



PD-100

USER MANUAL



PRO Devices A/S

Gadeledsvej 27C, DK-3400 Hilleroed, Denmark | www.pro-devices.com | CVR 36 45 63 88

Document Information

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1 Introduction

Thank you for buying an instrument from PRO Devices A/S. You have chosen a product, that gives you professional experience and innovation. PD-100 has been designed with you as a customer in mind.

This manual is a comprehensive document to accompany routine use of the PD-100 for reading Antimicrobial Susceptibility Testing (AST) plates after incubation using the Disc Diffusion Test Method. The routine mode that is described here can be adapted according to specific needs of the laboratory e.g. for rapid AST reading, however this document describes the recommended way to use the instrument.

PD-100 is an in Vitro Diagnostic Device (IVD) and functions as a visual aid in determining the inhibitions zones for Disk Diffusion Tests. The PD-100 is registered in the Eudamed Database with the UDI-DI code: 05700002250209 under the IVDR (Regulation (EU) 2017/746 on In Vitro Diagnostic medical devices).

Please visit our webpage www.pro-devices.com/en/ to get more information or

Contact us at support@pro-devices.com.

Please register your product at our webpage to ease our assistance:

www.pro-devices.com/en/product-registration

Please have the following data ready, when you contact us regarding service or issues: Model & serial number printed on the CE Mark on the backside of the instrument.

Unpacking and first installation of PD-100 should be performed by a PRO Devices A/S representative.



2 Safety Instructions

Please read this manual thoroughly before using the PD-100 instrument. Only personnel trained by PRO Devices A/S or PRO Devices A/S legal representative are authorized to install the PD-100 instrument and software. PRO Devices A/S cannot be held responsible if the instrument is wrongly installed by unauthorized personnel. Always keep the User Manual together with the instrument.

Always refer to labelling and PRO Devices A/S instructions to avoid compromising application integrity. The user must always operate with full knowledge and appreciation of application warnings, comments, and alarms. Local or national regulations must be applied during all operations.

2.1 Warranty Limits

The duration of warranty is stipulated in the General Terms and Conditions of Sales associated with the purchase of this application/instrument.

To ensure valid warranty, the following must be fully observed:

1. The PD-100 application must be installed on a computer provided or approved by PRO Devices A/S.
2. The application/instrument is operated under the instructions of this manual.
3. The software must be the original copyrighted version.
4. Services and repairs are provided by a PRO Devices A/S authorized technician, using only PRO Devices A/S approved spare parts.
5. The electrical supply of the laboratory follows national regulations.
6. Proper tools are used when maintenance or troubleshooting operations are performed.



If this instrument was supplied to you by anyone other than PRO Devices A/S or a PRO Devices A/S authorized representative, PRO Devices A/S cannot guarantee this product in terms of specification, latest software version and latest documentation. Further information may be obtained from your PRO Devices A/S authorized representative.

2.2 Safety Precautions

PD-100 application is working in connection with the PD-100 instrument which contain electric/electronic components.

Do not tamper with the instrument and do not remove any components (panels etc.) unless otherwise instructed within this document.

2.3 Biological Risk

Consider all Samples, Specimens and Reagents as potentially infectious! Use established, good laboratory working practices when handling specimens. Follow safety practices as specified in your laboratory.

All accessible surfaces of the instrument can be potentially contaminated and pose a biological risk. Local and national regulations must be applied in all the operations.

Refer to chapter 7 Cleaning & Maintenance, for cleaning procedures.

3 Working Conditions for Hardware Items

Failure to respect the following working conditions and safety instructions may compromise the user safety.

3.1 Environment & Location

The operation of the PD-100 application installed on a computer is restricted for indoor use only.

Please contact your local PRO Devices A/S representative for any information regarding the operation location when it does not comply with the recommended specifications.

The instrument should be placed on a clean and levelled table or workbench.

Avoid direct exposure to sunlight.

Place your instrument where it is not exposed to water or vapor.

Place your instrument where it is free from vibration or shock.

3.2 Humidity and Temperature Conditions

Temperature: from 18°C to 30°C (65°F to 86°F)

Humidity: Maximum relative humidity should be 80% for temperatures up to 30°C (86°F) without condensation. If the system is kept at a temperature of 10°C (50°F) or less, it must be allowed to sit at room temperature for at least 1 hour before it can be used for operation.

3.3 Disposal

The instrument must be disposed of, in accordance with local legislation.



The crossed out wheeled bin symbol indicates the product requires appropriate treatment, collection, and recycling for Waste of Electrical and Electronic Equipment (WEEE) under the Directive 2012/19/EU in the European Union.

Your correct disposal according to WEEE will contribute to reducing wasteful consumption of natural resources and protecting human health and the environment from potential negative effects caused by hazardous substance in products.

Due to the local changing regulations in each country, please contact your local representative for detailed and up-to-date information on how to appropriately dispose of the instrument.

4 Unpacking and Installation



Unpacking and first installation of PD-100 should be performed by a PRO Devices A/S representative.

4.1 Setting up the PD-100

PD-100 is composed of the following elements:

- PD-100 instrument
- PD-100 application software
- A dongle for protection of the software
- MicroConnect USB cable 2.0 A-B (connection to PC)
- This User Manual, which will also be available electronically and placed on the PC desktop.

The PD-100 must be connected to a PC via the delivered cable and the PC must be connected to a power supply. The PD-100 is calibrated with one PC and, in case you have more than one PD-100, cannot be connected to the other PC without a re-calibration done by PRO Devices A/S. The dongle must be inserted in the PC.

4.2 Technical Features and Installation

4.2.1 Technical Features

Instrument dimensions (L x D x H): 19 cm x 19 cm x 21 cm

Weight net: 5 kg

Power supply: DC 5V/500 mA (via USB supply from PC)

4.2.2 PC & Screen Requirements

The following is required for the PC to run the PD-100 program.

PC type:	Laptop PC
Hard drive:	Preferred SSD-disc
Processor:	2 Core (can also use more, but not necessary) i5 or i7 with at least 2,3 GHz
RAM:	At least 8GB SD-RAM
Capacity:	256 GB (An external hard drive/server can be used for storing data and photos)
Screen:	Full HD (min. 1080p)
Screen size:	At least 15.6"
Graphic card:	No requirements
License:	Windows 10
Connections:	At least 2 USB Ports

4.2.3 IT Network

PD-100 should be connected to the laboratory network to allow complete functionality. This is particularly important to be able to transfer data to the LIMS system.

4.2.4 Environmental Features

PD-100 should be placed at room temperature. Machine performance decreases in very cold or very hot environments. Do not place PD-100 near a hot source to avoid overheating.

5 PD-100 – General Introduction

PD-100 is an in Vitro Diagnostic Device (IVD) and functions as a visual aid in determining the inhibitions zones for Disk Diffusion Test of Antimicrobial Susceptibility Testing (AST).

PD-100:

1. improves the quality of measuring Inhibition zones during AST testing.
2. optimizes and streamlines the manual routine workflow within AST measurements using modern technology. Thereby reducing the work-related injuries in connection with manual reading.
3. is helping laboratory professionals meet EUCAST guidelines and enables standardization of the AST reading, helping with laboratory accreditation.
4. ensures that important data are automatically saved and traceable.

5.1 Intended Use

PD-100, see Figure 1, takes a photo and measures the inhibition zones on the AST agar plate and is intended for use by laboratory professionals.

PD-100 has four different functionalities/features:

1. Measure AST Agar Plates
2. Photo AST Agar Plates for later analysis
3. Measure via “Image from File”
4. Verification

1. feature, *Measure AST Agar Plates*, is the routine reading of inhibitions zones on AST agar plates, see chapter 6.2.

PD-100 identifies the antibiotic disc on the agar plate (disk diffusion method) and comes with a suggestion for the diameter for all zones but will not give a diagnose.

The Biomedical Laboratory Scientist or Laboratory Technicians controls the antibiotic disc ID's and the zone measurements and make changes to the measurements if needed.



Figure 1 – PD-100

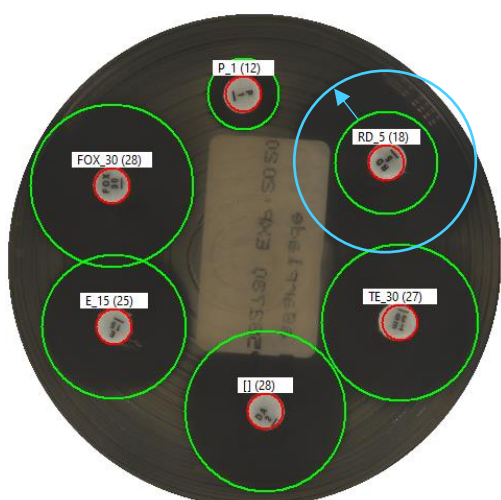


Figure 2 – Screenshot of measurements from PD-100, where the zone for RD_5 is too small due to the label

Sometimes PD-100 does not detect the correct zones, e.g. if there is a label on the bottom, see RD_5 in Figure 2 and in this case the Scientist/Technicians must manually set the circle for the measurements, see chapter 6.3.

2. feature, *Photo AST Agar Plates for later analysis*, is only saving the images without analyzation, see chapter 6.4.

3. feature, *Measure via “Image from File”*, is when you wish to analyse a previous measured AST agar plate, or images saved for later analysis. Then the PD-100 can load the photos from a measurement made e.g. 2 weeks ago and the program can analyse it again, see chapter 6.5.

4. feature, *Verification*, a Verification Plate can be used for self-calibration, see chapter 6.6.

6 Routine Use

6.1 Start the Software Program

1. Make sure that the PC is connected to the power supply.
2. Make sure that the PD-100 is connected to the PC with the USB cable and that the Dongle is in the PC.
3. Start up the PC.

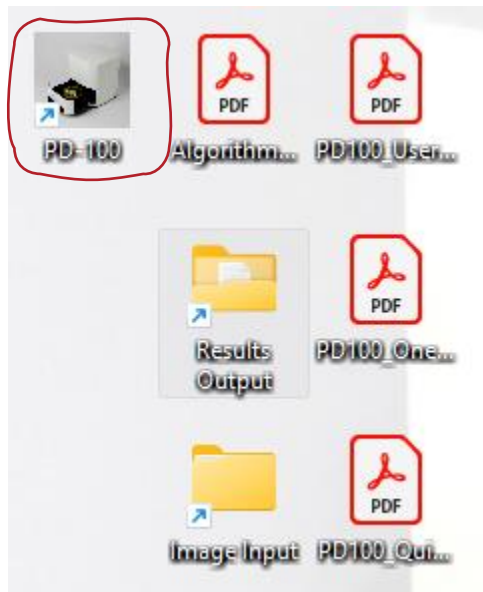


Figure 3 – PD-100 Icon

4. Start the PD-100 program by clicking the Icon on the desktop, see Figure 3.
1. If the program does not start, the license may have expired, please contact PRO Devices support@pro-devices.com or your local representative.
5. See chapter 8 Trouble shooting – PD-100 program, if the program does not start correctly.

6.2 Measure AST Agar Plates

1. The cursor is placed in Journal ID, see **1** in Figure 4, if not press **F4** (some PC's Fn+F4) and read the barcode (if available) of the AST agar plate with the scanner.
2. Open the drawer on PD-100, remove the lid from the AST agar plate and place it inside.
3. Close the drawer.
4. The PETRIDISH TYPE shows Round 90 [mm], see **2** in Figure 4. Currently it is only possible to measure round 90 mm plates. Other sizes will be implemented later.

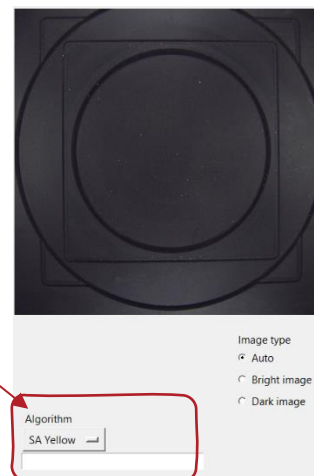


Figure 4 – PD-100 Program

5. SA Yellow is the preferred algorithm and default from start. The Bacteria Specie on the AST sample determines which algorithm to choose. See Figure 5 or see the overview in the file "ALGORITHME OVERVIEW" found on the desktop, see Figure 3.

IRIS-100 Algorithm	Bacteria Specie	Characteristics	Picture Example
EC Yellow	<i>Escherichia Coli</i>	YELLOW WEAK OR STRONG GROWTH WEAK OR GOOD CONTRAST	
EF Yellow	<i>Enterococcus Faecalis</i>	YELLOW WEAK GROWTH WEAK CONTRAST	
HI Red	<i>Haemophilus Influenzae</i>	RED WEAK GROWTH WEAK CONTRAST	
PA Green	<i>Pseudomonas Aeruginosa</i>	GREEN-GREEN/YELLOW STRONG GROWTH – GOOD CONTRAST	
		WEAK GROWTH – WEAK CONTRAST	
SA Yellow	<i>Staphylococcus Aureus</i>	YELLOW STRONG GROWTH GOOD CONTRAST	
SP Red	<i>Streptococcus Pneumoniae</i>	RED STRONG GROWTH GOOD CONTRAST	

Figure 5 – Algorithms



6. Click the START button, see **3** in Figure 4, or press **F5** (some PC's Fn+F5).
7. The PD-100 program will now take a photo and make the analysis. This will take a few seconds.

6.3 The Results

1. Once the analysis is done, the program will show the following screen, see Figure 6.
2. The program will automatically show 3 pictures, a Dark Image, the Zones, and a Bright Image, see Figure 6.

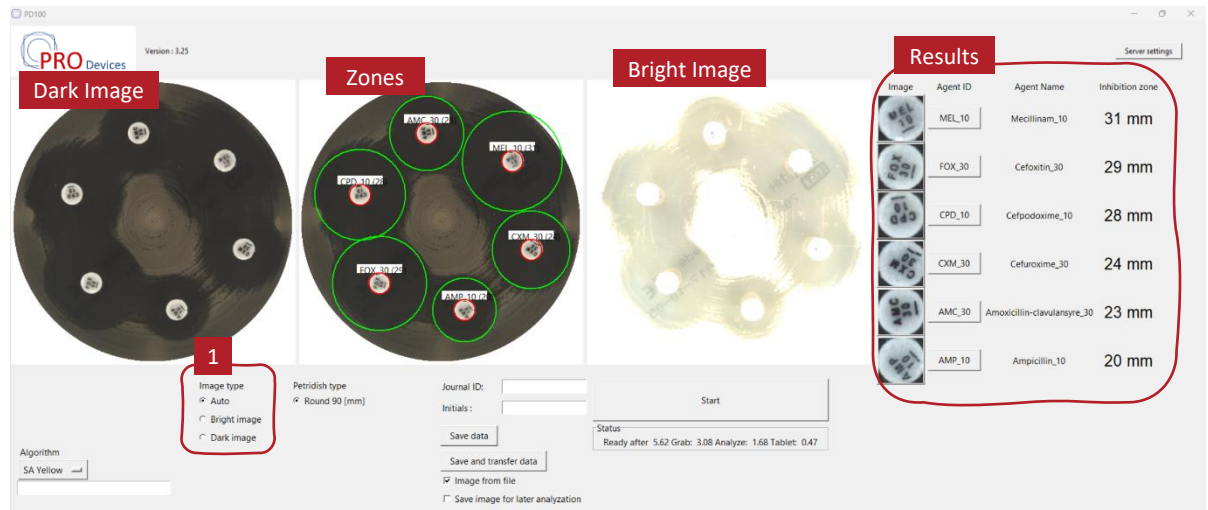


Figure 6 – PD-100 with results

3. The results are shown to the right on the screen, see Figure 6. The results will be shown with the largest found zone first and consists of:
 - a. Image – this is a photo of the individual discs found on the AST agar plate.
 - b. Agent ID – this is the identification of the discs determined by PD-100.
 - c. Agent Name – this is the name of the antibiotic disc
 - d. Inhibition zone – this is the diameter of the zone determined by PD-100.
4. The AST agar plate can now be removed for possibly manual inspection or disposal.
5. Check that the found antibiotics are correct. If PD-100 cannot identify a disc, the Agent ID is missing or wrong, see examples in Figure 7. The reason can be that the text is very skewed ("DA_2" is not in the centre of the disc) or unclear (the "F" is not clear), or that the Disc ID is not in the database, which can be remedied by PRO Devices A/S, see point 9. Data cannot be saved if a Disc ID is missing.

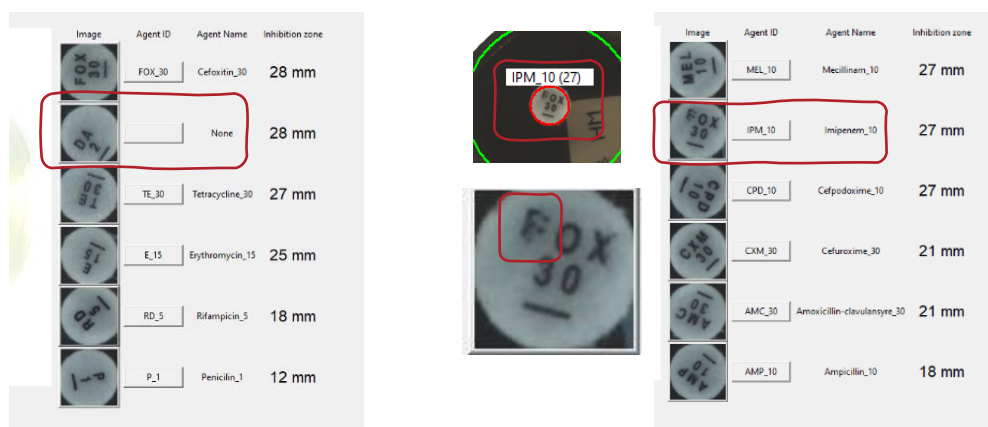


Figure 7 – Example of PD-100 with respectively missing and wrong Agent ID

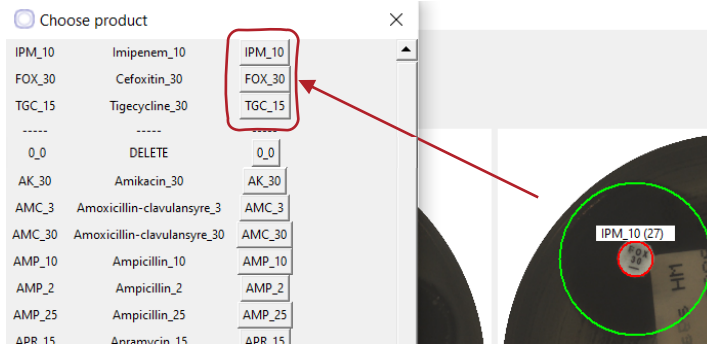


Figure 8 – Change Disc ID

6. If the Agent ID is not found or wrong, please click the Agent ID and a list with all known antibiotics are shown, the most likely disc IDs are the top 3 ones, see Figure 8. Click on the right one and the Agent ID and Name will automatically change, see Figure 9.

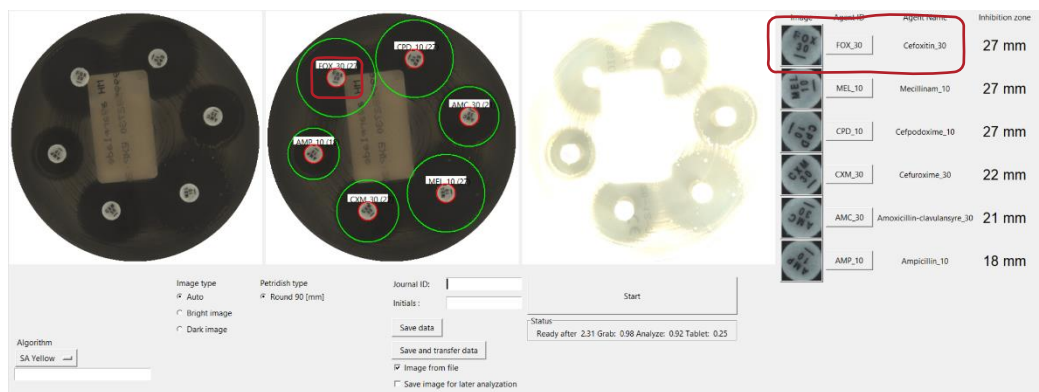


Figure 9 – New Disc ID

7. If the disc is not read with the message “Not Mast”, then you only have the right to use Mast discs. The disc cannot be changed, and the zones cannot be read, see Figure 10. Please contact PRO Devices or your local representative to upgrade your system.



Figure 10 – Not Mast – License only gives access to read Mast Discs

8. The label may disturb the readings, see point 14 below. The edge of the label may be seen as a disc, see , then select “DELETE – 0_0” as Disc ID and it will not be saved. This can also be chosen if the zone is not relevant for the bacteria and data will not be saved.

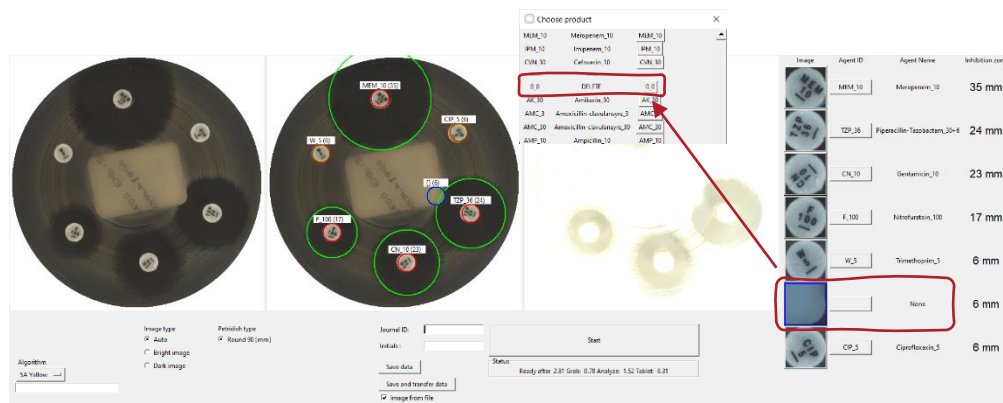


Figure 11 – Label found as disc



9. The PD-100 will normally find the right Disc ID if the discs are known by PD-100. The disc list is customized to your antibiotics. If you are adding new discs to your AST program, please contact your PRO Devices A/S representative or contact us at support@pro-devices.com, then the disc will be added to your PD-100 disc list.
10. If there is no zone around the disc, the value will automatically be 6mm.
11. Remember to compare the bright and dark image to verify if the zone is correct.
12. If the zone determined by PD-100 must be adjusted or has not been found, then
 - a. Click on the disc for the zone in question on the photo in the middle and a new enlarged photo will appear, see Figure 12.
 - b. Use the left mouse button to set the zone in the right place. You can also use the keyboard arrows:

←	Left arrow	2 mm smaller
↓	Down arrow	1 mm smaller
→	Right arrow	2 mm larger
↑	Up arrow	1 mm larger
 - b. When you are done with that zone click OK or press the Space Bar. The circle will change colour to Blue, if the zone is adjusted, see Figure 12.
 - c. The results will automatically change, ranked with the largest zone at the top.



Figure 12 – Adjusting zone diameter – Circle color changes after adjustment



13. If the zones are not found satisfactory, please try another ALGORITHM, see Figure 5, choose either the Dark or Bright Image, see **1** in Figure 6 or turn the plate and read again. For further instruction see chapter 8 Trouble shooting – PD-100 program.
14. If the zones are not found due to a white label on the bottom of the agar plate, try removing the label and test again, or use labels with a black adhesive side. We recommend using labels with a black adhesive side, please contact us at support@pro-devices.com for more information.
15. If no scanner was used, then write the Journal ID, see **1** in Figure 13.
16. Write in the user Initials see **1** in Figure 13. This must only be done at the first measurement of the day.
17. When all Discs and Zones sizes are correct then click Save Data, see **2** in Figure 13 or press **CTRL S** (some PC's Shift+CTRL S). The results and photos will now be saved.
18. All data is saved in "Results_output" folder or on a server defined by you. There is a Shortcut to the folder on the desktop, see Figure 15.

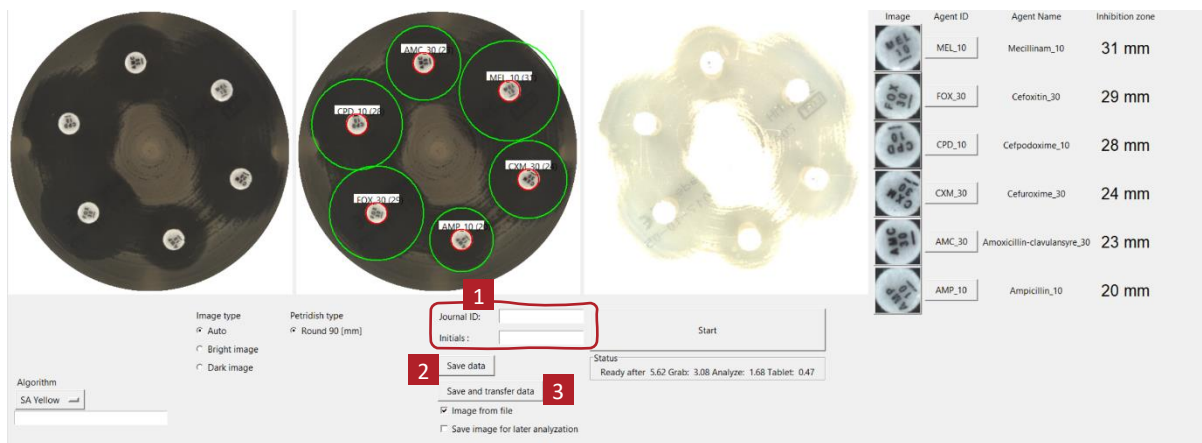


Figure 13 – Saving Data

19. All files related to this measurement are saved in a folder with the title "Journal ID". You cannot overwrite a previously used Journal ID. If you have 2 plates with the same Journal ID, the second plate will be saved under "Journal ID_002".
20. The results are saved as a text file with the name "Journal ID.txt" (example Test.txt) together with the 3 shown photos, see Figure 14.
21. The result file (Test.txt) is shown in Figure 16. If the zone is adjusted the *Human corrected radius = True* and if the Disc ID has been changed the *Human corrected txt = True*. If no change is made the value is *False*.
22. The Photo with results (Test_diagnostic) is shown in Figure 17.
23. The 2 photos are shown in Figure 18 and Figure 19.
 - a. Dark Photo – Test_untouched_low_exp
 - b. Bright Photo – Test_untouched_high_exp
24. The results can be saved and at the same time transferred to your LIMS system if a connection has been created. Click the Save and Transfer Data, see **3** in Figure 13 or press **CTRL T** (some PC's Shift+CTRL T). During installation of PD-100 this setup will be specified.



Figure 14 – Files saved by PD-100

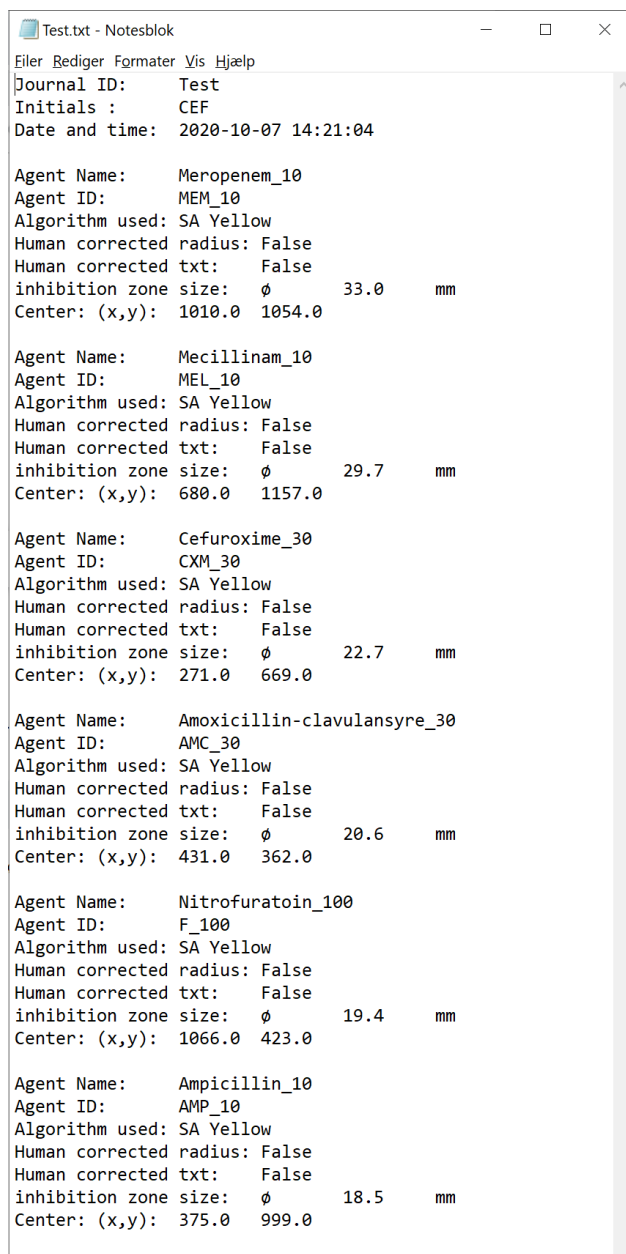


Figure 16 – Result File (Test.txt)

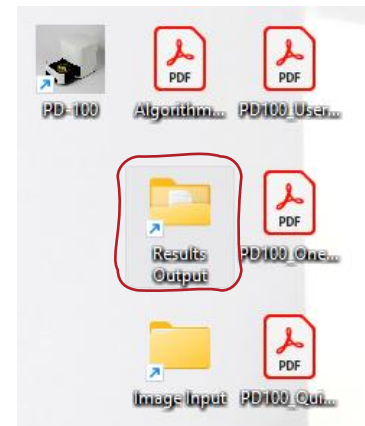
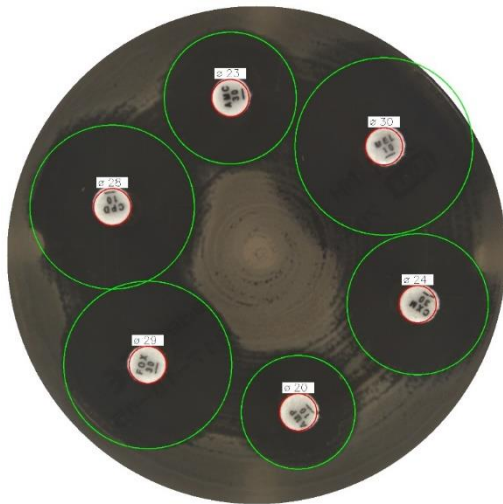


Figure 15 – Desktop



Date and time: 2020-10-07 14:49:00
Journal ID: Test
Initials : CEF

Figure 17 – Photo with results (Test_diagnostic)

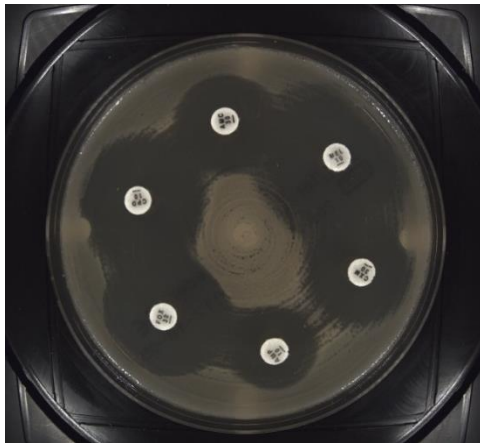


Figure 18 – Dark Photo – Test_untouched_low_exp



Figure 19 – Bright Photo – Test_untouched_high_exp

6.4 Photograph AST Agar Plates for later analysis

If you are not qualified to interpretate and save the results, the feature “Save image for later analyzation” can be used. Here only the images and no results will be saved.

Follow the instructions above from Chapter 6.2 and place the agar plate in the PD-100.

1. Click “Save image for later analyzation”, see **1** in Figure 20.

Figure 20 – Function “Save image for later analyzation”

2. After you have clicked the START button, see **2** in Figure 20, or pressed **F5** (some PC's Fn+F5), the results will appear, see Figure 6.
3. Click Save Data, see **3** in Figure 20 or press **CTRL S** (some PC's Shift+CTRL S). The photos will now be saved for later analyzation. This is shown in the next chapter.

6.5 Measure via "Image from File"

If you wish to analyse a previous analysed AST agar plate (which has been saved) or analyse images, that are saved without analyzation (see above), you can load the images, and the program can analyse it again.

1. For previous analysed plates you need to copy the plate for the patient in question (in this case "Test"), see Figure 14. Copy the whole folder "Test" from C:\ProDevices\Results_Output\ (shortcut on the Desktop) to C:\ProDevices\test_server_folder\input\20XX_YY (shortcut "Image Input" on the Desktop) where XX is the current year and YY is the current month.
2. If the feature "Save image for later analyzation" has been used, the images are already in the "Image_Input" folder.
3. SA Yellow is the preferred algorithm and default from start. Choose another ALGORITHM if needed. The Bacteria Specie on the AST sample determines which algorithm to choose. See the Figure 5 or see the overview in the file "ALGORITME OVERVIEW" found on the desktop.
4. Click "Image from file", see **1** in Figure 21.

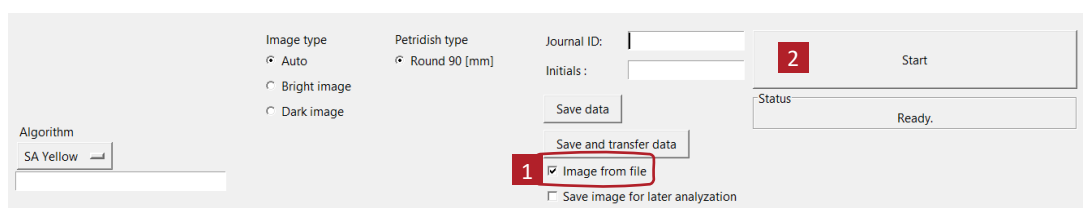


Figure 21 – Function "Image from File"

5. Click the START button, see **2** in Figure 21, or press **F5** (some PC's Fn+F5) and a list of the saved plates appear. Under "Selectable Folders", see Figure 22, click on the Journal ID of the AST plate to be analysed.

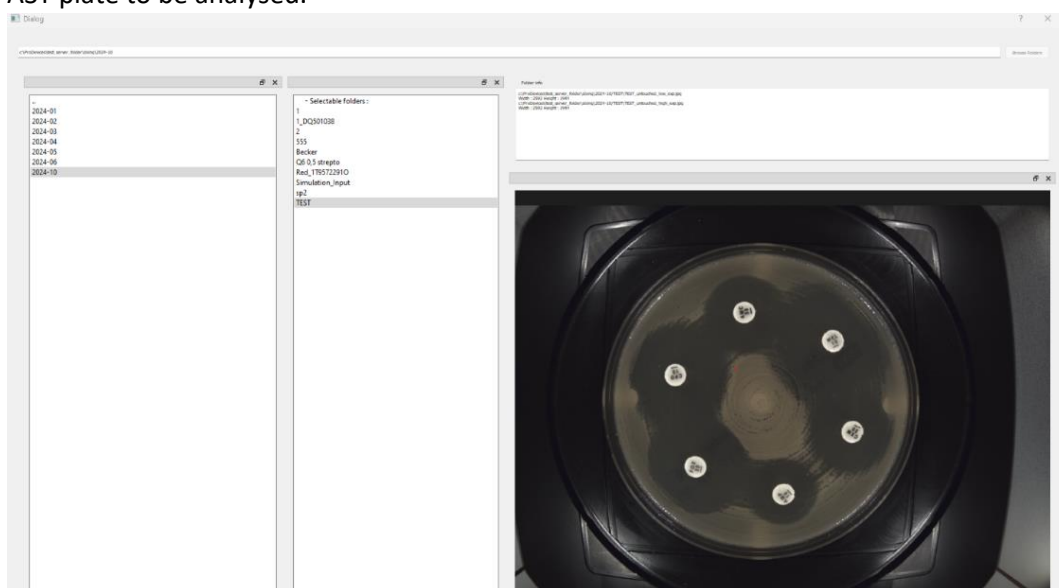


Figure 22 – "Selectable Folders" with "Image from File"

6. The PD-100 program will now analyse the photo. This will take a few seconds.
7. Then follow the instruction in chapter 6.3 for reading the results.
8. The folder structure is the following `C:\ProDevices\test_server_folder\`
 - a. *Input*
 - b. *Doing*
 - c. *Done*
 - d. *Failed*
9. The image of the chosen plate will automatically be moved from “Input” to “Doing” once it has been selected. If you have more than one PC with the PD-Tech program, this will prevent that 2 persons are analysing the same plate.
10. As soon as the results are Saved, the image will automatically be moved from “Doing” to “Done”.

6.6 Calibration & Verification

PD-100 will be calibrated on a yearly basis by PRO Devices A/S or a representative from PRO Devices A/S. PD-100 is calibrated with one PC and in case you have more than one PD-100, cannot be connected to the other PC without a re-calibration done by PRO Devices A/S or a PRO Devices A/S representative.

For the daily use the PD-100 Verification Plates, see Figure 23, can be used to verify that PD-100 is measuring the correct value. The interval (daily, weekly etc.) for using the verification plates is defined by each laboratory. The verification plates come with a certificate from the Danish Technological Institute. The Danish Technological Institute is accredited by The Danish Accreditation Service (DANAK) for providing proficiency tests and a wide scope of calibration and testing services. DANAK is a member of EA (European Co-operation for Accreditation) and ILAC (International Laboratory Accreditation).

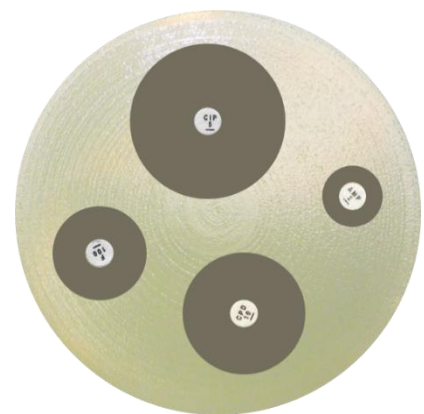


Figure 23 – Verification Plate

The verification plate must be placed in PD-100 instrument and measured like any other agar plate. Please follow the instructions above, see 6.2 and 6.3. The results are then compared with the certificate. If a disc is not found, please rotate the plates, and try again.

This verification is not necessary but can be carried out on a routinely basis as needed.

The verification plates are, when stored in the supplied box and under normal conditions of temperature and humidity, not subject to change and may reliably be used for verification of the measurements.



In the case that the results are NOT aligned with the certificate ($\pm 1\text{mm}$), please repeat the reading. If it remains incorrect, contact PRO Devices A/S or your local PRO Devices A/S representative support.

6.7 List of Short-cuts

The following Short-cuts can be used:

- **F4** Moves cursor to Journal ID
- **F5** Start – starts the reading of plates
- **CTRL S** Save – save data

- **CTRL T** Save & Transfer – save and transfer data to LIMS (if this is implemented)
- **CTRL Q** Quit – closes the program
- **TAB** Moves cursor to Initials

For some PC's the Fn button must be used together with the shown function keys and SHIFT must be used together with the shown short-cuts.

7 Cleaning & Maintenance

The PD-100 is an instrument with very low cleaning and maintenance needs.

The PD-100 can be cleaned on the outside using a soft cotton cloth. The black bottom plate in the drawer (material POM) can be taken out for cleaning with ethanol or it can be autoclaved. Chlorine can be used in a low concentration (3-5%), but the bottom plate will degrade over time. Please contact us if you want it replaced.



PRO Devices A/S recommends a yearly maintenance and calibration of the PD-100 system. This will include:

- Check of the camera and lightning
- Check of focus
- Calibration of the whole system



Your PRO Devices A/S representative will carry out the maintenance and calibration.



8 Troubleshooting – PD-100 program

1. If the program doesn't start, please check that the software license is paid. Please contact PRO Devices A/S or your local PRO Devices A/S representative.
2. If you get the error message "No device found", click OK, please check that the USB cable between the PC and PD-100 is in place and restart PD-100.
3. If you get the error message "Dongle not valid", click OK, insert the dongle in the PC and restart the PD-100 program.
4. Error message on the PC screen with "Camera not found", restart the program, see 6.1.
5. If the program doesn't start up correctly, please close it and try again. If you get the error message "Camera communication error", you might need to restart the PC, this might happen if more users are logged on to the PC with an open PD-100 program.
6. If the photos show only part of the agar plate, open the drawer, and check that the agar plate is in the right position on the black bottom plate.
7. If the photos are not centred or in focus, make sure that you have connected your PD-100 to the right PC, this is only in case you have more than one PD-100.
8. If the PD-100 program doesn't find the right disc ID's, please choose the correct one from the list, see 6.3.
9. If the PD-100 program doesn't have the right disc ID available please contact your PRO Devices A/S representative or contact us at support@pro-devices.com, then the disc list will be verified and updated.
10. If the disc is not read with the message "Not Mast", then you only have the right to use Mast discs. The disc cannot be changed, if you try the message "Unauthorized disc. Not recognized as a Mast product" will appear, see Figure 10, and the zones cannot be read. Please contact PRO Devices or your local representative to upgrade your system.
11. If the zones are not found satisfactory, please try another ALGORITHM, see Figure 5, or choose either the Dark or Bright Image, see **1** in Figure 6. If this doesn't help and the program consistently has trouble finding the zones, please contact your PRO Devices A/S representative or contact us at support@pro-devices.com.
12. If the program doesn't find the right zone diameters, please manually set the right diameter, see 6.3.
13. If the zones are not found due to a white label on the bottom of the agar plate, try removing the label and test again, or use labels with a black adhesive side.
14. If the Barcode is not read, then check the connection to the barcode reader.

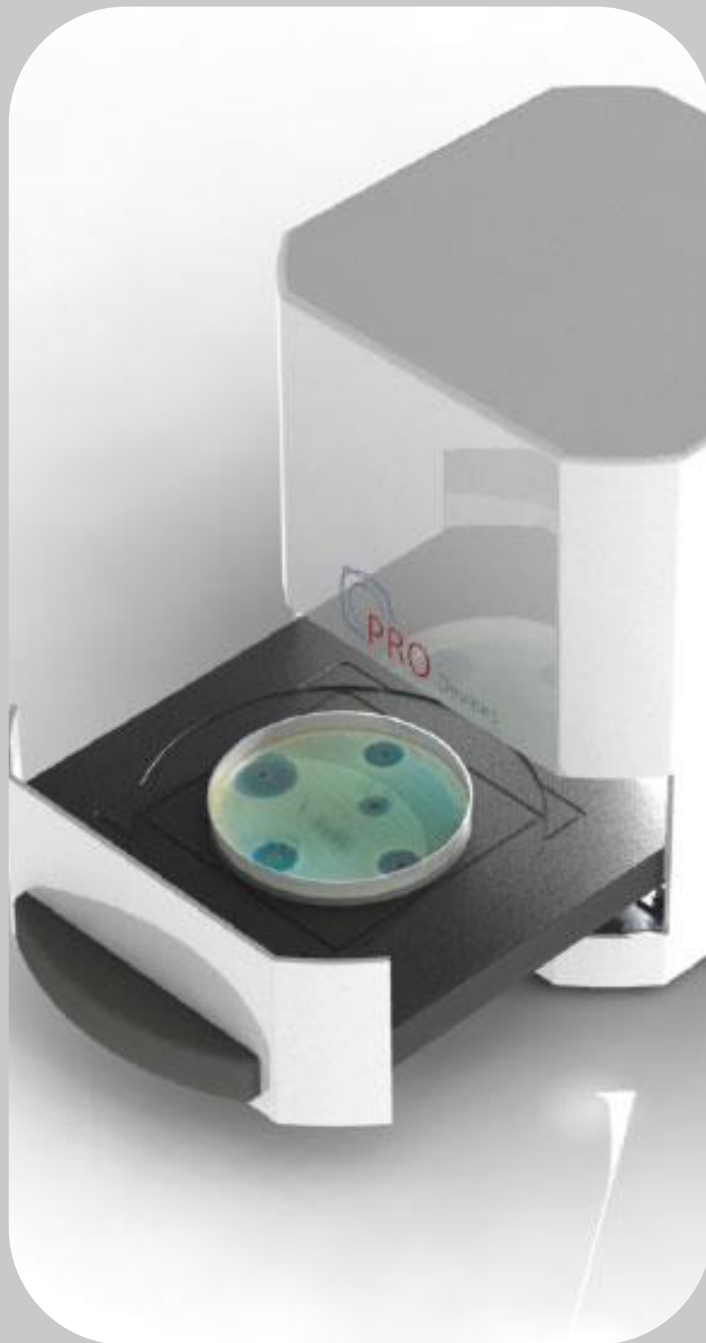


9 Contact support



If other problems arise, any of the above problems persists, or if this manual fails to answer your questions, further information may be obtained from your PRO Devices A/S authorized representative or by sending an email to support@pro-devices.com.

We can also be contacted by phone +45 40 30 88 66.



PRO Devices A/S

Gadeledsvej 27C, DK-3400 Hilleroed, Denmark | www.pro-devices.com | CVR 36 45 63 88