ISE QC Case Sharing

Moath Altalla

IVD Clinical Application Specialist , UAE , Middle East

CONTENTS

Case Background

Analyzer : BS-230.

ISE Module : Direct ISE MEDICA (No dilution).

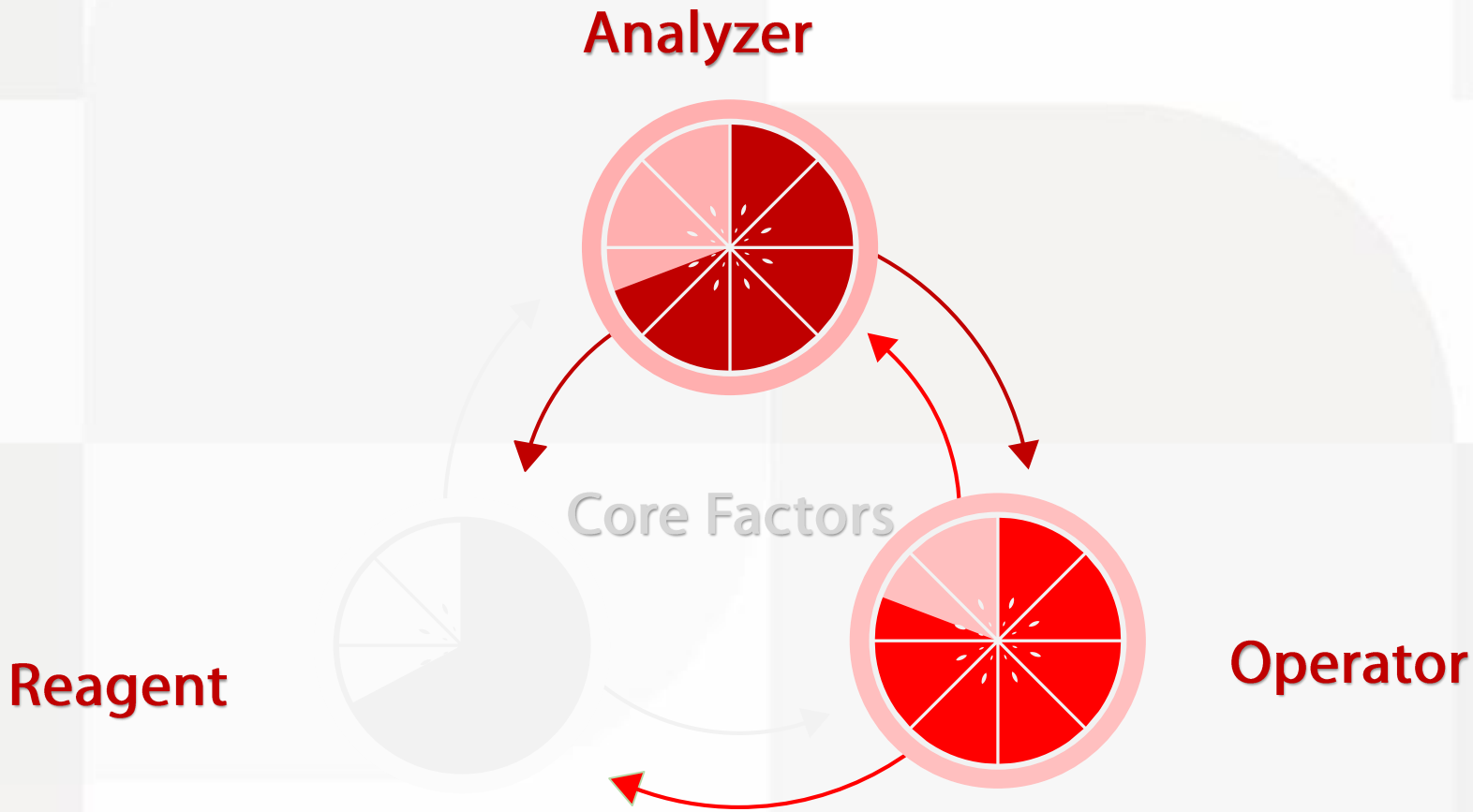
Customer type : Primary Health Care.

Complain: The customer run QC, the results show QC out of range -3SD for NA , CL , K parameters.

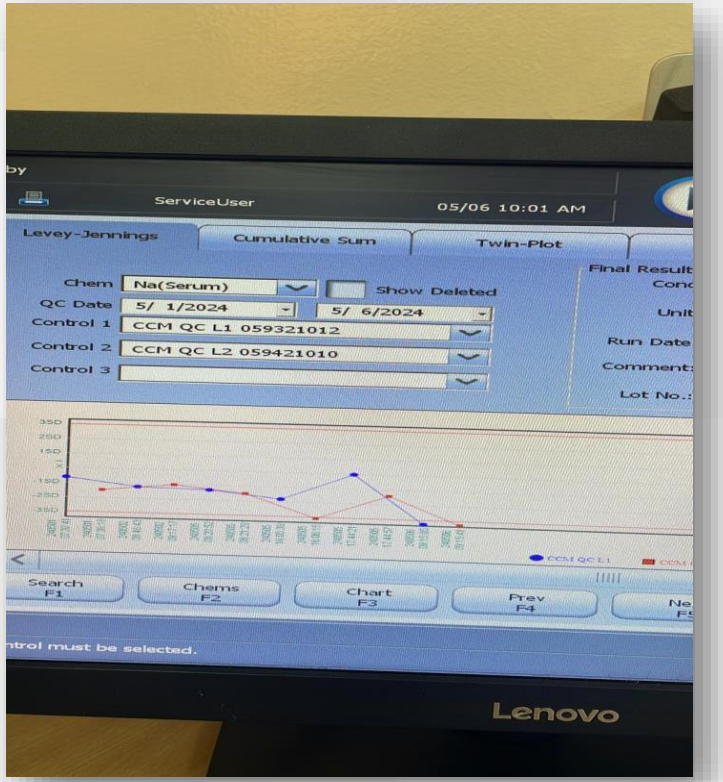
The customer call the distributor application specialist , advise them to do ISE maintenance and recalibration .

The results was same , complain sent to Mindray regional CAS , advise them to visit the site and do the troubleshooting steps .

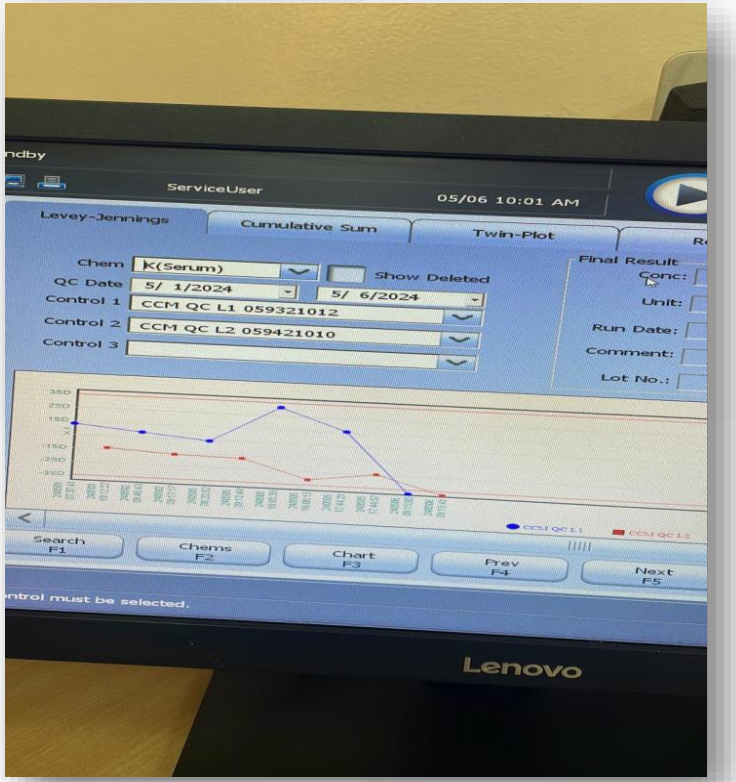
Core Factors Affect Results



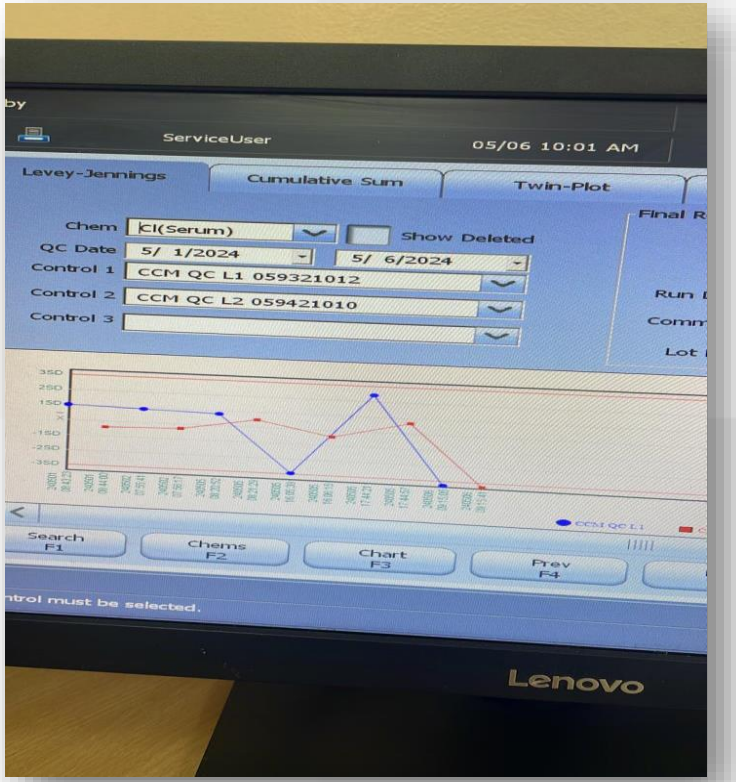
QC Results



NA: -3SD



K: -3SD

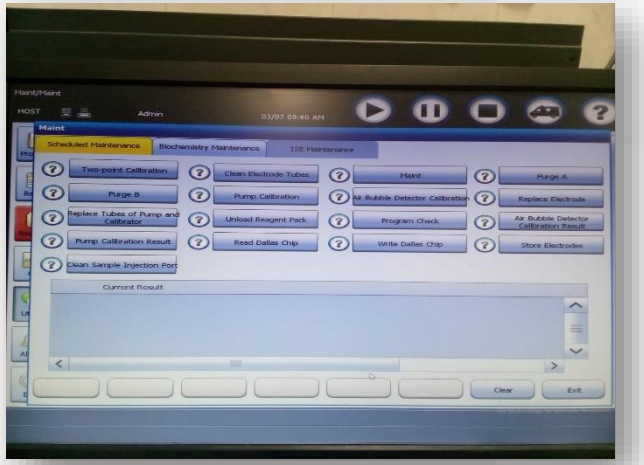


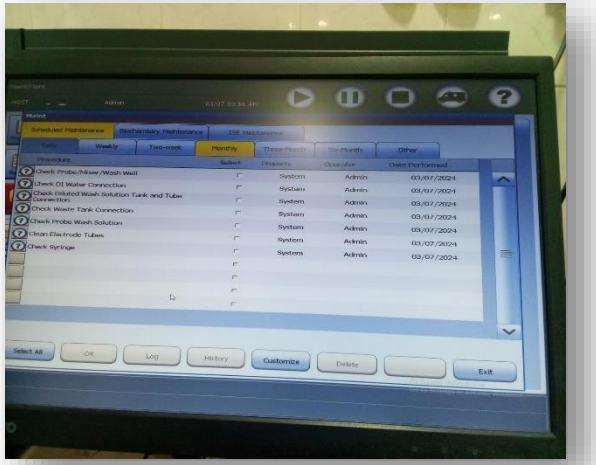
CL: -3SD

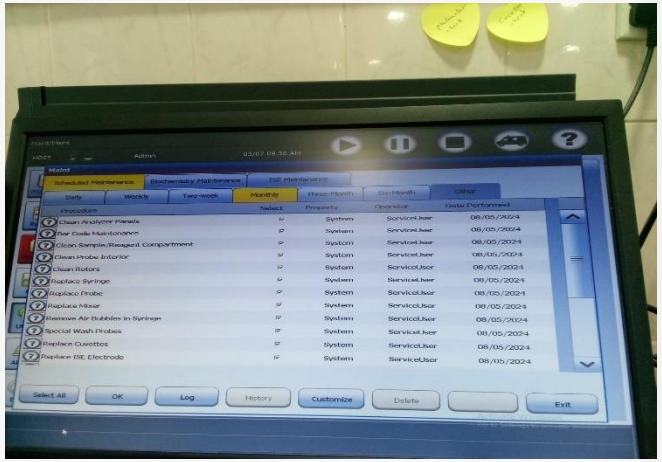
Case Ideas

Troubleshooting steps:

- ✓ Check random or systematic error , rerun with new QC material , the results of QC same -3SD! **Systematic error .**
- ✓ Check the ISE reagent Module ! **The ISE reagent module installed recently .**
- ✓ Maintenance for ISE module ! **Done successfully**
- ✓ Prime for Calibrator A,B ! **Done**
- ✓ Recalibration for ISE module ! **Done**
- ✓ Rerun QC ! -3SD

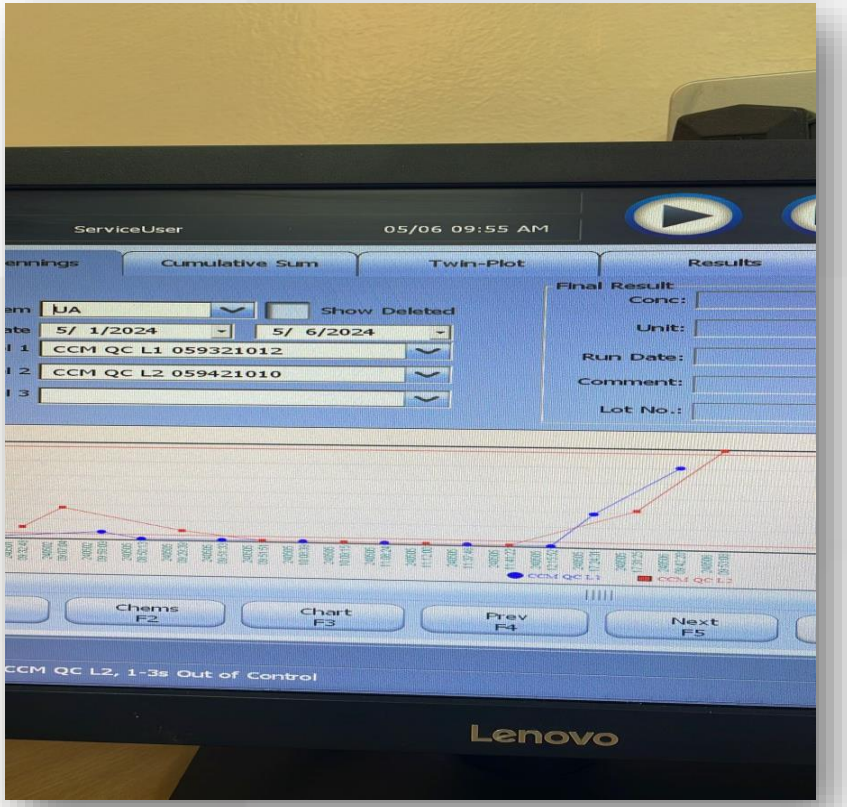




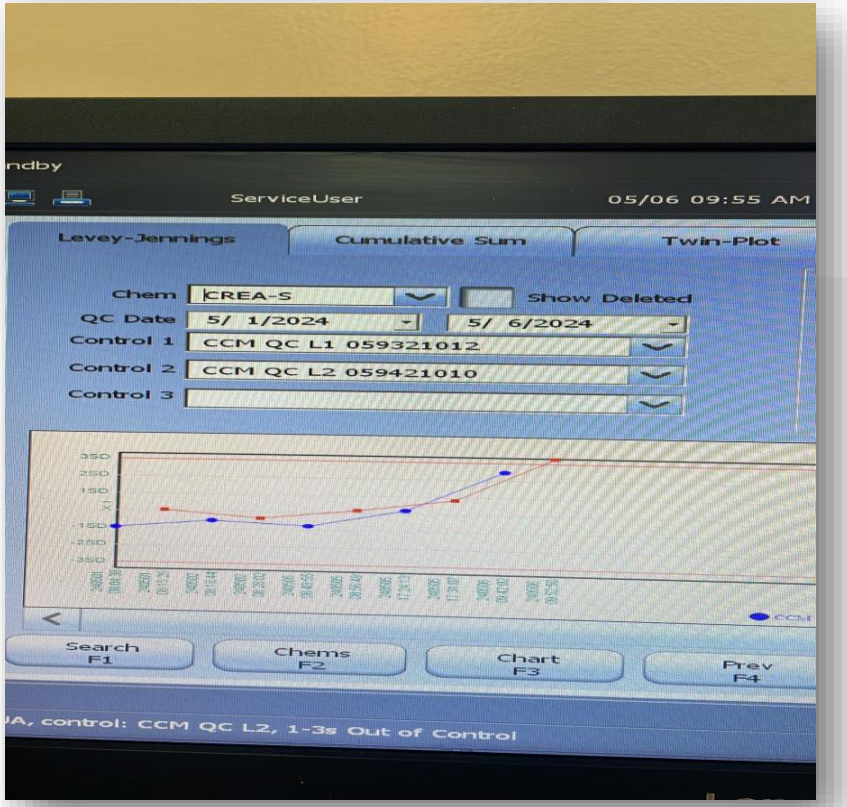


Troubleshooting Ideas

- ✓ Run QC for other parameters to check the analyzer status! **All chemistry parameters QC results Out of range.**
- ✓ Lamp , syringe checked by Engineer! (No bubbles, No leakage) Working properly .
- ✓ Review maintenance schedule ! **No record for Maintenance manually checks**



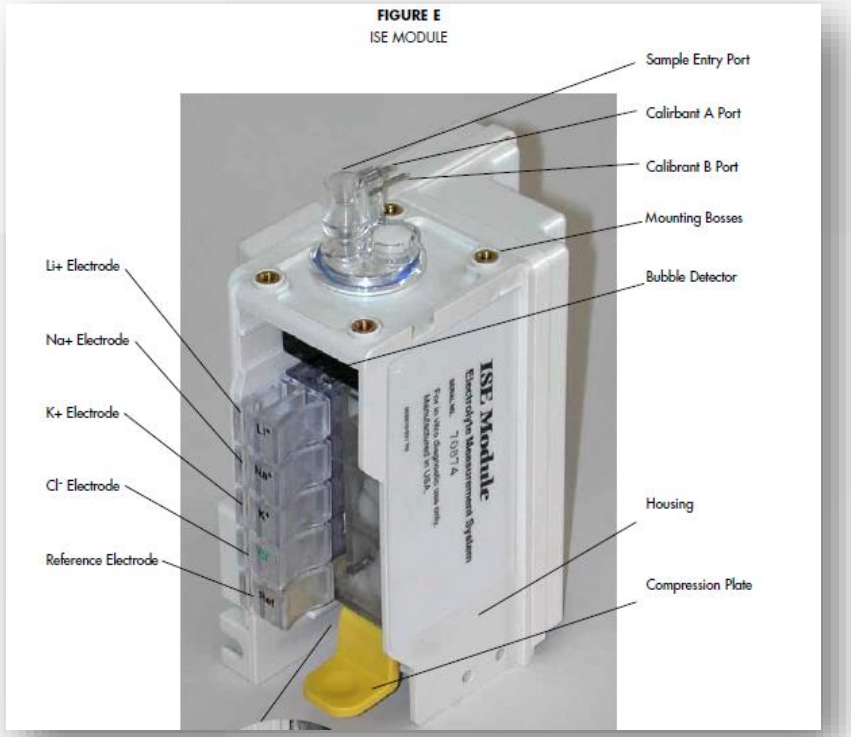
UA: +3SD

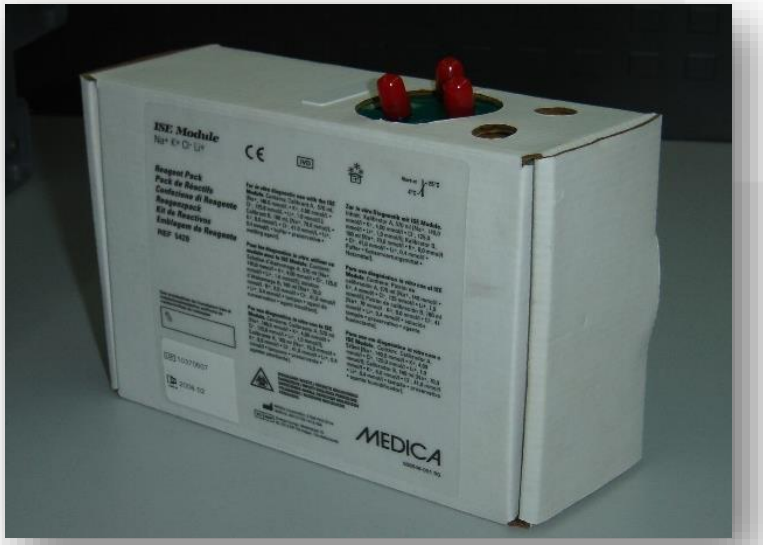


CREA: +3SD

Troubleshooting Ideas

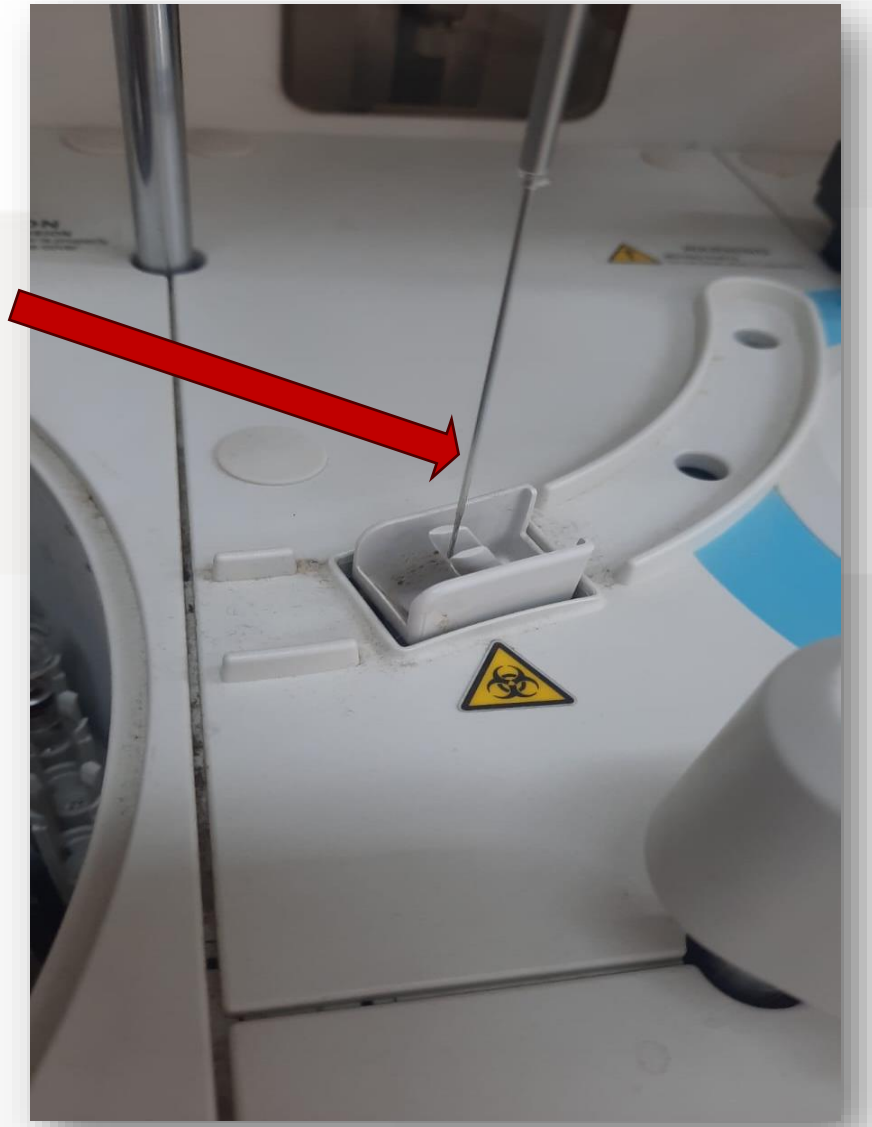
- ✓ Review the Medica ISE workflow .
- ✓ Review the Hardware correlation between ISE module and Chemistry module ? **Sample probe used for aspiration of chemistry and ISE tests**





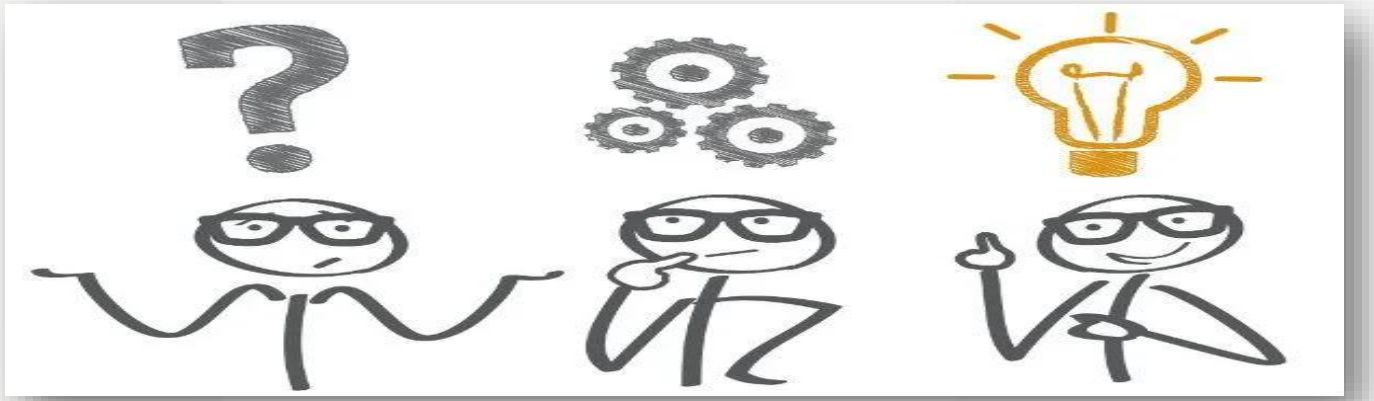
Root Cause

The customer neglected to clean the sample probe and check it regularly, which led to it becoming dirty and affecting the performance of sample aspiration .



Case Solution

- ✓ The prob checked which showed abnormal appearance and partially dirty ! **Probe replaced**
- ✓ **Results of all parameters within ranges**



Importance of maintenance

Maintenance of the system should be performed regularly by trained personnel to ensure reliable performance and reduce unnecessary service calls.

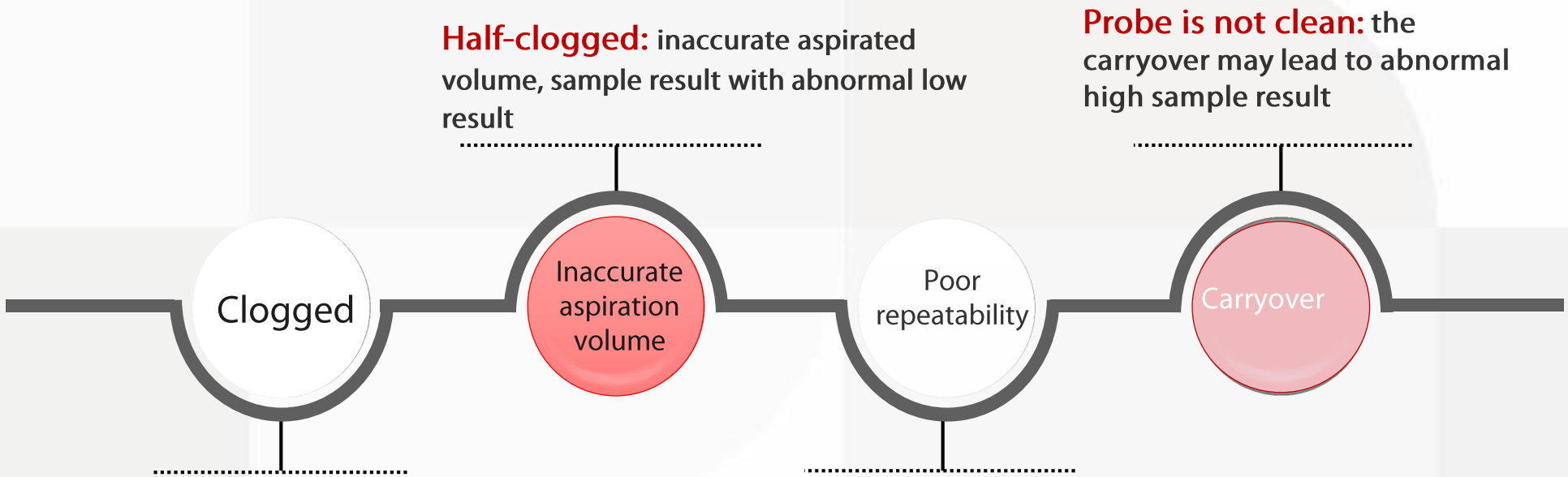
Your thorough understanding will help you obtain the best performance of the system.

Analyzer maintenance is essential for several reasons :

- ✓ It leads to increased uptime , more working hour.
- ✓ Fewer repair costs , ultimately resulting in increased revenue.
- ✓ Improperly maintaining your equipment can result in operational inefficiencies that negatively impact run time.
- ✓ Decrease output.
- ✓ Increase costs.

Importance of maintenance

What will happen if the sample probe is not maintained?



Half-clogged: inaccurate aspirated volume, sample result with abnormal low result

Probe is not clean: the carryover may lead to abnormal high sample result

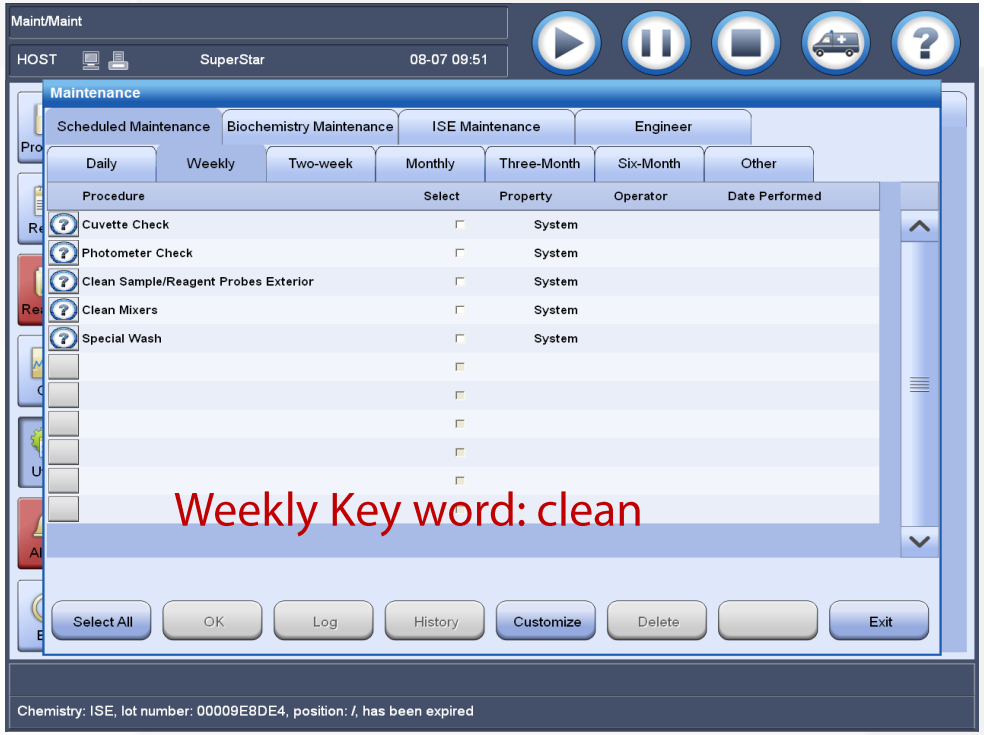
Clogged: Aspirated error, it will take long time to solve it

Half-clogged: poor repeatability

Maintenance period

The scheduled maintenance procedures are divided into the following periods:

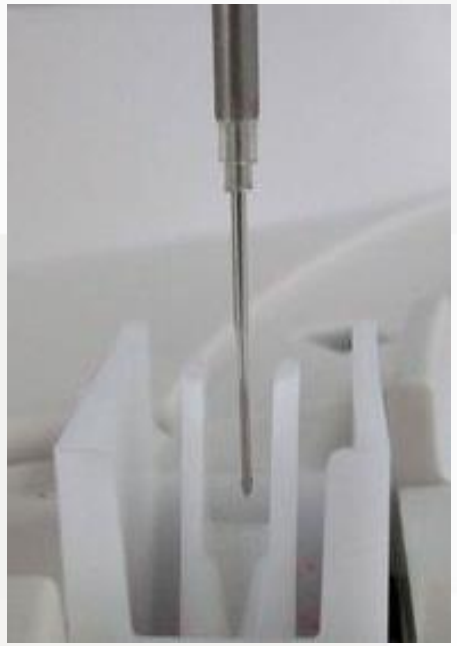
- ✓ Daily: 1 day
- ✓ Weekly: 8 days
- ✓ Monthly: 31 days
- ✓ Three-month: 91 days
- ✓ Six-month: 181 days
- ✓ Other (As-needed/As-required)



mindray 迈瑞
生 命 科 技 如 此 亲 近

Clean Sample /Reagent/Probe Exterior

Sample/Reagent Probe Exterior Clean



Forceps is recommended

Use gauze soaked with ethanol gently wipe the probe exterior

Direction: up to down

Conclusion

The importance of :

- ✓ Analyzer maintenance and physical check for probe , syringes .
- ✓ Proactive visits for customers
- ✓ Extensive Operation training for end user
- ✓ Training for new staff joiner

If the dirty probe was not found, what could be the troubleshooting ideas?

Extension

Thanks!

mindray 迈瑞