

The Amebis Stability Testing System



The Amebis Stability and Testing System offers Pharmaceutical and Biotech companies the ability to quickly and easily test product quality for humidity and temperature stability. Smaller product samples and speedy results allow for inexpensive testing saving time and money.

- Flexible and compliant Small Scale Stability Testing System
- 21 CFR Part 11 and GAMP compliant
- Wireless technology used for data transmission
- No humidity chambers required
- Each test monitored in its own micro-humidity chamber
- Full range of humidity conditions available (0-95%RH)
- Continuous data collection throughout with automatic data backup
- Improved sample integrity and less risk of cross contamination
- Incorporates latest sensor technology (ROTRONIC HygroMer® humidity sensor with Airchip 3000)
- Sensors can be easily calibrated

The Amebis Stability Testing System is a flexible and compliant means of performing small scale stability testing. The system can be set up in minutes with a full range of environmental conditions available. The humidity capsule which generates the required humidity and the test material are placed in separate compartments within the test chamber and the chamber is then sealed with a sensor cap. The humidity capsule controls the humidity within the test chamber and the sensor on the inside of the sensor cap measures the temperature and humidity within the chamber. Humidity capsules providing relative humidity in the range 0-95% are available in 5% increments. The color coded humidity capsules are labeled with a product code and batch number.

The sensor cap contains the latest in sensor technology, the ROTRONIC HygroMer® humidity sensor with Airchip 3000. Each sensor cap contains a unique serial number and is supplied with a calibration certificate. A logger cap is docked to the base station which is connected to the laptop via a USB cable. Test settings are sent to the logger cap which is then attached to the sensor cap. The logger cap is powered by a 9V battery and contains a memory chip and a short range transceiver. The logger cap collects and stores the temperature and humidity readings and transmits the data wirelessly to the control software. If the initiated tests are outside wireless range for communication with the base station then cabling and aerials can be provided to ensure wireless communication.



1. Pierce humidity capsule seal and place in test chamber

2. Place test material in either or both of the two smaller compartments

3. Seal the chamber with a sensor cap

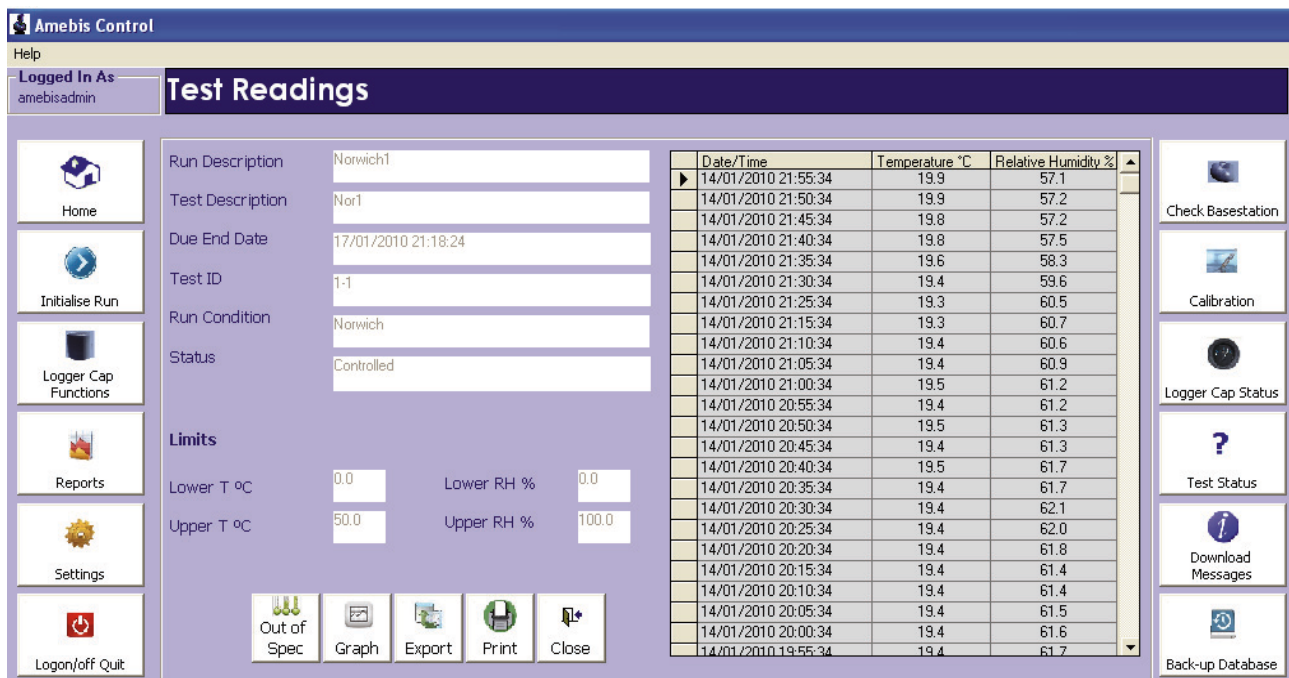


4. Dock logger cap on base station for programming

5. Connection of the logger cap to the sensor cap initiates the test. Temperature and relative humidity readings are collected and stored on the logger cap. The data is transferred wirelessly to the control software as required by the user.



Through the control software tests are initiated and data is collected. Reports can be generated on the click of a button. The software is 21 CFR Part 11 compliant and a full range of qualification documentation (IQ/OQ/PQ) is available.



The screenshot shows the 'Amebis Control' software interface. The main window is titled 'Test Readings' and displays a table of test data. The table has three columns: 'Date/Time', 'Temperature °C', and 'Relative Humidity %'. The data shows a series of readings over time, with temperatures ranging from 19.3 to 19.9 °C and relative humidity ranging from 57.1 to 62.1%.

Date/Time	Temperature °C	Relative Humidity %
14/01/2010 21:55:34	19.9	57.1
14/01/2010 21:50:34	19.9	57.2
14/01/2010 21:45:34	19.8	57.2
14/01/2010 21:40:34	19.8	57.5
14/01/2010 21:35:34	19.6	58.3
14/01/2010 21:30:34	19.4	59.6
14/01/2010 21:25:34	19.3	60.5
14/01/2010 21:15:34	19.3	60.7
14/01/2010 21:10:34	19.4	60.6
14/01/2010 21:05:34	19.4	60.9
14/01/2010 21:00:34	19.5	61.2
14/01/2010 20:55:34	19.4	61.2
14/01/2010 20:50:34	19.5	61.3
14/01/2010 20:45:34	19.4	61.3
14/01/2010 20:40:34	19.5	61.7
14/01/2010 20:35:34	19.4	61.7
14/01/2010 20:30:34	19.4	62.1
14/01/2010 20:25:34	19.4	62.0
14/01/2010 20:20:34	19.4	61.8
14/01/2010 20:15:34	19.4	61.4
14/01/2010 20:10:34	19.4	61.4
14/01/2010 20:05:34	19.4	61.5
14/01/2010 20:00:34	19.4	61.6
14/01/2010 19:55:34	19.4	61.7

The interface also includes a sidebar with navigation buttons (Home, Initialise Run, Logger Cap Functions, Reports, Settings, Logon/off Quit) and a right-hand panel with buttons for Check Basestation, Calibration, Logger Cap Status, Test Status, Download Messages, and Back-up Database. A 'Limits' section shows input fields for Lower T °C (0.0), Lower RH % (0.0), Upper T °C (50.0), and Upper RH % (100.0).

By replacing the sample chamber with a stand the same software and hardware can be used for monitoring and mapping applications.



The sensor caps are easily calibrated and adjusted by the use of ROTRONIC humidity standards, a calibration chamber and ROTRONIC HW4 Professional software.



Calibration chamber



Calibration chamber connected to sensor cap



Sensor cap connected to laptop via calibration cable.

Technical Specifications

Operating Range	0-60 °C; 0-100% Relative Humidity
Sample Chamber	Plastic Construction Volume 170 cm ³ ; Dimensions 4.5cm (h); 7.0cm (d)
Sensor Cap	Incorporates the ROTRONIC HygroMer® humidity sensor with Airchip 3000 housed within a plastic casing and containing a D-sub connector for connectivity to the logger cap and calibration cable. Supplied with a calibration certificate (SCS – Swiss & UKAS – UK traceable). Dimensions 7.5cm (d); 2.5cm (h)
Logger Cap	Plastic housing containing a short range transceiver and a memory chip for storage of 8,000 temperature and humidity readings. Also contains recess for holding 9V battery. Dimensions 7.5cm (d); 5.5cm (h)
Humidity Capsule	Color coded plastic capsule with aluminium seal. Dimensions 3.2cm (d); 2.0cm (h)
Base Station	Plastic housing containing a short range transceiver for wireless communication with logger caps. Also contains a D-sub connector for connectivity with a docked logger cap during test set-up. Connectivity between the base station and computer is via a USB cable which also powers the base station. Dimensions 15.5cm (d); 4.5cm (h)
Amebis Control Software	21 CFR Part 11 compliant software for the initiation of tests, data capture and the presentation of data
Laptop	ASUS EEE PC Laptop. 1gb RAM, 160 GB Hard disk, Microsoft Windows XP, Microsoft Sql Server Desktop 2000, Clockwatch V 4.

Ordering Information

Product Code	Product	Qty	Details
F035	Amebis Stability Testing System	1	Contains base station, laptop with Control Software, 5 sensor caps, 5 logger caps, 5 batteries (9V) and 5 test chambers.
F00X	Sensor Cap	1,10,20	Contains the temperature / humidity sensor and seals the test chamber. Logger cap connects to the sensor cap to power the sensor and capture the readings. Supplied with calibration certificate. F001 =1, F002= 10, F003=20 Sensor Caps
F00S	Logger Cap	1,10,20	Connects to the sensor cap and stores the temperature and humidity readings. Transmits the data wirelessly to the Control Software. F004 =1, F005=10, F006 =20 Logger Caps
F014	Test Chambers	50	Hold the test material and humidity capsule during testing and are sealed by sensor caps.
F018	Humidity Capsules	50	Provide the humidity control during testing. Contact ROTRONIC for the range of humidity capsules available.
F0XX	Stands	5	Fit to sensor cap to allow monitoring of environmental conditions in rooms or cabinets. Plastic construction. Dimensions 8.3cm (d); 5.7cm (h) F056 = 5, F020 = 10, F021 = 20 Stands.
HW4-E	Calibration Software	1	ROTRONIC HW4-E Software license. Single User Edition. Enables calibration of single sensor cap at a time.
HW4-P	Calibration Software	1	Rotronic HW4-P Software license. Professional Edition. Enables calibration of multiple sensor caps at a time.
F028	Calibration Chamber	1	Stainless steel chamber which fits to sensor cap. Dimensions 7.0cm (d); 3.9cm (h)
F038	Calibration Cable	1	USB connectivity to computer and D-sub connectivity to sensor cap.
EAXX	Calibration Standards	Box of 5	ROTRONIC humidity standards for calibrating sensor caps. Supplied with Calibration Certificate. XX = %RH Example: EA10 = 10%RH. Standards available 0.5%RH, 5.0%RH, 10.0%RH, 11.3%RH, 20.0%RH, 35.0%RH, 50.0% RH, 65.0%RH, 75.0%RH, 80.0%RH, 95.0%RH.
PS40	Calibration Chamber Liners	100	Placed in calibration chamber and hold calibration standard during calibration of sensor cap.

Please contact us for a quotation or if you require further information.
More detailed information on our products can be found on our website.