

Guidance for Administration of the Growth Direct System[®]

Procedure TSC0175
Revision B

Microbial Contamination Detection

The Growth Direct System[®]



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1. Revision History

Revision	Author	Date	Description
A	Thanh Pham	July 2021	Initial Release
B	S. Ahlawat	Feb 2022	General content update and realignment

2. Purpose

The purpose of this document is to provide guidance for the administration of the Growth Direct System® (GD) to be incorporated into client standard operating procedures (SOP) for use of the system.

3. Scope

This guidance document applies to the use of the GD. For use of the Central Manager (CM) functionality, please refer to TSC0177: GD Central Manager User Guide.

4. Responsibilities

4.1. System Administrator

- Incorporate guidance within this document into site specific standard operating procedures or work instructions.
- Ensure site specific safety requirements are taken into consideration.
- Oversight of the Administration of the GD.
- Oversight of compliance to 21 CFR Part 11.

4.2. Rapid Micro Biosystems

- Periodically review this document for required updates.
- Provide continued support according to system warranty or service contract, including preventative maintenance and troubleshooting.

5. Safety Considerations

- 5.1. Workplace safety and proper disposal of biohazard waste is the responsibility of the end user(s). Local safety protocols should be adhered to at all times.
- 5.2. The Growth Direct System has built in physical locks and interlocks to maintain safety during operation of the system. Access to input queues, output queue, and trash bin and should be initiated via the Growth Direct Application following the instructions within the Growth Direct User Guide to ensure the system is paused prior to any maintenance activity.

6. References

TSC0177: GD Central Manager User Guide

7. Software User Interface

7.1. Main Software Screens

- 7.1.1. “Home” Screen appears when the device is switched on. The screen displays important information about continuing tests and the overall system status.
- 7.1.2. The “Home” Screen also provides access to print labels, opening the input doors, approving test results, retrieving, and canceling tests, emptying the trash bin, and opening the output queue door.



Figure 1: Home Screen

7.2. Menu Bar



Figure 2: Menu Bar

7.2.1. Print Button

- 7.2.1.1. Select “Print” button to access the “Print Worklist”, which is used to print out worklist labels on the barcode printer or worklist sheets on a regular printer for scanning into the system

7.2.2. Load Buttons

- 7.2.2.1. Select the “Load” buttons to load cassettes into the Growth Direct System. The green color indicates which door is ready to load the next carousel. The amber color indicates which door was opened last and that the carousel is in the loaded position

7.2.3. Approve Button

- 7.2.3.1. Select the “Approve” button to access the “Approve Tests” screen, which is used to select, review, add comments and approve results after a test is completed.

7.2.4. Retrieve Button

- 7.2.4.1. Select the “Retrieve” button to access the “Cancel/Retrieve Tests” screen, which is used to select tests for cancelation or retrieval, and placement in the output queue or trash bin.

7.2.5. Trash Bin Button

- 7.2.5.1. Select the “Trash Bin” button to empty out the trash bin. Selecting the trash bin can only be done by users assigned with appropriate permission. Enter the username and password and select OK. The trash bin door opens, and a “Confirmation” screen appears to confirm that the trash bin has been emptied. Ensure all cassettes are removed as the system assumes the trash bin is empty on closure and confirmation.

7.2.6. Output Queue Door Button

- 7.2.6.1. Select the “Output Queue Door” button to open the door for removal of cassettes.

NOTE: After unloading cassettes from the output queue; slide tray to ensure it is fully engaged and locked into place. Ensure all cassettes are removed as the system assumes the output queue is empty on closure.

7.3. Menu Button



Figure 3: Menu Options Button

- 7.3.1. Provides access to “Menu Options” screen and all other areas of the Growth Direct System

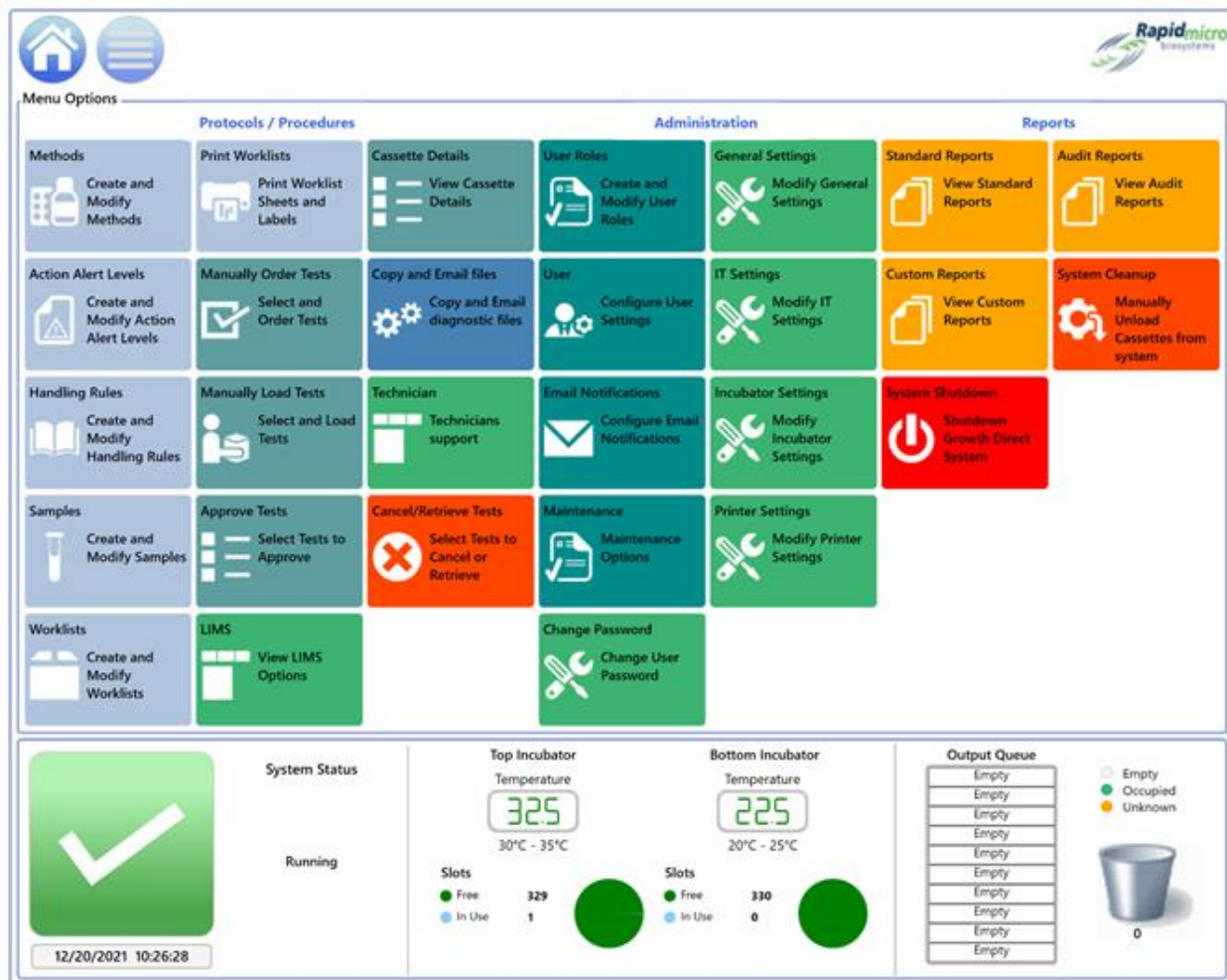


Figure 4: Menu Options Screen

7.3.2. Protocols/Procedures

- 7.3.2.1. **Methods:** for specifying application type (Environmental Monitoring, Bioburden, together with serial incubation), incubation duration (in hours) and incubation temperature (in degrees Celsius).
- 7.3.2.2. **Action Alert Levels:** for defining thresholds (Actions, Alerts, and Specifications) for CFU counts for the test being conducted. Also includes an option to keep passed cassettes that exceed CFU count in incubator.

- 7.3.2.3. **Handling Rules:** for specifying the destination of cassettes into an output queue, trash bin, or incubator based on the cassette status: OOS (Out of Specification), Passed, Canceled, Count Prior to Endpoint.
- 7.3.2.4. **Samples:** for grouping a collection of predefined test parameters, including a Method, an Action and Alert level, and a Handling Rule. Together, these specify all the details required to run a complete test.
- 7.3.2.5. **Worklists:** for creating and modifying worklists, which are comprised of collections of predefined samples.
- 7.3.2.6. **Print Worklists:** for printing out sample labels on the barcode printer or sheets of labels on a regular printer for scanning into the system.
- 7.3.2.7. **Manually Order Tests:** for selecting and ordering tests manually by worklist or by sample ID.
- 7.3.2.8. **Manually Load Tests:** for manually selecting and loading tests.
- 7.3.2.9. **Approve Tests:** for selecting, reviewing, adding comments, and approving results after a test is completed.
- 7.3.2.10. **LIMS:** Laboratory Information Management System and Growth Direct Interface settings page.
- 7.3.2.11. **Cassette Details:** for monitoring status and CFU count readings once cassettes have been successfully loaded into the system. Also used for creating and printing reports and identifying cassette errors.
- 7.3.2.12. **Copy & Email files:** allows the user to select and send system application log files and images.
- 7.3.2.13. **Technician:** for RMB Validation and Field Service Engineers only.
- 7.3.2.14. **Cancel/Retrieve Tests:** for cancelling and retrieving select Cancel to bring active cassettes to the output queue. Select Retrieve to bring any cassette to the output queue. Select Trash to bring any cassette to the Trash bin.

7.3.3. Administration

- 7.3.3.1. **User Roles:** for defining levels of access and permissions for each user role.
- 7.3.3.2. **User:** for inputting user information including name, password, email notification and selected the designated User Role for each individual user.
- 7.3.3.3. **Email Notifications:** for setting up automatic email messaging (concerning alarm, test out of specification (OOS), security, and data transfers) for users.
- 7.3.3.4. **Maintenance:** Reserved for personnel authorized to maintain the system. This area allows the user to access the interior of the system, home all robotics, return all cassettes to incubators, and clear errors from the system. Within this section is the Enable Remote Desktop (see Figure 5) which is required for sites utilizing tier 4 of the Remote Management System (RMS).

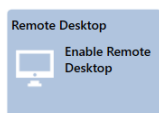


Figure 5: Enable Remote Desktop



Note: Accessing this screen will pause the operation of the Growth Direct unit. A warning is provided to the user.

7.3.3.5. **Change Password:** for each user to change their password.

7.3.3.6. **General Settings:** for the following General Settings:

- **Password change notification options**
- **Help prompts toggle**
- **“Home” Screen cassette display options**
- **“Weekend rule” (site specific) definitions**
- **Test approval options**
- **Bridge computer settings,**
- **LIMS ID and Activation code**
- **Signature comment options**
- **Print Out Report options**
- **Test Not Loaded options**

7.3.3.7. **IT Settings:** for configuring database backup scheduling, setting system email credentials, copying logs, exporting test results data, and entering network credentials.

7.3.3.8. **Incubator Settings:** for enabling/disabling the incubators and setting incubator temperatures and temperature alarm thresholds.

7.3.3.9. **Printer Settings:** for adding new USB/network printer or modifying label printer settings

7.3.4. **Reports**

7.3.4.1. **Standard Reports**

- **Test Report:** Reports on test status, start and completion times, and any conditions associated with an individual test.
- **Lot/Batch Results Report:** Reports on test results by date or by range of dates that a lot/batch was loaded into the system.

7.3.4.2. **Custom Reports:** Customer-specific reports created and deployed at the request of the customer beyond the standard and audit reports.

7.3.4.3. **System Shutdown:** for a controlled shutdown of the system. The user is asked to confirm shutdown choice.

Note: Additional manual switch offs are required at this point.

7.3.4.4. **Audit Reports:** Reports on an individual audit history of Methods, Action Alert Levels, Handling Rules, Samples, Worklists, General and IT Settings, Incubator Settings, User Roles, Users, System Events, User Activity, Cancelled Tests, Summary Audit Reports, and Focus Calibrations.

7.3.4.5. **System Cleanup:** Helps you manually remove all cassettes on the system.

7.4. Create a User Account

- 7.4.1. From the “Menu Option” screen, select “User”.
- 7.4.2. Select the “New” button.
- 7.4.3. Fill in the following information:
 - First Name, Middle Initial, Last Name
 - Username
 - Email Address (optional)
 - Password and confirm: Type in at least 8 alphanumeric characters, including 1 upper case character and 1 numeric. Retype to confirm.
 - Telephone and Extension (optional)
 - User Role – select the field to get a drop-down list of options. Select the desired role to select it.
- 7.4.4. Save the entries by selecting “Save”.

7.5. Edit Existing Entries

- 7.5.1. From the “Menu Options” screen, select “User Roles”.
- 7.5.2. Under the User list, select the name of the role to highlight it.
- 7.5.3. Click the “Edit” button at the top of the screen.

Note: The default Administrator and FieldService users cannot be edited.

- 7.5.4. Select changes to modify the role.
- 7.5.5. Save changes.

7.6. Change Password

- 7.6.1. From the “Menu Options” screen, select “Change Password”.
- 7.6.2. Enter in the required User Name and confirm old password.
- 7.6.3. Enter in New Password and retype this password in order to confirm.
- 7.6.4. Select “OK”.

7.7. Troubleshooting

7.7.1. System Status

- 7.7.1.1. Any error will be displayed on the System Status bar at the bottom of the screen. (See Figure 6 for example)



Figure 6: System Status Bar in Error Mode

- 7.7.1.2. Notify Quality Control Management (QCM) or supervisor/system administrator for further instructions and contact the vendor for any system error and required troubleshooting.

7.7.2. Copy and Email Diagnostic Files

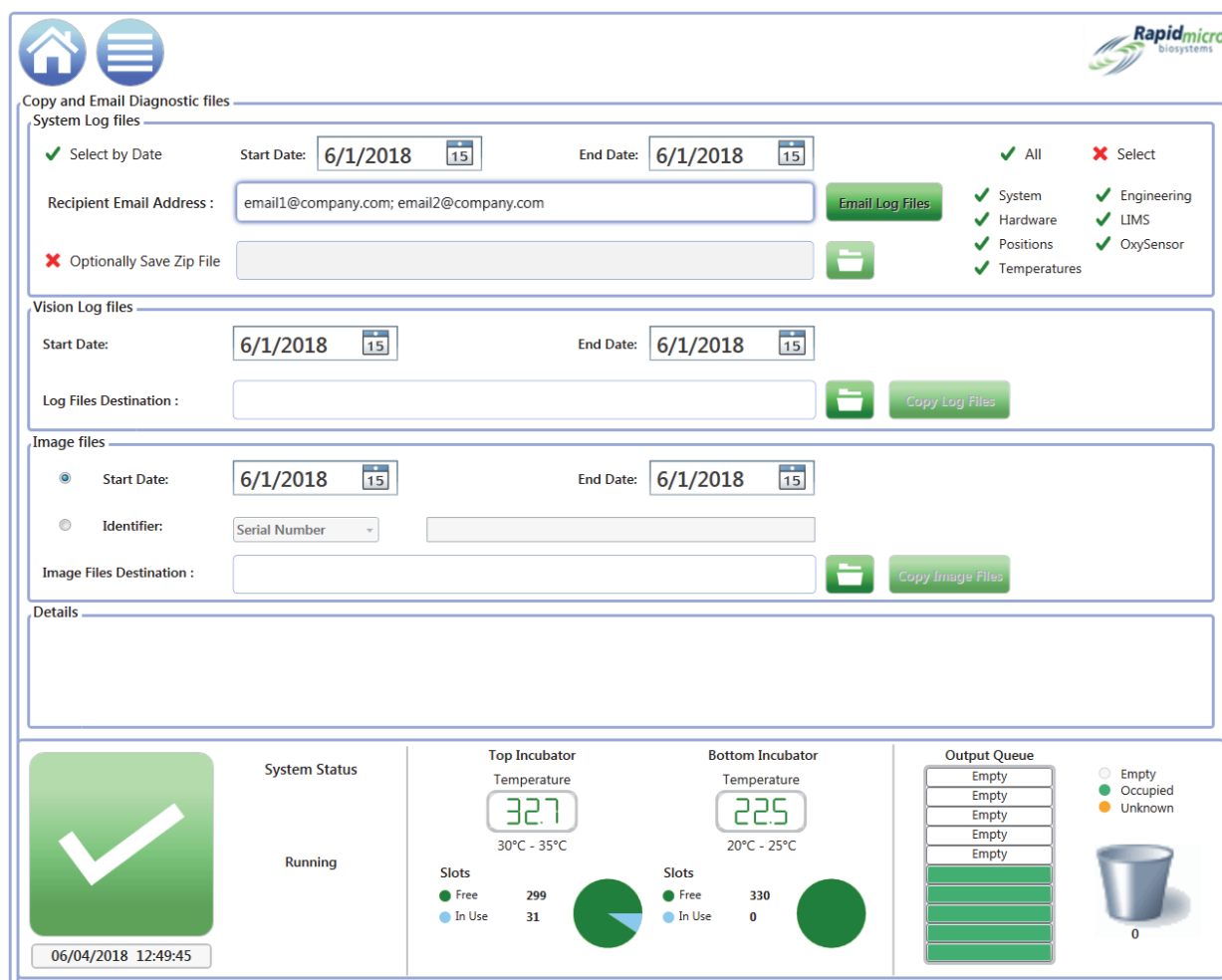


Figure 7: Copy and Email Diagnostic Files Screen

- 7.7.2.1. If requested by the vendor, perform the steps listed below to send diagnostic files to the vendor for analysis and troubleshooting.
- 7.7.2.2. Select “Copy and Email Diagnostic files” button on the Menu Options screen.
- 7.7.2.3. **System Log files:**
- Start Date - End Date: Select the specific time for the log files, use the “Start Date” and “End Date” fields to specify a range of dates.
 - Recipient Email Address: Enter in valid email address(es) where the system log files will be sent. Click the “Email Log Files” Button to send files.



- Optionally Save Zip file: Select this option if you also want to save the system log files to a storage location. Click the folder icon to select local save location.

7.7.2.4. Vision Log Files:

- Start Date - End Date: Select the specific time for the log files, use the "Start Date" and "End Date" fields to specify a range of dates.
- Log Files Destination: Select the "Browse" Button and select the desired storage and click OK. After selecting OK, select "copy log files."

Note: Vision files cannot be emailed due to size.

7.7.2.5. Image Files: Can use dates or other identifiers.

- Start Date - End Date: Select the specific time for image log files, use the "Start Date" and "End Date" fields to specify a range of dates.
- Identifier: Choose option between "Serial Number", "SampleID/Batch", and "LIMS ID". Enter appropriate identifier value in textbox.
- Image Files Destination: Select the "Browse" Button and select the desired storage and click OK. After selecting OK, select "copy image files".

7.7.2.6. Details: Displays the copying progress in the Details area.

7.7.3. Screen Capture

7.7.3.1. To capture the screen as an image file, press Ctrl+Shift+S.

7.7.3.2. The system will then display a file browser dialog box.

7.7.3.3. Navigate to the location of where the image will be saved and select OK.

7.7.3.4. The image will be saved in the location that was specified and file format will be YYYY-DD-MM_<unique-number>_Screenshot.jpg. A prompt stating successful screen capture is displayed to the user. Select "OK" to exit the window.

7.7.4. Accessing Samples Event Description

7.7.4.1. On the "Home" screen, double click on the samples that alarmed or have an event generated.

7.7.4.2. "Tests" screen will display and verify that the sample that alarmed is selected and click the "Cassette Events" button.

7.7.4.3. "Cassette Events" screen will display along with the alarm or event description.

END OF PROCEDURE