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Your signature indicates that this document has been prepared in accordance with company standards or guidelines and adequately reflects the tasks and deliverables necessary.

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1.0 PURPOSE

1.1. The purpose of the document is to define the SOP (Standard Operating Procedures) to be followed by ADVANEX EUROPE Ltd, in order to ensure that the clean room working areas are used and maintained in a controlled and consistent manner to assure compliance with ISO 14644 for the required class of operation.

2.0 SCOPE

2.1. The scope of this documents covers the methods of working, maintenance and qualifying of the water purification system within the clean rooms at Advanex Europe Ltd.

3.0 TERMS, DEFINITIONS & ABBREVIATIONS

3.1. ISO 14644 – The International Standard Organisation Specification for clean rooms.
3.2. CR1 - Clean Room 1, the Upstairs clean room.
3.3. CR2 - Clean Room 2, the new Downstairs clean room.

4.0 HEALTH, SAFETY & ENVIRONMENTAL

4.1. Within the factory area safety footwear is mandatory.

5.0 ASSOCIATED DOCUMENTS

5.1. Cleanroom Activity Log (Document Number AEU00496).
5.2. Cleanroom UV Filter Replacement (Document Number AEU00508).
5.3. Purite System Water Change (Document Number AEU00498).
5.4. Purite System Filter Replacement (Document Number AEU00497).

6.0 PROCEDURE

6.1. **Test Procedure.**

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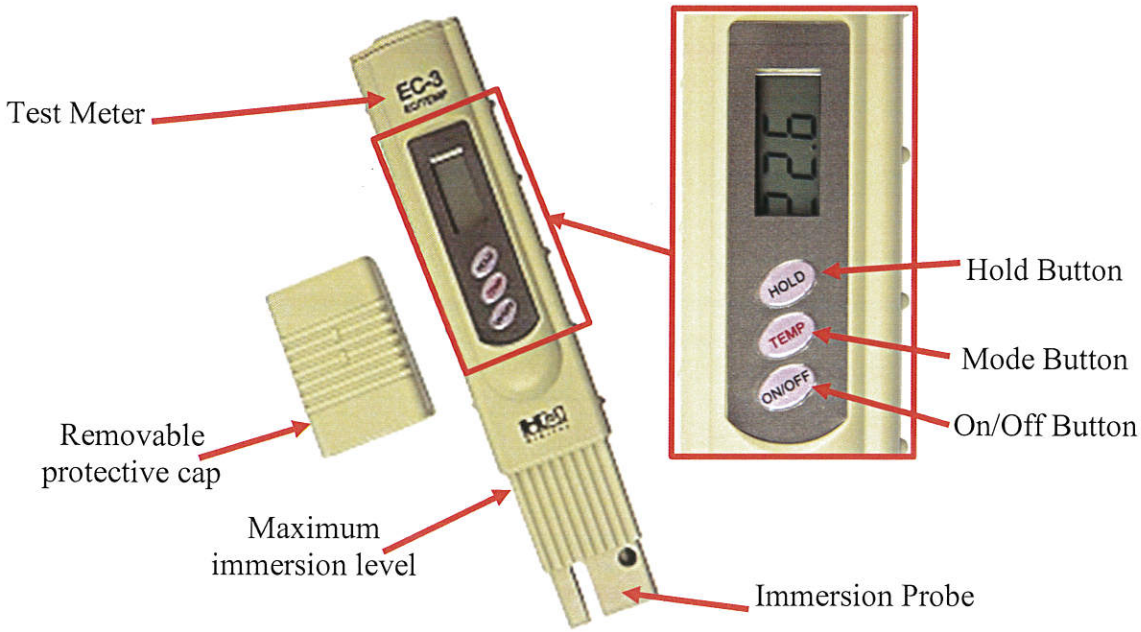

Figure 1: Example of the water conductivity test equipment, with a zoomed in view of test meter.

6.1.1. **Source Water Conductivity Meter.** Use hand held water conductivity meter, an example of the type is shown in Figure 1:

6.1.2. **Set Meter Up.** Switch on the meter by use of the ON/OFF button identified in Figure 1: and ensure that the mode is set to Conductivity, if the mode requires changing press the Mode button labelled 'Temp', as identified in Figure 1:

Figure 2: Testing the water conductivity.

6.1.3. **Test the Water.** Submerge the probe into the ultrasonic cleaning bath/tank up to the maximum immersion level, as identified in Figure 1: and as shown in the example in Figure 2: after the reading has settled down, this usually approximately 10 seconds, press the Hold button identified in Figure 1: remove the probe from the ultrasonic cleaning bath/tank.

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6.1.4. **Repeat Test in Four Locations in Tanks.** Make note of the reading taken in step 6.1.3 then release the hold button and repeat steps 6.1.3 and 6.1.4 four times in different random positions.

Note: If The Flashing 10x Symbol Is On Screen The Reading Shown Is To Be Multiplied By 10.

6.1.5. **Record Highest Reading.** Take the highest reading of the four samples and record this onto the Cleanroom Activity Log (Document Number AEU00496). Once all readings have been taken the probe is to be shaken to remove any excess water and the cap replaced.

Table 1: Acceptance criteria.

Result	Result Condition	Required Action
≤ 20µS	Good	No corrective action required goto step 6.2
20 - 30µS	Alert	Follow actions described in step 6.1.7 to 6.2.1 as appropriate
≥ 30µS	Action	All product processed since the last good results scrapped then corrective action as described in steps 6.1.9 to 6.2.1

6.1.6. **Analyse Results Taken.** Compare the results taken against Table 1: and follow appropriate action required.

6.1.7. **Repeat Test if High Results Are Observed.** If the results taken are at the level described in Table 1: that requires a second set of readings, this second set of results are to be taken after 5 minutes with the Ultrasonic bath/tank not being used, this will give the filters time to reduce the conductivity and avoid any false positive results triggering unnecessary actions.

6.1.8. **Results for Second Test.** Compare the second reading taken against Table 1: If the second readings are now found to be below the level described in Table 1: as "Good" then proceeded to step 6.2. If the results are still above the level described in Table 1: as "Alert" then proceed with actions described from step 6.1.9.

6.1.9. **Corrective Actions.** The clean room supervisor must be informed immediately. Then the following actions should be undertaken in the order described below;

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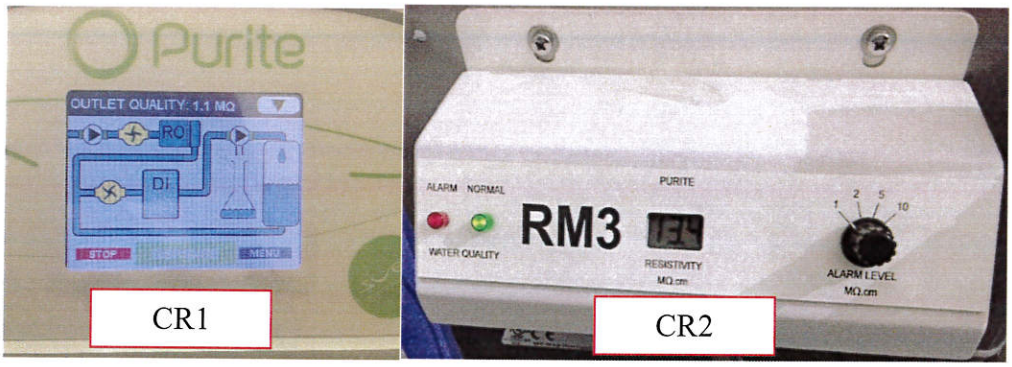
Purite control panel



RM3 Resistance meter

Figure 3: Resistance meter idenifications.

6.1.9.1. **Confirm Resistance Reading.** Confirm the resistance reading by checking the external resistance meters fitted on the Purite control panel for Clean Room 1 (CR1) or on RM3 fitted on the filter raft for Clean Room 2 (CR2).

Note: The Reading Taken In The Ultrasonic Cleaning Bath/Tank Maybe Effected By Any Recent Cleaning Operations, The Reading Measured On The External Resistance Meters Are More Stable And Representative Of The Condition Of The Water In The System.

6.1.9.2. **For CR1, Replace Pretreat 8 and PP8 Filters.** Replace the filters as described in procedure Purite System Filter Replacement (Document Number AEU00497).

6.1.9.3. **For CR2, Check Operation of DC9 Filter.** Check the date the DC9 filter was last replaced as described in the relevant steps in the procedure Purite System Filter Replacement (Document Number AEU00497) and if required replace the filter as described in procedure Purite System Filter Replacement (Document Number AEU00497).

6.1.9.4. **Replace Water.** If none of the previous checks appear to have resolved the issues then the water in the system is to be drained out and replaced with fresh deionised in accordance with procedure Purite System Water Change (Document Number AEU00498) and the clean supervisor informed.

6.1.9.5. **Confirm Effectiveness of Actions.** Retest the conductivity as described in steps 6.1.1 to 6.1.6 once any corrective action has been completed.

6.2. **Task Completion.**

6.2.1. **Record All Activity.** Record on Cleanroom Activity Log (Document Number AEU00496).