Application Notes: N_2 Pharmacopoeia

Application:

Quality Control of Nitrogen (N_2) for Medical Use
Per European Pharmacopoeia Standards

Key Requirements as per the European Pharmacopoeia:

i. Definition: Nitrogen contains not less than 99.5 per cent V/V of N_2.
ii. Must be examined by gas chromatography (TCD) and an analytical column packed with appropriate molecular sieve using ambient air and a suitable Nitrogen reference gas.
iii. The assay is not valid unless the chromatograms obtained show a clear separation of oxygen and nitrogen.
iv. The retention time of the principle peak in the chromatogram obtained with the substance to be examined is approximately the same as that of the principle peak in the chromatogram obtained with the reference gas.

Solution:

Gas Chromatograph:	AGC NovaCHROM 4000 GC
Detector:	Thermal Conductivity Detector (TCD) @ 110°Celsius
Column:	Molecular Sieve (3m x 1/8") @ 100°Celsius
Sample Volume Control:	Pressure Equalisation Valve (PEV) and Temperature Regulated Sample Valve and Loop
Ancillary Components:	AGC TrendVision PLUS Chromatography Software and Solenoid Control Unit to monitor Air, Calibration Gas and Sample Gas Lines.

Measurement Procedure:

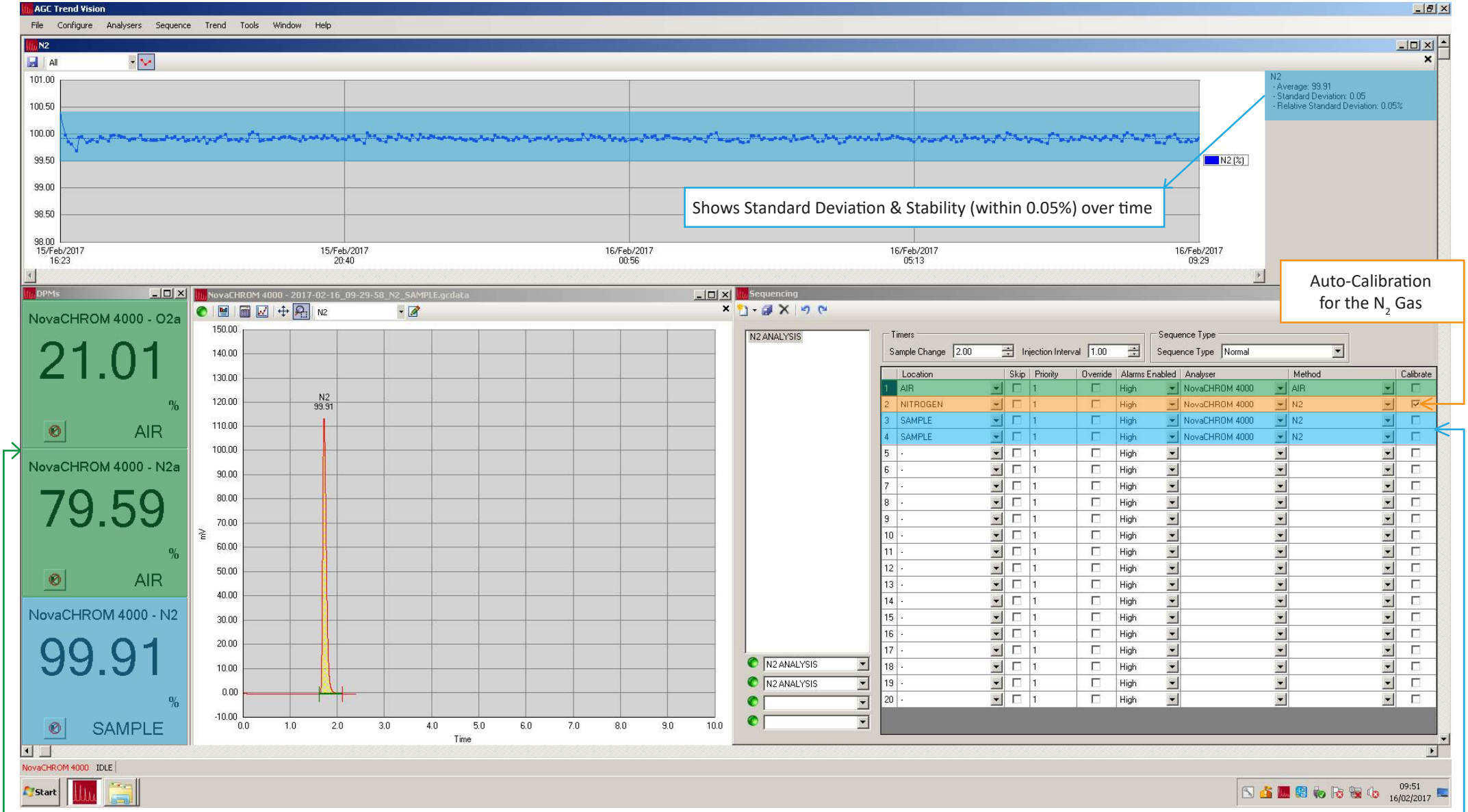
1. **Column Performance Check**
A molecular sieve is required to separate O_2 and N_2.
Air is injected to determine the retention time of O_2 and N_2.
If column separation is degraded, an alarm is generated.

2. **Detector Response**
The Detector Response is verified when the O_2 and N_2 peaks are within tolerance. An alarm is activated if the retention time is outside a pre-set time band or the expected value is not reached.

3. **Nitrogen Calibration**
A certified 100% Nitrogen Reference is used to calibrate the system. The Nitrogen Reference is injected to automatically calibrate the system.

4. **Sample Measurement**
The sample gas is injected, and Nitrogen is measured.
This phase is repeated to confirm measurement results.

NovaCHROM 4000 Rack System - Analysis of Medical N_2 to EU Pharmacopeia Standards



Air Sample to check:

1) Column Separation of O_2 & N_2 (with alarm function)
2) Detector Response/Sensitivity (with alarm function)
3) Retention Time (with alarm function)

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Sample Repeated to double check the purity of the sample gas (Optional - User Defined)

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System Alarms:

The status fail safe alarms are supported by alarms for the Carrier Gas and Air supply pressure rates and the Oven Temperatures. If any of these parameters change, then the results will fall outside the preset thresholds which will also trigger the Detector Response and Column Function alarms. This interlinked alarm system is also complimented by a locked cabinet door on the system which prevents unauthorised changes to the calibration settings.

Typical System Sequencing:

1. Air Injection
2. Calibration Reference Gas
3. Sample 1
4. Sample 2

Results Displayed as:

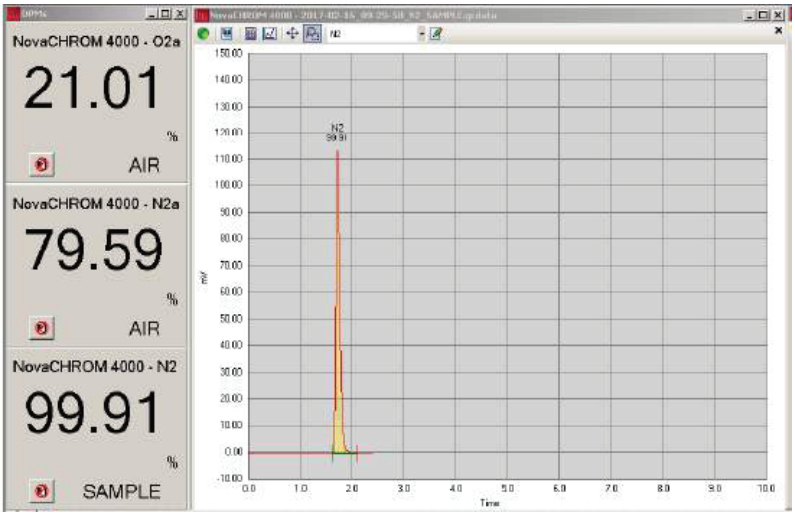
1. Digital Panel Meter (DPM)
2. Chromatogram
3. Trend

4-20 mA outputs are included as standard to transfer the results from the GC to the Control Room or DCS.

This sequence involves a run time of 10 minutes and is repeated for every sample to ensure the validity of the results.

The stability of the GC System has a stated value of 0.1% but typically records results within 0.05% of the value required for this application.

Typcial DPM and Chromatogram Screen on TrendVision



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