UniCel® DxI 600/800 Troubleshooting Job Aid

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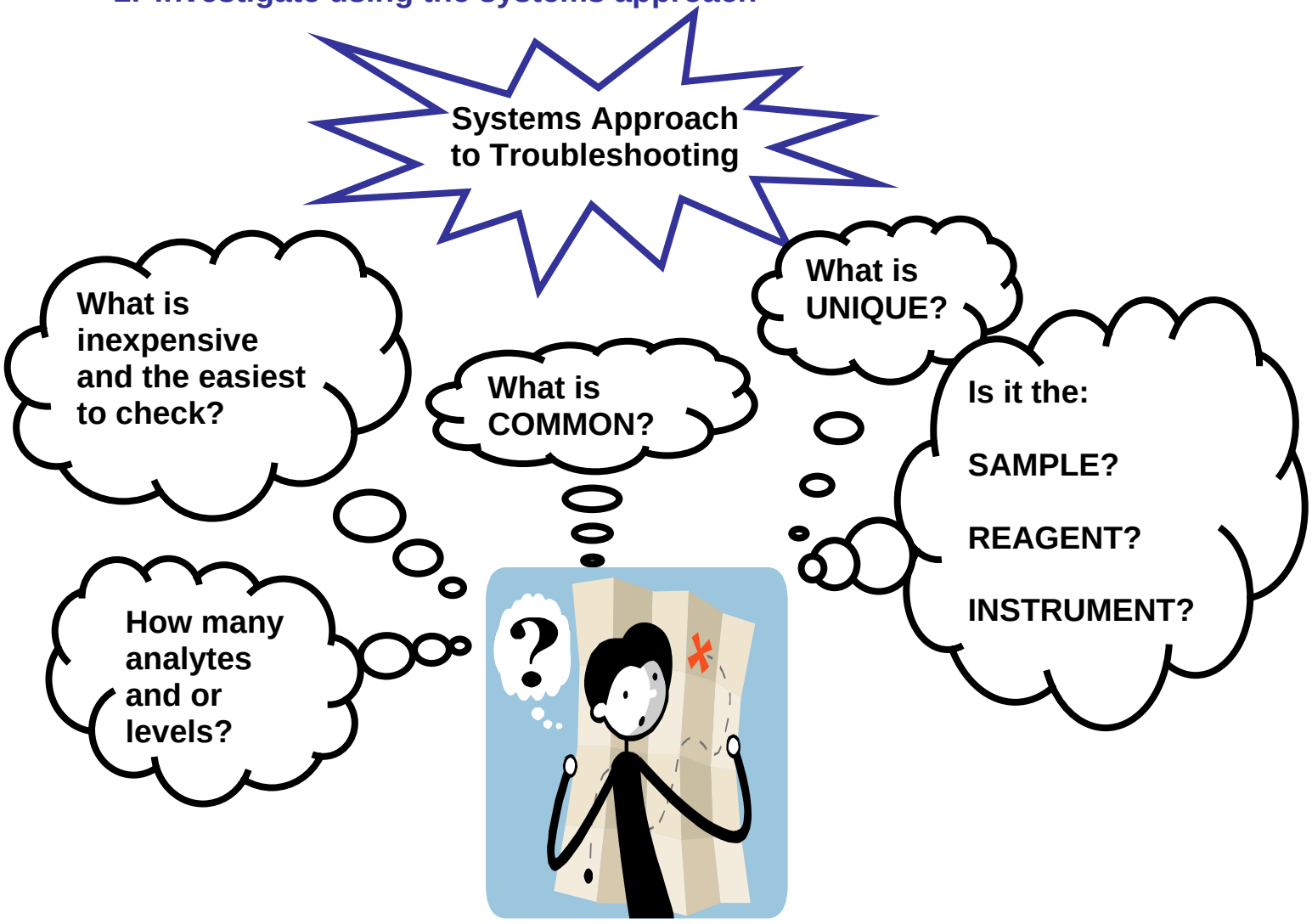
Troubleshooting Process

1. Identify the problem using clues

- Observed Problem
- Event Log entry
- Calibration failure
- Quality Control out
- Unexpected Patient Results
- System Check failure

2. Investigate using the systems approach



3. Use investigation and resources to devise a plan

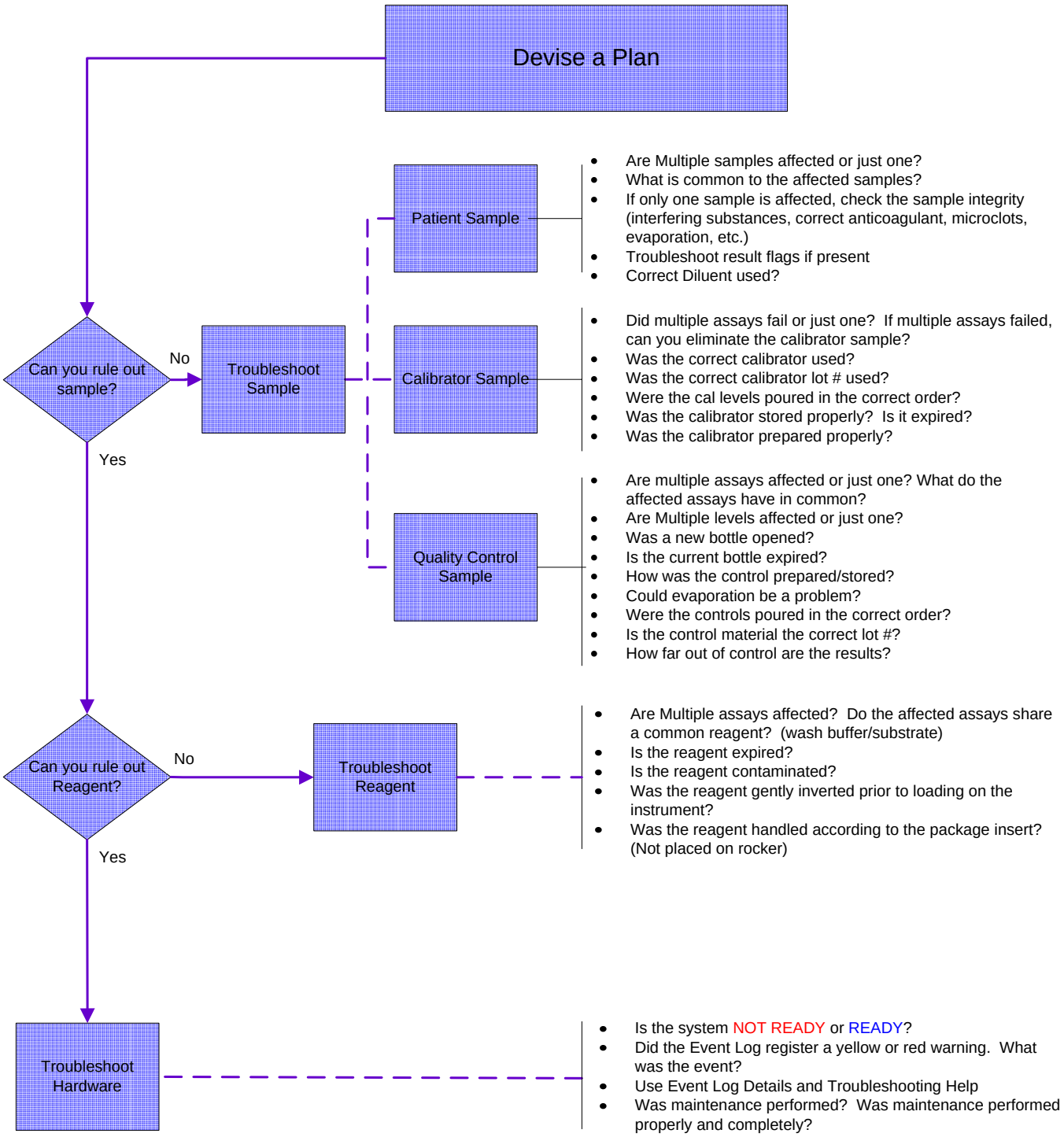
- Systems approach
- Help System
- Troubleshooting Log
- Coworkers
- Hotline
- Diagnostic tests

4. Implement the plan

- Perform identified corrective action

5. Evaluate effectiveness

- Continue investigation
- Problem resolved


Devise a Plan
Patient Sample
Are Multiple samples affected or just one?
What is common to the affected samples?
If only one sample is affected, check the sample integrity (interfering substances, correct anticoagulant, microclots, evaporation, etc.)
Troubleshoot result flags if present
Correct Diluent used?
Can you rule out sample?
No
Troubleshoot Sample
Calibrator Sample
Did multiple assays fail or just one? If multiple assays failed, can you eliminate the calibrator sample?
Was the correct calibrator used?
Was the correct calibrator lot # used?
Were the cal levels poured in the correct order?
Was the calibrator stored properly? Is it expired?
Was the calibrator prepared properly?
Yes
Quality Control Sample
Are multiple assays affected or just one? What do the affected assays have in common?
Are Multiple levels affected or just one?
Was a new bottle opened?
Is the current bottle expired?
How was the control prepared/stored?
Could evaporation be a problem?
Were the controls poured in the correct order?
Is the control material the correct lot #?
How far out of control are the results?
Can you rule out Reagent?
No
Troubleshoot Reagent
Are Multiple assays affected? Do the affected assays share a common reagent? (wash buffer/substrate)
Is the reagent expired?
Is the reagent contaminated?
Was the reagent gently inverted prior to loading on the instrument?
Was the reagent handled according to the package insert? (Not placed on rocker)
Yes
Troubleshoot Hardware
Is the system NOT READY or READY?
Did the Event Log register a yellow or red warning. What was the event?
Use Event Log Details and Troubleshooting Help
Was maintenance performed? Was maintenance performed properly and completely?

Calibration Troubleshooting

- Identify the failure code
- Identify any flags

Compare Last and Active with Previously Active Curves

- Review the precision of the calibrator points
- Review the curve for flatness
- Determine whether the RLUs of the points rose steadily (sandwich) or dropped steadily (competitive)

Review Investigation

- Verify calibrator storage
- Confirm maintenance was performed
- Review that the printed target concentration match those on the cal card
- Confirm Calibrators were processed in racks designated for the container used
- Confirm calibrators were stored/prepared properly

General Guidelines

-Operator Error

- Usually the precision is good but there is something else wrong that is detectable by viewing the curve
- The graph often points to the error

-System Error

- Often shows up as poor precision at one or more points
- May show up on more than one assay
- Many system problems look similar
- Perform System Check to aid in diagnosing problem

-Reagent Problems

- The curve may appear normal

Quality Control Troubleshooting

Review Levey Jennings

- How are QC Statistics handled?
- Is the imprecision consistent with the product insert?
- Were the mean and SD developed on your own instrument?
- Were proper statistical procedures followed to establish mean and SD?
- Are means and SDs within range of the QC peer group data?
- Are QC rules interpreted consistently by all lab personnel?
- Did you check with the manufacturer of the control material?

Establishing Control Ranges

-Gathering Data
- Run 1-2 replicates of each control each day (vary the sequence of processing)
- If one replicate is run, record that value. If 2 values are run, record both values.
- Obtain a minimum of 15 values of control on at least 3 different calibration curves (45 values minimum). Use both fresh and stored curves.
- Use 2 lots of reagent and two lots of calibrator if available.

-Calculating Ranges
- Calculate mean, %CV, 2SD and 3SD values
- Perform outlier evaluation
  - >Remove any values ouside of the 3 SD range and recalculate the statistics
  - >If the %CV is <6, consider widening the ranges by multiplying the stated SD by 1.5 then recalculated the 1SD, 2SD, and 3SD ranges
- Many system problems look similar
- Perform System Check to aid in diagnosing problem

Review Investigation

- Verify control storage/expiration date
- Confirm maintenance was performed correctly
- Review that the lot number is correct
- Review calibration curve

General Guidelines

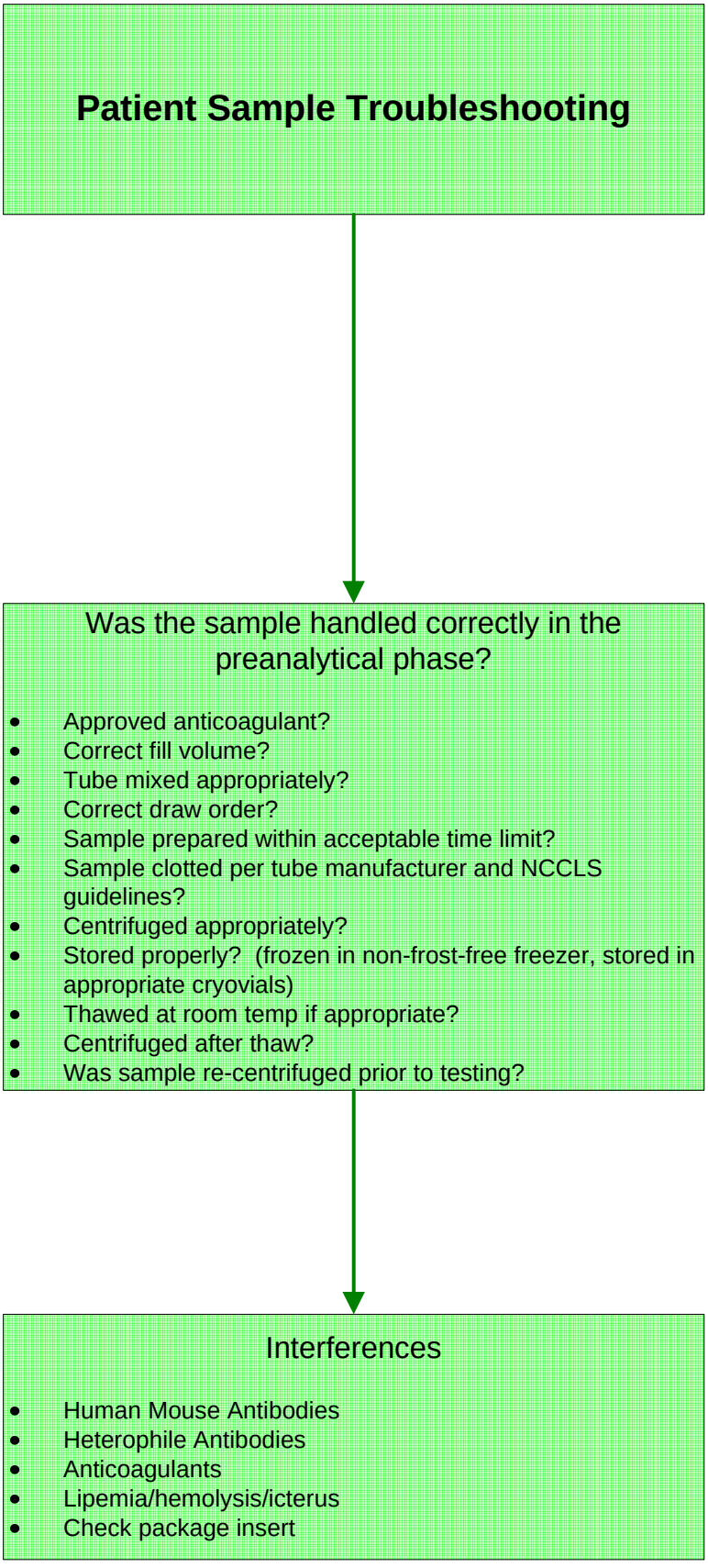
-Accompanying errors
- Event Log message-troubleshoot first
- Result Flags-troubleshoot first

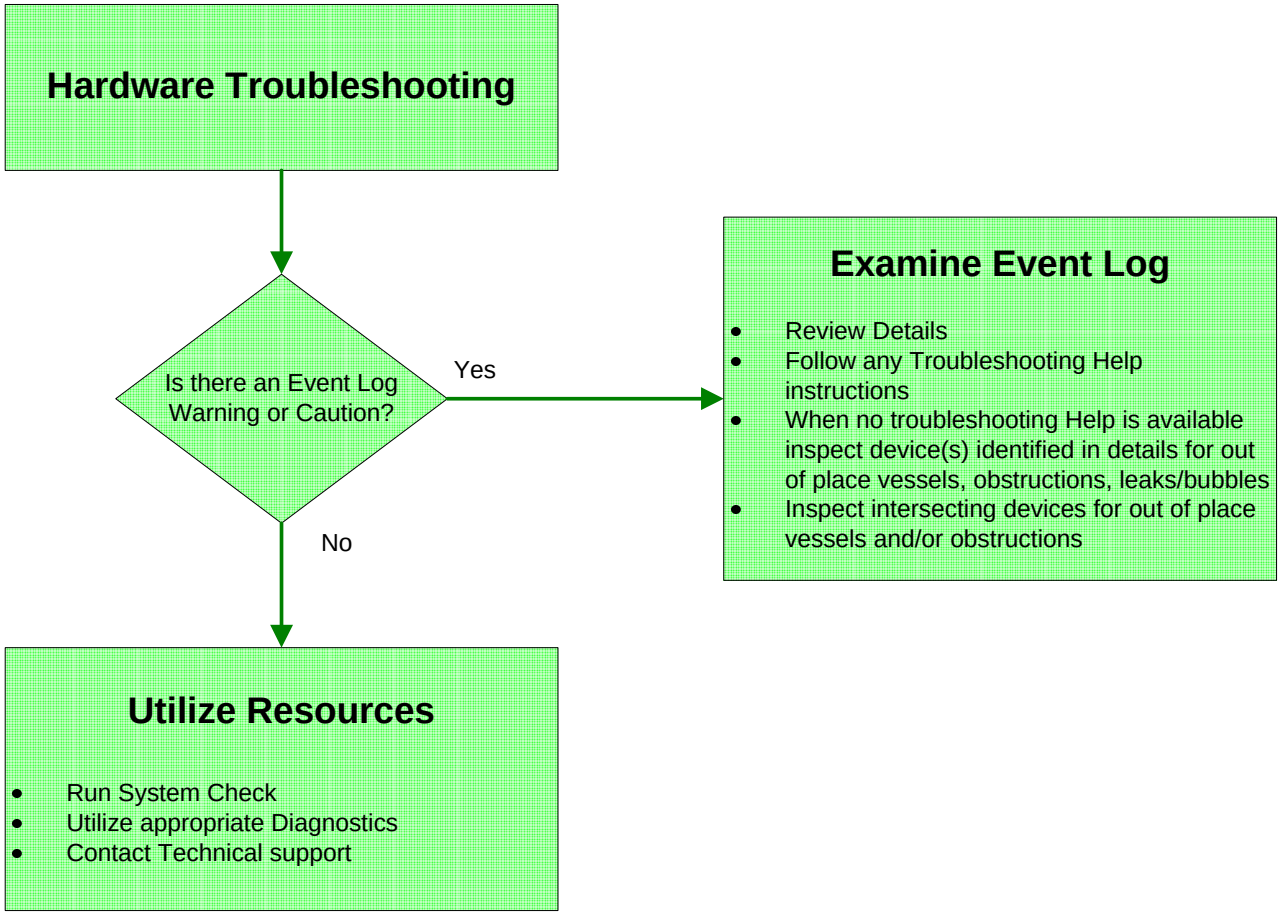
-Multiple Assays affected
- Suspect QC material or hardware
- If only one level affected, suspect QC material

-Erratic QC
- Process System Check for additional information

-QC trending
- Recalibrate

-QC shifts
- What changed?


Patient Sample Troubleshooting
Was the sample handled correctly in the preanalytical phase?
• Approved anticoagulant?
• Correct fill volume?
• Tube mixed appropriately?
• Correct draw order?
• Sample prepared within acceptable time limit?
• Sample clotted per tube manufacturer and NCCLS guidelines?
• Centrifuged appropriately?
• Stored properly? (frozen in non-frost-free freezer, stored in appropriate cryovials)
• Thawed at room temp if appropriate?
• Centrifuged after thaw?
• Was sample re-centrifuged prior to testing?
Interferences
• Human Mouse Antibodies
• Heterophile Antibodies
• Anticoagulants
• Lipemia/hemolysis/icterus
• Check package insert


Hardware Troubleshooting
Is there an Event Log Warning or Caution?
Yes
No
Examine Event Log
Review Details
Follow any Troubleshooting Help instructions
When no troubleshooting Help is available inspect device(s) identified in details for out of place vessels, obstructions, leaks/bubbles
Inspect intersecting devices for out of place vessels and/or obstructions
Utilize Resources
Run System Check
Utilize appropriate Diagnostics
Contact Technical support