

Wolverine Diener Plasma Treater Operation WI

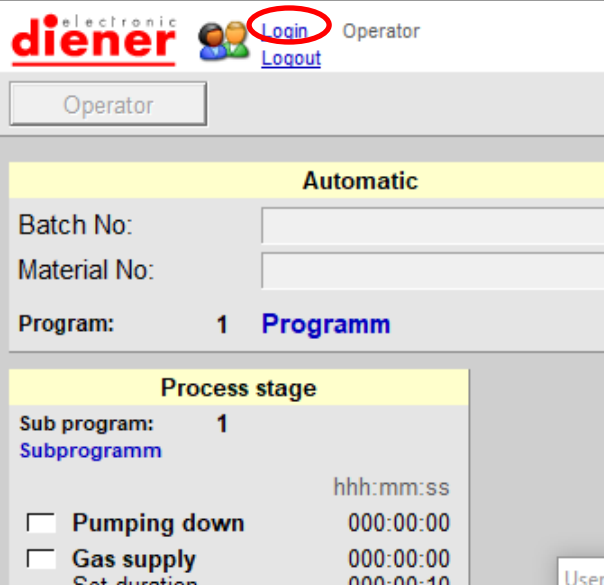
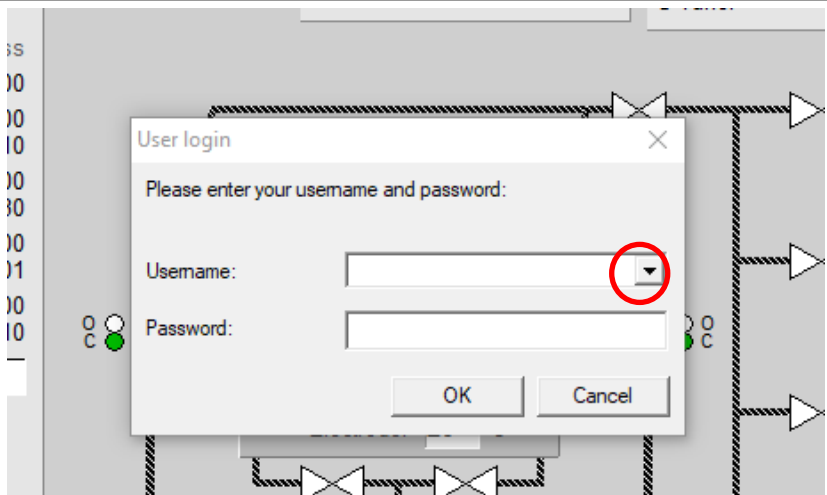
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|------------------------|---|
| Purpose | <i>This document describes the actions required to process Wolverine product through the PRS software system</i> |
| Scope | <i>The scope of this document encompasses only Wolverine activities and interaction with the Diener PRS software and Diener Plasma Chamber Hardware. No other product, hardware or software is captured in this document.</i> |
| Records Created | N/A |

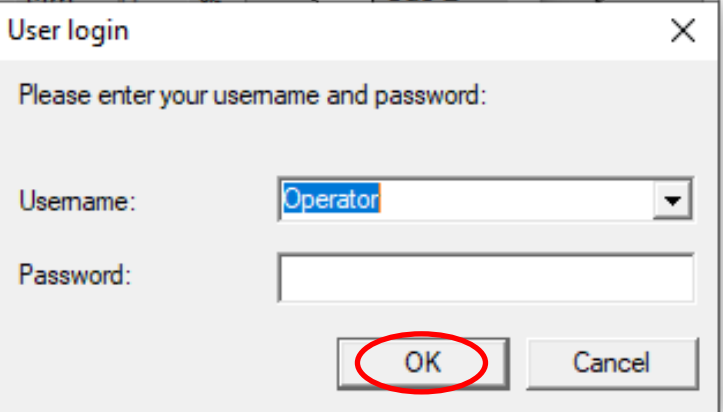
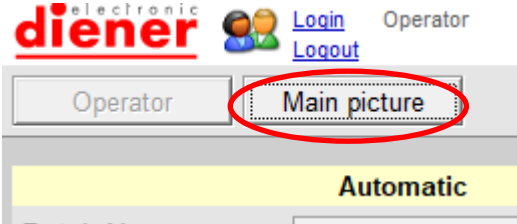
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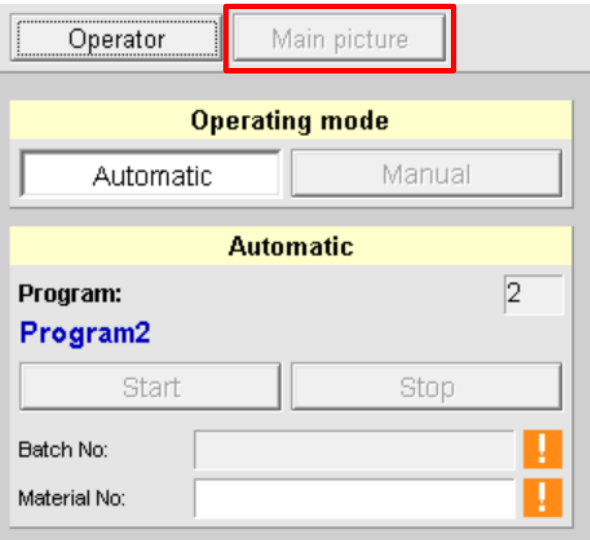
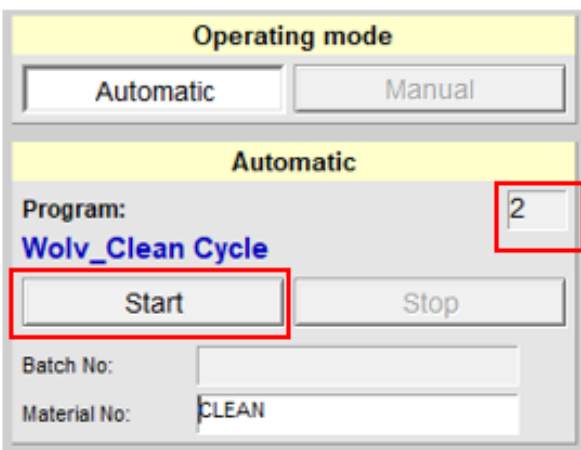

1. PRS Software Login

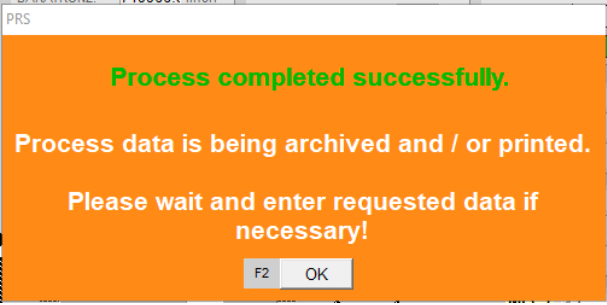
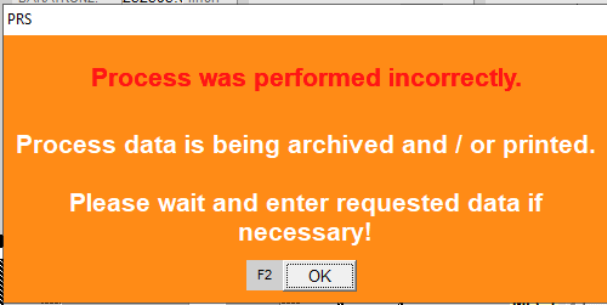
1.1. Login

| Step | Action | Description |
|------|---|--|
| 1. | Log into PRS software and select the required access level: Use the stylus to select "Login" at the top left-hand side of the HMI. |  <p>The screenshot shows the PRS software interface. At the top left, the 'Login' button is circled in red. Below it, the 'Operator' button is visible. The interface also displays fields for 'Batch No:', 'Material No:', and 'Program: 1 Programm'. A 'Process stage' section shows 'Sub program: 1 Subprogramm' and a list of stages with durations: 'Pumping down' (000:00:00), 'Gas supply' (000:00:00), and 'Set duration' (000:00:10).</p> |
| 2. | Login with designated access level: Select the dropdown menu and required access level. |  <p>The screenshot shows the 'User login' dialog box. It contains fields for 'Username:' and 'Password:'. A dropdown menu is circled in red next to the 'Username' field. The dialog box also has 'OK' and 'Cancel' buttons.</p> |

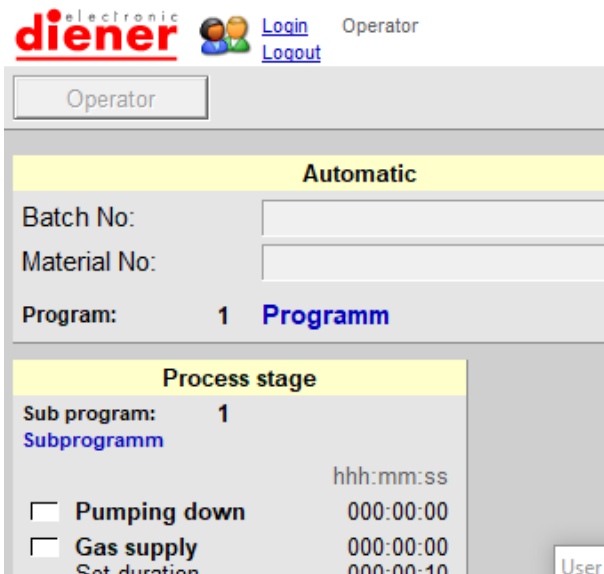
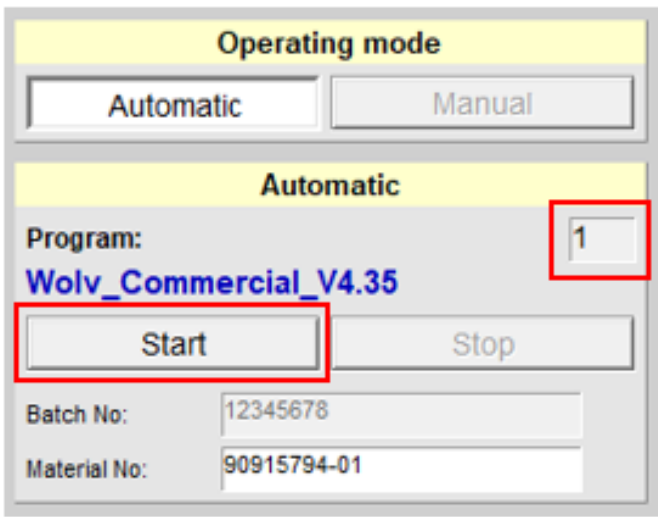
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| 3. | <p>Input designated password for required access level:</p> <p>Note: Operator access does not require a password – Operator level can be selected from Username drop down menu and select "OK" to proceed to main screen</p> |  <p>A 'User login' dialog box with a close button (X) in the top right. It contains the text 'Please enter your username and password:'. Below this, there is a 'Username:' label followed by a dropdown menu currently showing 'Operator'. Below that is a 'Password:' label followed by an empty text input field. At the bottom right, there are two buttons: 'OK' and 'Cancel'. The 'OK' button is circled in red.</p> |
| 4. | <p>Accessing "Main picture":</p> <p>Select "Main picture" in the top left-hand side of the HMI to be brought to the main operating screen.</p> |  <p>A screenshot of the HMI main screen. At the top left is the 'diener' logo with 'electronic' in smaller text above it. To the right of the logo are two user icons and the text 'Operator'. Below the icons are links for 'Login' and 'Logout'. In the center, there are two buttons: 'Operator' and 'Main picture'. The 'Main picture' button is circled in red. At the bottom, there is a yellow bar with the word 'Automatic' in black text.</p> |

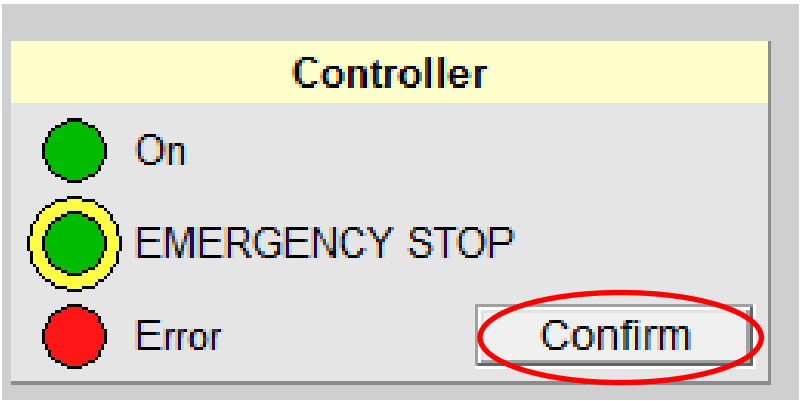
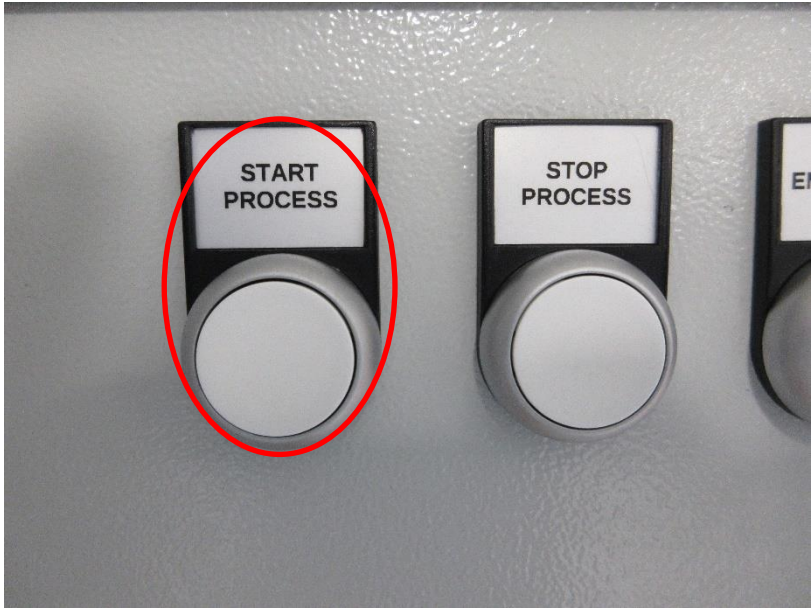
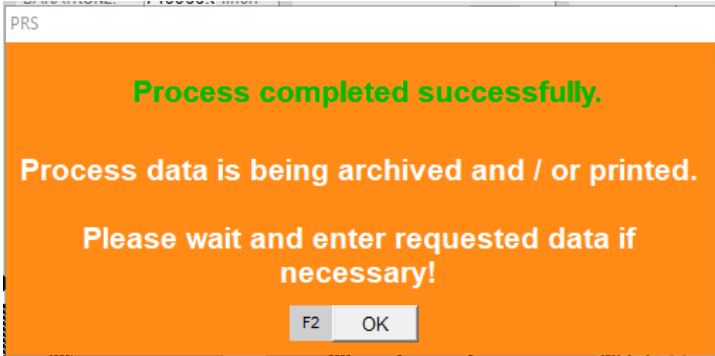
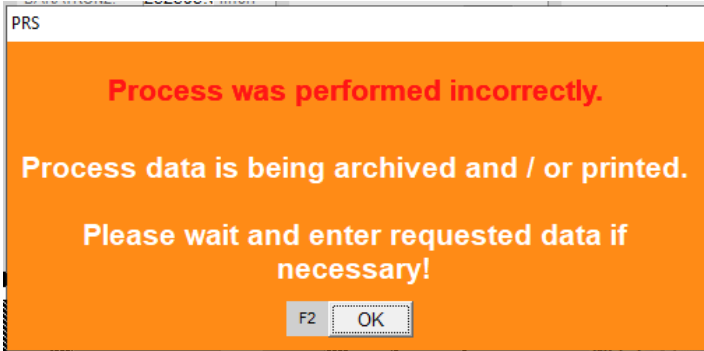
2. Clean Cycle Procedure



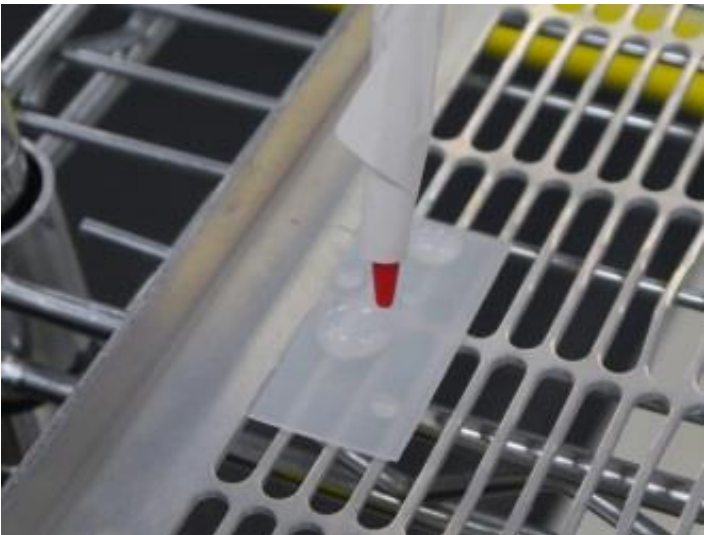
| | |
|--------------------------------|--|
| Daily Chamber Cleaning Process | <p>An O₂ cleaning cycle shall be performed on the plasma treatment chamber at least once per day at the start of the shift. Ensure there are 6 plasma trays loaded in all 6 shelves.</p> |
| 1. | <p>Program Selection</p> <p>Select the "Main Picture" tab</p> <p>Note: The material field must be populated first.</p>  |
| 2. | <p>Clean Cycle Program Selection:</p> <p>Use Keyboard or hand scanner to enter "CLEAN" into the material number field which will select Program 2.</p> <p>Note: The selection of Program 2 will grey out the batch field and the start cycle can be selected.</p>  |
| 3. | <p>Start Cycle</p> <p>Once the "Start" button has been activated.</p> <p>Press "Start Process" button located at the front of equipment</p>  |

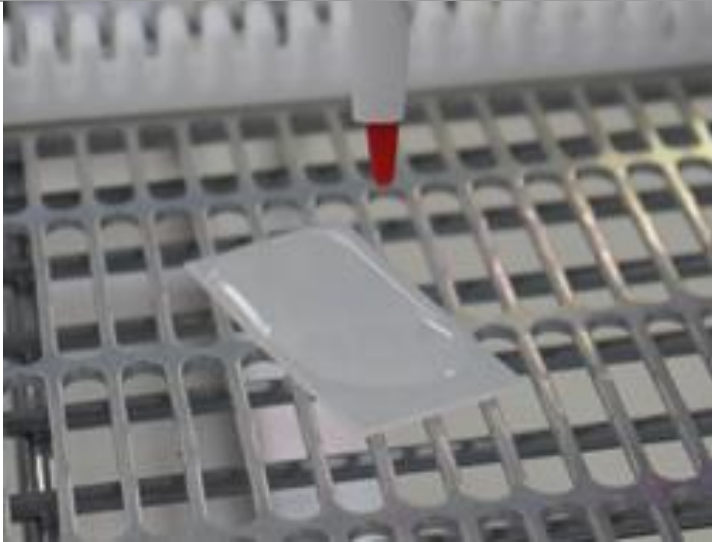
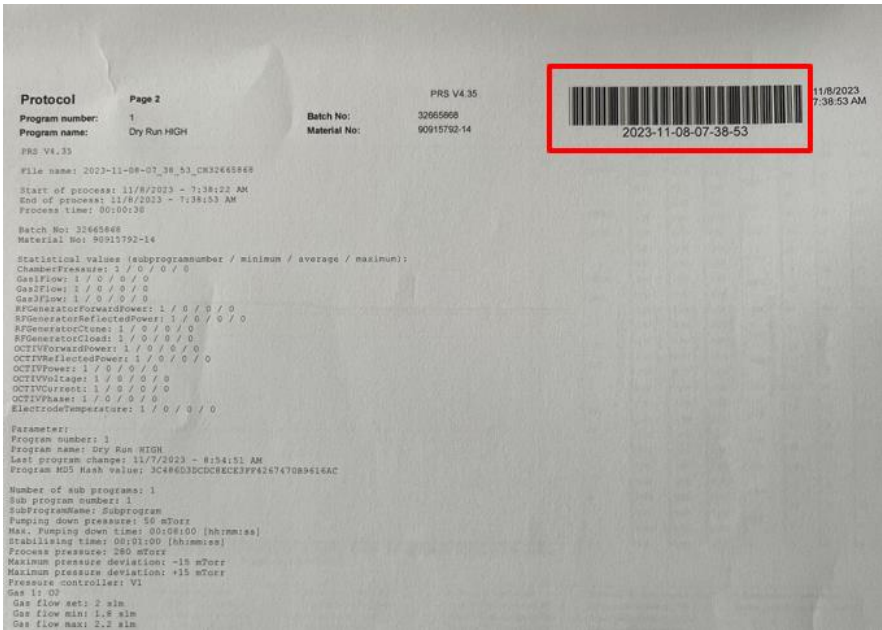
| | | |
|----|---|---|
| 4. | <p>Cycle Complete</p> <p>Once the cycle is complete verify that that the dialog box on the screen indicates that the cycle has been successful.</p> <p>Press ok to acknowledge.</p> <p>If the cycle is unsuccessful contact a member of the core team.</p> | <p>Successful cycle dialog box</p>  <p>Unsuccessful cycle dialog box</p>  |
|----|---|---|

3. Wolverine Plasma Process

| Wolverine Plasma Treat Process | | |
|--------------------------------|---|---|
| 1. | <p>Login to PRS software as per section 1.1 of this doc</p> |  |
| 2. | <p>Wolverine Cycle Program Selection</p> <p>Use Keyboard or hand scanner to enter the material number into the material number field</p> <p>Enter batch data into batch number field.</p> <p>Press the start button.</p> <p>Note: Program 1 will be selected once the material number has been entered. Batch Data can now be entered into batch number field. The start button can be selected once the batch number has been entered.</p> <p>Note: Ensure operator is in "Main Picture".</p> <p>Refer to section 1.1.4 for instruction on accessing "Main Picture".</p> |  |

| | | |
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| 3. | <p>Confirm Error Message</p> <p>Contact line support to clear any errors before cycle execution.</p> |  |
| 4. | <p>Wolverine Cycle Start</p> <p>Press "Cycle Start" switch at front of equipment</p> |  |
| 5. | <p>Cycle Complete</p> <p>Once the cycle is complete verify that the dialog box on the screen indicates that the cycle has been successful.</p> <p>Press ok to acknowledge.</p> <p>If the cycle is unsuccessful contact a member of the core team</p> <p>When the transfer trolley has space available for all the trays</p> <p>Open Rear Plasma Chamber Access</p> | <p>Successful cycle dialog box</p>  <p>Unsuccessful dialog box</p>  |

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| | <p>Door for Wettability Test</p> <p>Press "Door Up" Switch located at the back of the equipment</p> <p>Note: Ensure "Back Door" is highlighted on HMI</p> |  |
| 6. | <p>HDPE Coupon Removal</p> <p>Pull trays out individually (approximately 6 inches) and remove coupon from each tray</p> |  |
| 7. | <p>Perform Wettability Test</p> <p>Observe that the DI/RO water spreads out evenly (like a layer of film) and that it does not bead up</p> <p>The DI/RO water must not bead up. If the water beads up, the batch must be scrapped.</p> <p>DI/RO water should be changed daily. Record date on the DI/RO change sheet.</p> |  <div data-bbox="1270 1469 1489 1668">Pre-Plasma Treat</div> |

| | | | |
|----|--|---|------------------------------------|
| | Discard wettability coupons after testing. |  | <div>Post-Plasma Treat</div> |
| 8. | Wettability Test Failure. Contact Quality Technician If any coupon fails the wettability test, the batch must be scrapped | | |
| 9. | Once all the coupons have passed the Wettability test, complete Wolverine Plasma Treatment Log, 91131097 and scan the Plasma Report 'end of process' date and time barcode into MES. |  | Screenshot of Diener plasma report |
| 10 | <div>Tray Removal</div> <p>Note: Ensure that the transfer trolley area designated “Post Plasma treatment” has sufficient space for all the trays that have gone through a complete Plasma Treat cycle. If there isn’t enough space, stop and wait until space is available. Do not open the plasma chamber door until space is available.</p> <p>Starting from the bottom move one tray at a time to transfer trolley within designated area for “Post Plasma Treatment”.</p> | | |

Record Keeping

Complete paperwork or required station tasks in MES with all appropriate information.

4. Supporting Information

4.1. Definitions

Definitions for the terms exclusive to this document are identified below:

| Term | Definition |
|------|------------|
|------|------------|

| | |
|-----|--------------------------------|
| PRS | Plasma Reaktor Steuerung |
| HMI | Human-Machine Interface |
| MES | Manufacturing Execution System |

4.2. Applicable Documents

| Number | Title |
|------------|--|
| S842773-00 | Global Quality Systems Glossary |
| 91036186 | SGOI Plasma Tray Loading |
| 91131097 | Wolverine Plasma Treatment Log |
| S308938-00 | Good documentation Practices and SFP review (Lean) |
| 90509286 | Line Clearance Guideline Cutting Balloon |
| 92081060 | MES 4.5 Product Builder Work Instruction, BSC |
| 90395576 | MES Navigation and General WI |
| 97053330 | Cleaning Procedure CTS |
| 90362949 | MES – Glossary, Basic Functionality, Navigation and Procedures |
| S300155-00 | Cleaning Work Surfaces and Equipment |

4.3. Supplies and Equipment

| Description | P/N or ME# |
|-------------------------|-------------------------|
| High Density PE Coupons | 03500-01 |
| Distilled/R.O. Water | N/A |
| Plasma Trays | 51321755 |
| 70% IPA | 466720-02 |
| 99% IPA | 466720-01 |
| Alpha Wipes | N/A |
| Diener Plasma Chamber | 92730383 |
| Nitrile Gloves (Blue) | 90179967-01/-02/-03/-04 |
| Nitrile Gloves (White) | 321390-06/07/08/09/10 |