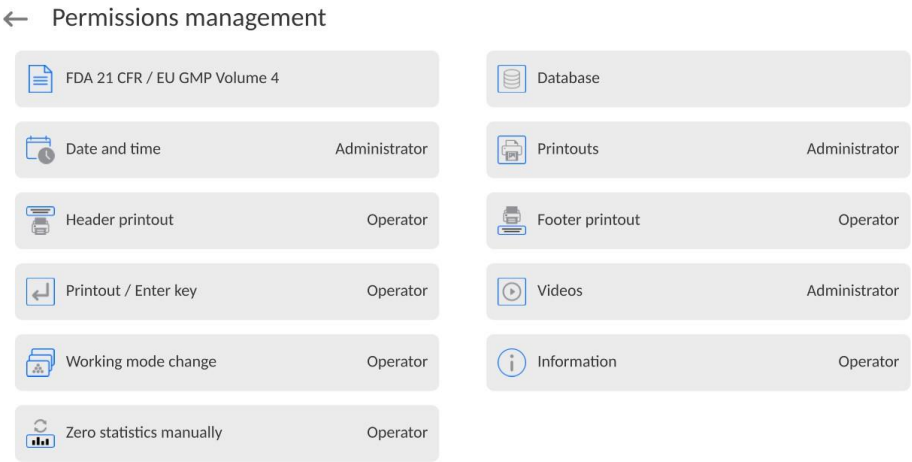
Note: *when login errors occur (when the operator enters a wrong password) in the amount specified in this parameter, the specific operator's account will be blocked. This being the case, the administrator must intervene in order to unblock the account.*

Hide mass when operator unlogged
This option allows you to disable the mass display if the operator is not logged in. By default this option is inactive in the balance (<None> setting).

Procedure:
Go to <Hide mass when operator unlogged> and then switch the option into active.

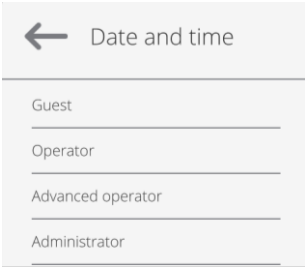


3.3. Permissions management

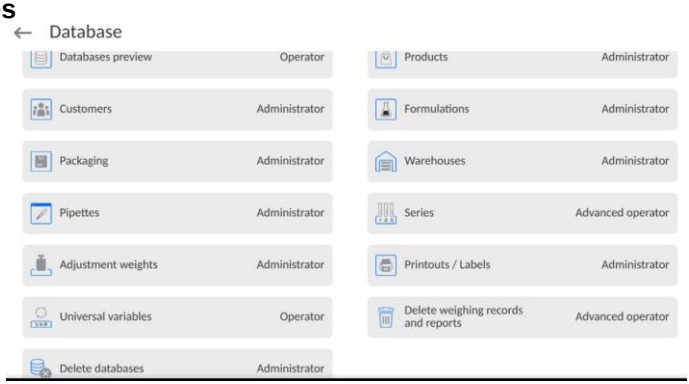


Note: *if you switch the value of permission into* ***<Guest>*** *for particular parameters, the access to settings will be open (no need to log in).*

For each option, you can assign the permission level for edition or preview. Available settings:



Databases



Default settings of the balance allow the operator logged as **Administrator** to make changes to particular databases. Depending on requirements, these permissions can be modified.
Similarly, you can change permissions for edition of other options available in this menu.

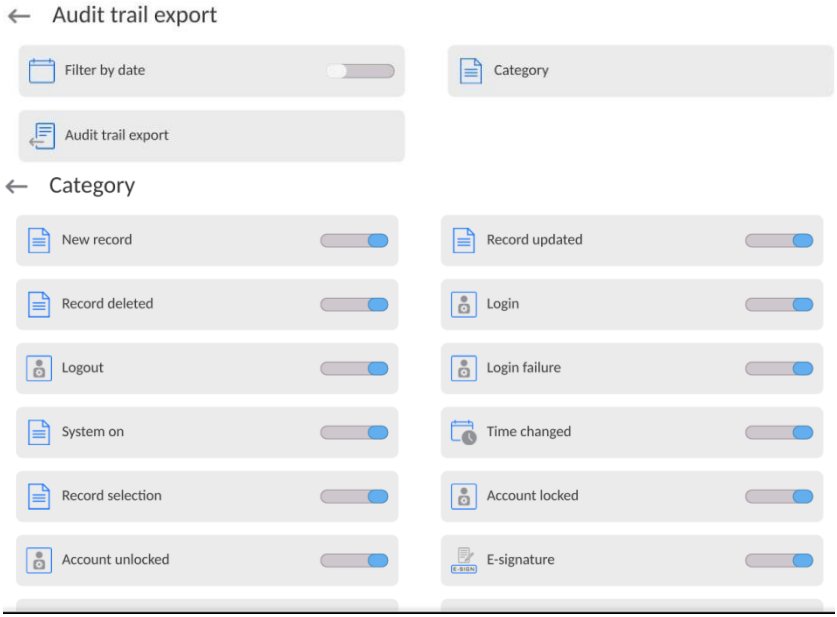
Default permission settings for particular options:

Data to be edited:		Default permission:
FDA 21 CFR / EU GMP Volume 4		
	E-signature	Operator
	E-signature: approval	Advanced operator
	E-signature: authorisation	Administrator
	Signed documents: Preview	Administrator
	Audit trail export	Administrator
	Delete archived audit trail data	Administrator
Databases		
	Database preview	Operator
	Products	Administrator
	Clients	Administrator
	Formulations	Administrator
	Packaging	Administrator
	Warehouses	Administrator
	Pipettes	Administrator
	Series	Advanced operator
	Adjustment weights	Administrator
	Printouts / Labels	Administrator
	Universal variables	Operator
	Delete weighing records and reports	Advanced operator
	Delete databases	Administrator
Date and time		Administrator
Printouts		Administrator
Header printout		Operator
Footer printout		Operator
Printout / enter key		Operator
Working mode change		Operator
Information		Operator
Manual statistics reset		Operator

3.4. Audit trail

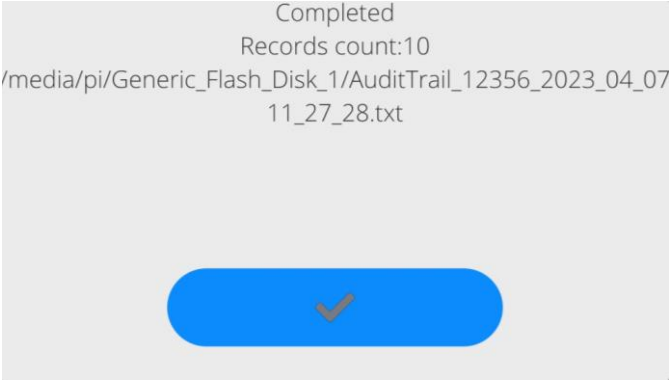
The balance software saves all operations that are required by 21 CFR part 11 in the balance memory. It applies to the operations, for example to adding, editing or deleting operators, that have been performed in the balance ever since it was activated.
The balance memory is limited and thus you need to remember to archive audit trail file systematically in accordance with provisions of the quality management system in force in the specific plant.

Before activating the function, put the Pendrive into the USB port and enable the function.



After enabling the function, a new information box will be displayed. It will show a process progress.

When it is completed, the box will be closed and the file „*AuditTrail_123123_2023_04_07 11_27_28.txt*" with data with '*readout only*' attribute will be saved on the pendrive.



The example of view and content of the *AuditTrail…*file:

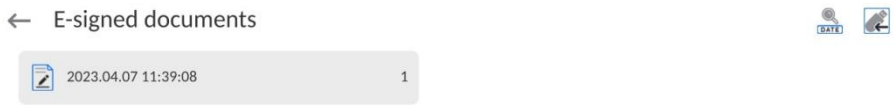
Date and time	Database name	Database name	Category	Category	Record id	Record name	Column name	Column name	Previo
2023-04-03 09:48:55	Audit trail	Ścieżka audytu	Record deleted	Usunięto rekord				2023-04-04 00:00:00	
2023-04-03 09:58:18		System on	Start systemu						
2023-04-03 09:58:19	Profiles	Profile Record selection		Wybór rekordu	1073741825		Fast		
2023-04-03 09:58:31	Operators	Użytkownicy	Login	Logowanie	1	Admin		1	Admin
2023-04-03 09:58:52	Parameters	Parametry	Record updated	Zmieniono rekord			Global/Compliance with 21 CFR		Global
2023-04-03 12:20:18	Parameters	Parametry	Record updated	Zmieniono rekord			Global/Compliance with 21 CFR		Global
2023-04-03 12:36:22	Parameters	Parametry	Record updated	Zmieniono rekord			Global/Compliance with 21 CFR		Global
2023-04-07 11:22:09	Parameters	Parametry	Record updated	Zmieniono rekord			Global/Compliance with 21 CFR		Global
2023-04-07 11:22:13	Operators	Użytkownicy	Logout	Wylogowanie		Supervisor			
2023-04-07 11:22:15	Operators	Użytkownicy	Login	Logowanie	1	Admin		1	Admin

Once the data have been archived, you can delete the audit trail so that you can make space for further data.
The following events are saved in the *AuditTrail…* file:

Scope of data	Scope of logged changes
Operators	Adding, deleting, editing and logging, logging out (also automatic), wrong login, account blocking, account unblocking.
Clients	Adding, deleting, editing.
Products	Adding, deleting, editing.
Profiles	Adding, deleting, editing and selecting specific profile.
Packaging	Adding, deleting, editing.
Warehouses	Adding, deleting, editing.
System start	
Date and time change	
Adjustment	Every adjustment completion event.
Database import	
Backup	Execution and restoration of backup.

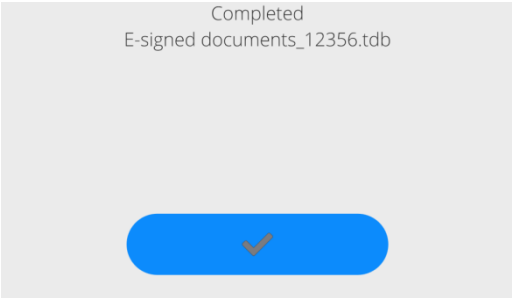
3.5. E-signature

The balance software can save data on completed weighing in the balance memory. These data can take a form of documents and can be signed via the so- called e-signature.
The balance memory is limited and allows saving up to 16 GB of data with documents.
For this reason please remember to archive the signed documents base systematically.



Before activating the function, put the Pendrive into the USB port and enable the signed document export function by using the key.
When the function is active, a new information box will be displayed. In the box, you will see a process progress.

When it is completed, the box will be closed and the „*E-signed documents_123123.tdb*" file with data will be saved on the Pendrive.



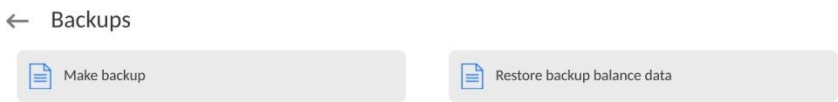
```
Working mode                    Weighing
----------------------------------------
Date                          2023.04.07
Time                            11:36:48
Operator                           Admin
Product
Net                            10.0018 g
Date                          2023.04.07
Time                            11:36:57
Operator                           Admin
Product
----------------------------------------

------------- E-sign data --------------
Date and time        2023.04.07 11:39:08
Operator                           Admin
Name and Surname
Action                            Signed
----------------------------------------
------------- E-sign data --------------
Date and time        2023.04.07 11:42:58
Operator                           Admin
Name and Surname
Action                         Confirmed
----------------------------------------
```

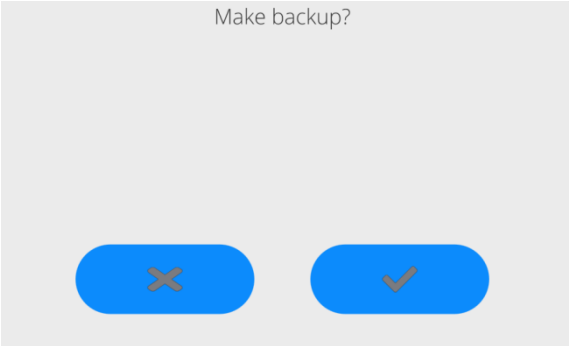
Once the data have been archived, you can delete signed documents in order to assure space for further data.

3.6. Backup

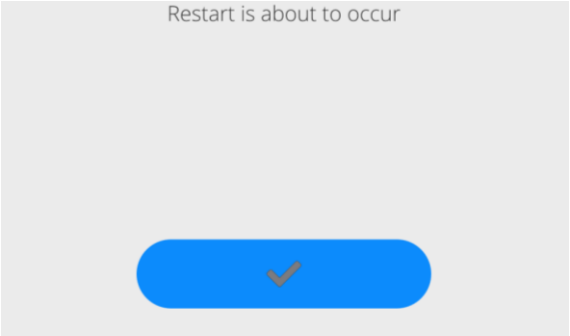
The balance software allows you to make a backup of settings and data saved in the balance memory, and in case of emergency, for example balance failure and a need to replace it, to import saved settings and data to a new balance. To make the data restoration procedure possible, a new balance must be identical in terms of the software and metrological settings to the previous balance.
The authorised operator can make a backup on the Pendrive at any time.

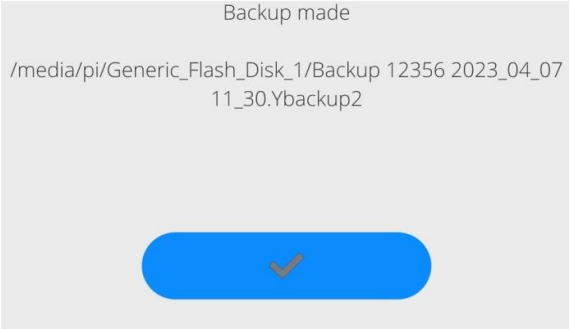


Before activating the function, put the Pendrive into the USB port and enable the function.

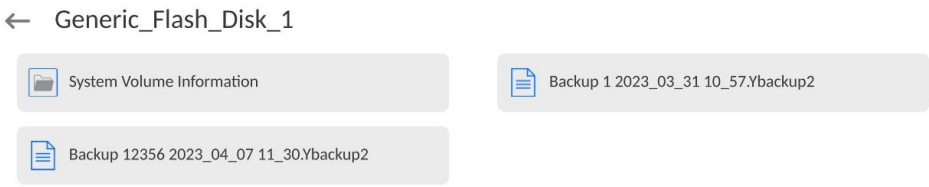


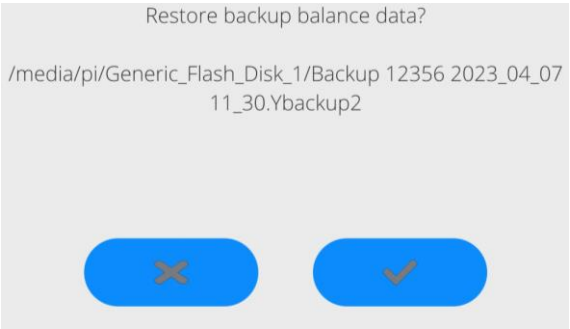
After activating the function, the backup making procedure will be initiated. Throughout the procedure, the balance settings and data saved in the balance memory will be saved in a relevant file.





When it is completed, the „*Backup 12356 2023_04_07 11_30.Ybackup2*" file (backup file with balance settings and data) will be saved on the Pendrive.
To restore the data, plug the Pendrive with files with backup in and activate the
<Restore backup balance data> variant.

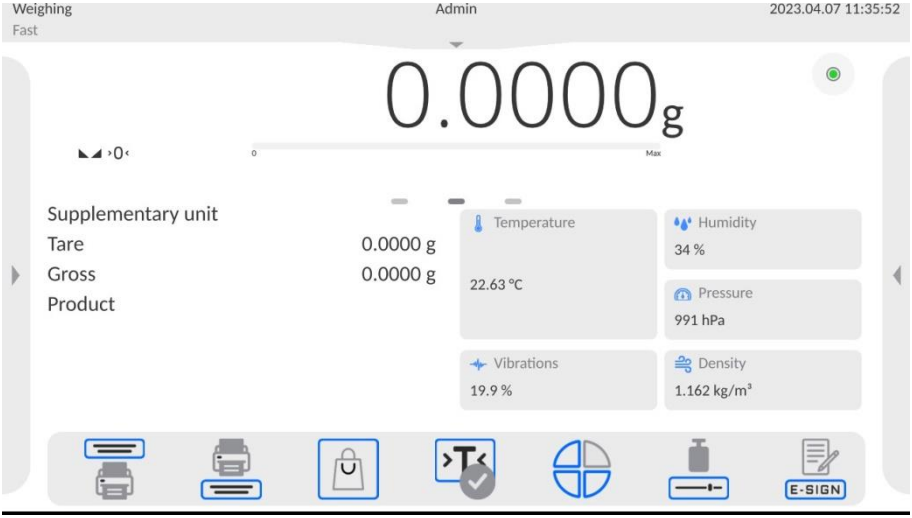




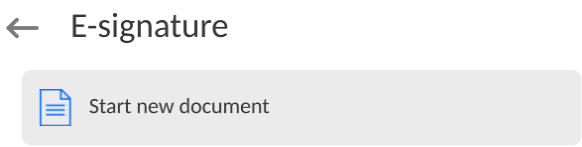
The balance software will check if the data are correct and if they can be copied into the memory. If the procedure is found feasible, the backup restoration procedure will be initiated automatically and the operator will be notified of the progress through relevant messages in the home screen. Once the procedure has been completed, the information on restoration of data will be saved in the Audit Trail file.

4. CREATING A DOCUMENT AND SIGNING IT VIA E-SIGNATURE

Any operations in the balance must be performed by the operator after he has logged in. He will be allowed to perform operations attributable to his permission level (permission level for the operation is determined by the administrator).

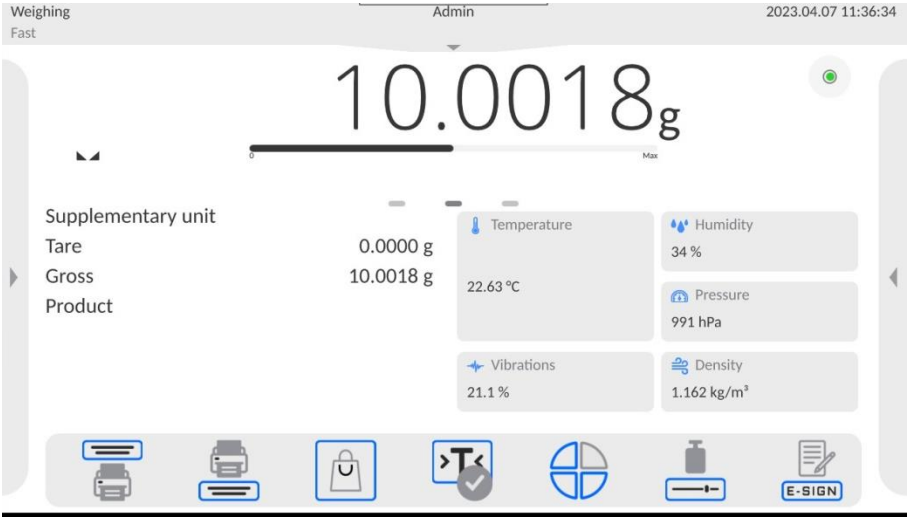


To start the document, click and the communication box will be displayed. Activate <Start new document>.

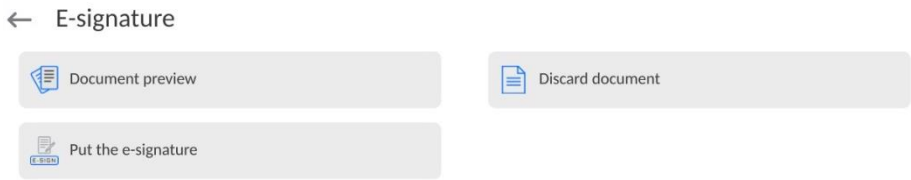


The procedure of creating a new document will be initiated automatically and the home screen of the software will be displayed again.

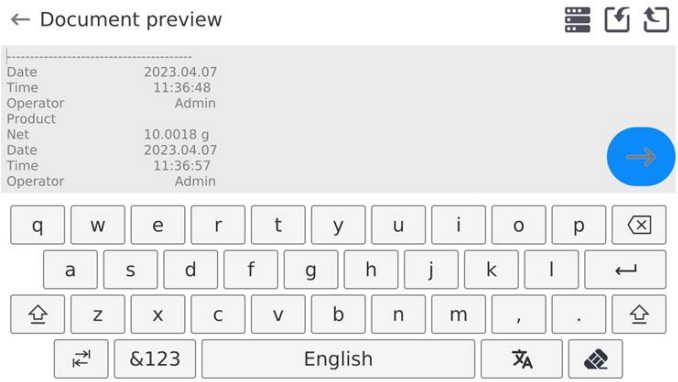
From now on, every approved measurement (PRINT key on the balance screen) will be saved in the open document.



To preview the content of the document, press and select <Document preview>.



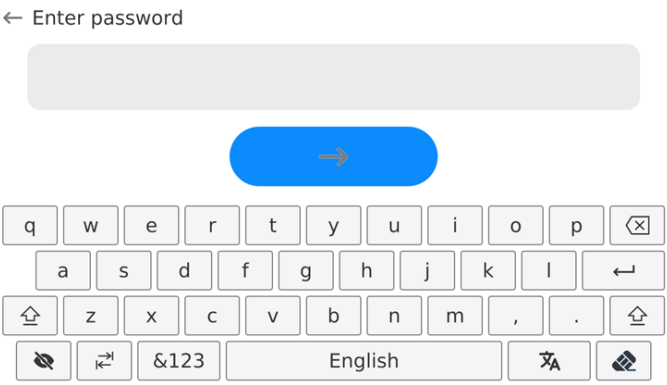
Once you have selected it, the home screen will show the content of data saved in the document.



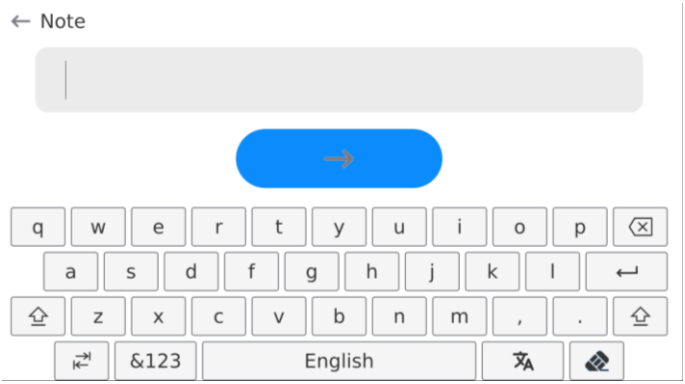
At any time you can abort saving data in the document. To do so, press E-SIGN and select Discard document. After selecting it, you will see a message with the question: <Abandon document>?. If you confirm the operation with ✓, the document will be finished and will not be saved in the database.

To save the document in the database, press E-SIGN and select Put the e-signature. Next a document preview box will be displayed.

To continue the document signing procedure, press →. You will see a box with a keyboard.



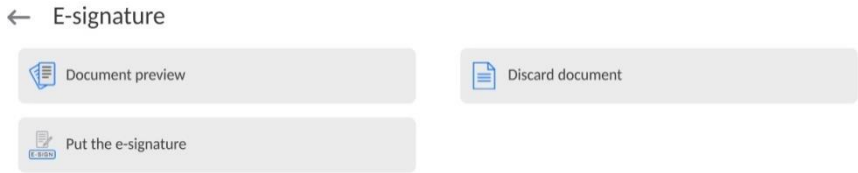
Enter a correct password of the logged operator and press to confirm it. You will see another box with a keyboard. There, the operator can add a comment on completed measurements.



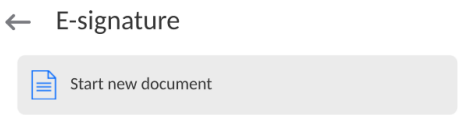
After entering the comment and saving it in the document through , the following message will be displayed:

The operator can do either of the following:

1. Keep on working with this document and add further measurements by clicking . This being the case, the message box will be closed and another window will pop up:



2. Stop saving measurements by clicking . This being the case, the document will be closed and the box will be displayed:



You can start another document or go back to the home screen of the software.

The balance memory is limited and allows saving up to 16 GB of data with documents. For this reason please remember to archive the signed documents base systematically.

The balance software checks the free space for documents on an ongoing basis. If it determines that 90% of memory is taken, the message that reminds the operator to archive data will be displayed.
After this message has been showed, the operator can keep on saving documents.
If the data are still saved and the software detects full memory, another message on lack of space will be showed.

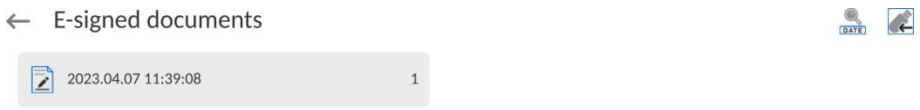
This being the case, it will not be possible to save further measurements. Finish the document you have started by signing it. Archive data afterwards.
The documents are related to the current working mode of the balance. The software allows creating documents in any working mode at a time. This means that you can have several active documents in various working modes.

5. SIGNING A DOCUMENT FROM DATABASE LEVEL

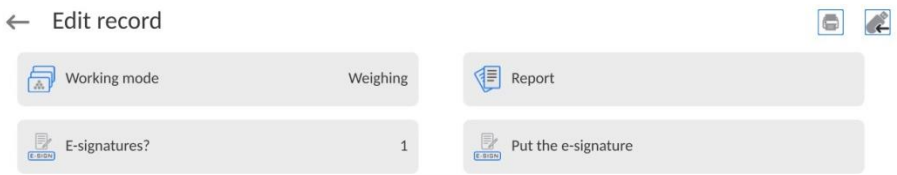
You can only sign documents from the working mode level. Signing and finishing the document results in saving it in the database in the <Signed documents> parameters group.

To sign, approve or authorise the document again, enter the reports base and go to the <Signed documents> base.

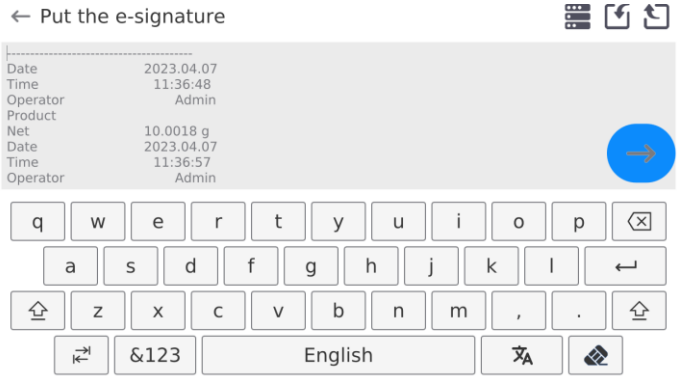
The box will show saved documents and each of them will be assigned a number specifying the number of e-signatures for a specific document.



To add another e-signature, click the document field to display details:

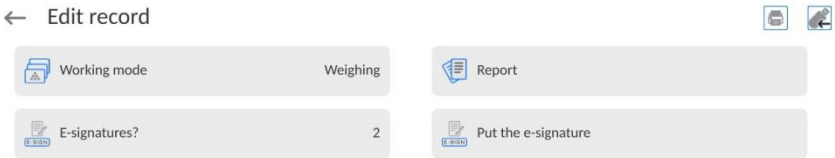


Select the <Put the e-signature> variant. The document preview box will be displayed:



Press to display the box with available operations:

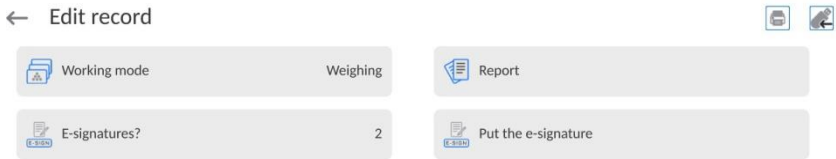
Select one of the options, e.g. <Confirmed>, and following the description above on signing the document, sign the document via the password and add, if necessary, a comment. After confirming it, the box with details will be displayed, and the number of signatures in <E-signature> field will rise by one.



You can add up to 10 e-signatures to a specific document.

5.1. Saved document printout

To print the document out using a connected printer, click in the <Details> box.



The document with data on e-signatures in this document will be automatically printed out.

```
Working mode                    Weighing
----------------------------------------
Date                          2023.04.07
Time                            11:36:48
Operator                           Admin
Product
Net                           10.0018 g
Date                          2023.04.07
Time                            11:36:57
Operator                           Admin
Product
----------------------------------------

------------- E-sign data --------------
Date and time        2023.04.07 11:39:08
Operator                           Admin
Name and Surname
Action                            Signed
----------------------------------------
------------- E-sign data --------------
Date and time        2023.04.07 11:42:58
Operator                           Admin
Name and Surname
Action                         Confirmed
----------------------------------------
```