Amebis Control Software

Version 1.0.0

Manual

Table of Contents

1. Important Notes

1. Never connect more than one basestation to the Amebis Control Software

2. Never connect two or more Remote stations with the same Id to the Amebis Control Software

3. Only use Amebis supplied cables for connecting basestation and remote stations to Amebis Control Software

4. Never download data from a logger cap which was set up on a different system

5. We recommend that the user designate the backup directory as an external drive which can then be transferred to another PC.

2. Hardware

Approved for use with version 1.0.0 of Amebis Control Software;

- Basestation (Part Number: U003001)

- Remote Station (Part Number: U004001)

- Logger Cap (Part Number: U001001)

- Sensor Cap (Part Number: U002001)

3. Home

Active runs in Amebis Control

Details of active tests for the selected run

View the main screen and active runs

Check basestation online

Commence a new run

Open calibration software

Reset a logger cap

View table of tests whose logger cap memories are nearly full .

View data and reports for tests

View table of tests near or past their end date.

Set up run conditions, view audit trail and adjust system settings

View messages from automatic and manual downloads

Log-on or quit Amebis Control

Create a backup of the Amebis MS SQL ® database

Amebis Control

Help

Logged In As amebisadmin

Home

Runs

Id	Description	Start Date	Active Tests
4	test5	14/12/2009 16:32:09	1
5	test6	14/12/2009 16:37:24	1

Home

Initialise Run

Logger Cap Functions

Reports

Settings

Logon/off Quit

Tests

Download   End   Change ▾   Select All   Select None

Check Basestation

Calibration

Logger Cap Status

? Test Status

Download Messages

Back-up Database

12:32:11   Last automatic download: 13/12/2009 Next due at: 11:00   Database memory available : 1.99 G

Perform a manual download of selected tests

End the selected test

Change the end date, sensor cap or logger cap for selected test

Select all tests in the current run

Deselect all tests in the current run

The Home screen is the main screen which is on view after logging on. This allows you to navigate Amebis Control. From this screen, you can perform most of the tasks related to setting up runs, downloading data and viewing information.

4. Run Condition set-up

Run conditions must be set up before any runs can be created. These are the general settings to control a test. There is no limit to the number of runs and tests which can be associated with a Run Condition. The Station Id is the remote station or basestation to which tests will be associated and through which data will be remotely downloaded. Each remote station and basestation has a station Id on its base. Up to six remote stations can be connected to a system. The test interval sets the frequency for taking a reading. A choice of 5, 30 and 60 minutes test intervals are available. The temperature and humidity limits set the level for readings that will be deemed outside of specification. The limits allowed are between 0-60^{0}C for temperature and 0-100% for Relative Humidity. If Relative Humidity readings are not required then un-ticking the 'Humidity Readings Required' will mean that Relative Humidity readings will not be displayed. If limits are not entered then there will be no Out of Specification (OOS) results to display. If the user does not wish OOS readings to be displayed or alarmed at the beginning of a run then a 'Ramp Up Time' can be entered up to a maximum of 48 hours. If left blank there will be no 'Ramp Up Time'.

Enter a description for the run condition.

Choose the remote station or basestation Id for this run condition.

Choose the frequency for taking readings

Choose the lower temperature limit for this run condition.

Un-tick this box if humidity readings are not required.

Choose the lower humidity limit for this run condition.

Time at beginning of run exempt from Out of Specification messages.

Set up the run condition with the above settings

Choose the higher temperature limit for this run condition.

Choose the higher humidity limit for this run condition.

Cancel setting up this run condition

New run condition

Run Conditions

Description:

Station id

Sample interval

Temperature limits: Lower   Upper

Humidity readings required?   ☑

Humidity limits: Lower   Upper

Ramp-up time (hrs)

OK   Cancel

5. Run set-up

A run is a number of tests set up for monitoring the same environmental conditions and with the same limits on these conditions. All tests within a run (maximum of 20 tests allowed) are linked to a run condition. A run needs to be set up before tests can be initiated. A run and all its tests must be setup within 50 minutes of commencing set-up otherwise the set-up process will automatically end and no more tests can be added to the run.

Initialise Run

Enter a description for the run. This must be unique

Enter the number of tests for the run

New run

Run Description:

Number of Tests:

Run Conditions:

View

OK

Cancel

Choose the run condition for this run

View a list of the active run conditions

Set up this run with the designated settings

Cancel the set-up of the run
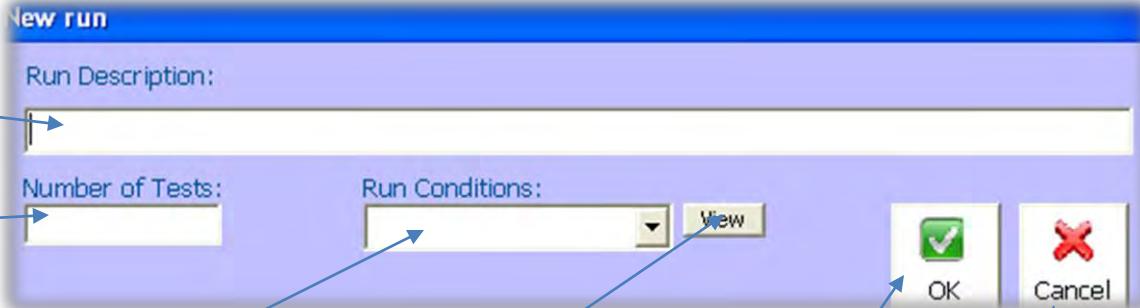
6. Test Set-up

A logger cap must be docked on the basestation in order to initiate a test. When all the fields are completed correctly and the 'Submit' button is pressed you will be prompted to connect the logger cap to the sensor cap. Following the on screen instructions will initiate the test. Once initiated a test will be assigned a unique identification number and details for the test can be viewed in the 'Reports' section. If the test just initiated is not the last test for set up within the run then the 'New Test' dialog box will appear populated with the same entries for the last test and can be edited for this test set up. The status for a test when initiated is 'Controlled' which means readings are checked against limits for Out of Specification and alarmed to user. When the 'Run Time' has expired for a test the status changes to 'Monitoring' which means readings will not be compared to limits for Out of Specification and the remote download of data will occur from the basestation. Tests in Monitoring Mode will not be part of an Automatic Download (see section 8).

Enter a description for the test. This must be unique

Choose this test as last for this run

Enter the serial number of the logger cap

Set the test duration. The 1st drop down choose hours, days, weeks or months and from the 2nd choose the required number

New test

Test description:

Logger cap id: Sensor cap id:

Run time:

☐ Last test   Submit   Clear   Cancel

Enter the serial number of the sensor cap

Set up this test with the designated settings

Clear all entered details to start again

Cancel setting up the test This will also end the run set-up and limit the run to the number of tests already set up.

7. Manual Download

Manual download is the process by which data for a test is transferred from the logger cap to the control software via radio frequency. In order for a manual download to be successful the test must be within the vicinity of the remote station or basestation associated with the run condition linked to the test. When the run time for a test has expired manual downloads can only take place within the vicinity of the basestation. Only readings which have not yet being transferred to the control software will be downloaded.

To begin the process select a run on the Home screen of Amebis Control and then select the tests for downloading. Click the download button and the 'Manual Download' screen will appear. Click the 'Begin Download' button. Once the download is complete details for the download can be viewed by clicking the 'Download Messages' button on the main screen. Downloaded data can be viewed in the Reports section.
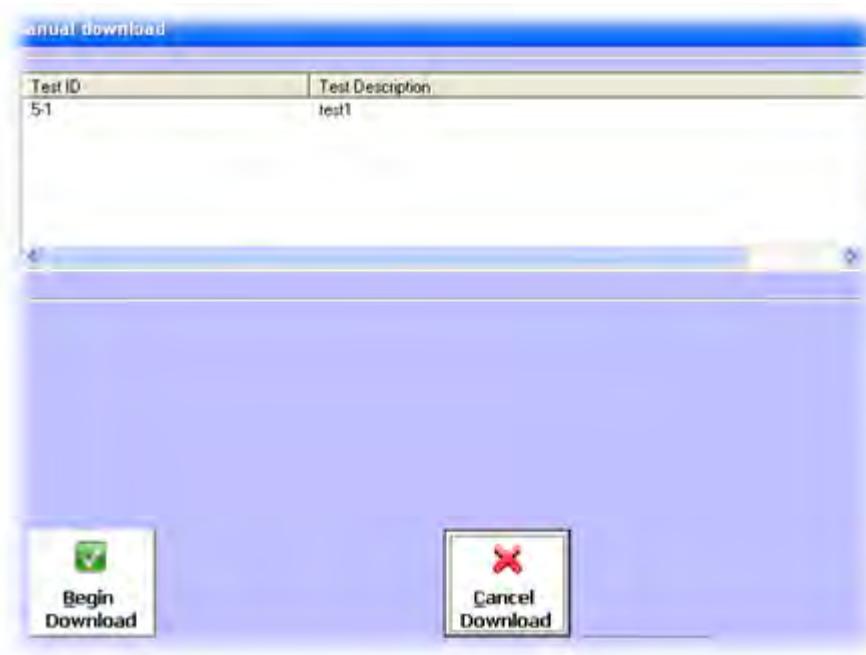
If the tests to undergo download are in Monitoring mode the user will be warned that downloads for these tests can only take place from the basestation and to make sure the tests are within the vicinity of the basestation.

8. Automatic Download

Automatic Download is a process by which data for tests are transferred from the logger cap to the control software via radio frequency every 24 hours at a time chosen by the user. Automatic downloads can only take place for tests which have a 'Controlled' status and 'Automatic Downloads' are allowed for the run condition linked to the test (see Settings Screen – section 16). Once the download is complete details for the download can be viewed by clicking the 'Download Messages' button on the main screen.

Automatic download begins approximately one hour after the program starts, if it has not already been performed that day.
If the program is continuously running, automatic download will begin at the time set for automatic downloads in the settings screen.
When the automatic download procedure begins the screen below will appear. You may delay the downloads, by selecting a delay period from the drop-down list and clicking set.
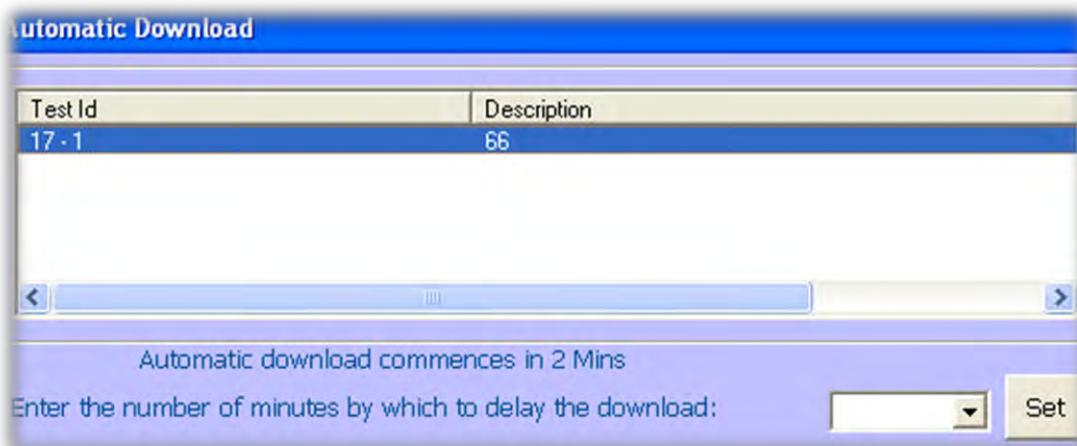
Once you click set, the screen will disappear and you may continue using Amebis Control.
Ideally you will have set a time for automatic downloads when Amebis Control is not in use.

9. End Test

Select the test for ending and then click the 'End' command on the Home screen. Follow the on screen instructions to end the test. It is important to note that once a test is ended it will not be possible transfer data from a logger cap to the control software for this test. The user can add notes if they wish as part of the end run process. The notes can be viewed in the Reports section.

To end the test click ok. The test will no longer appear on the main screen, but all data in the reporting section remains available.

10. Change Test
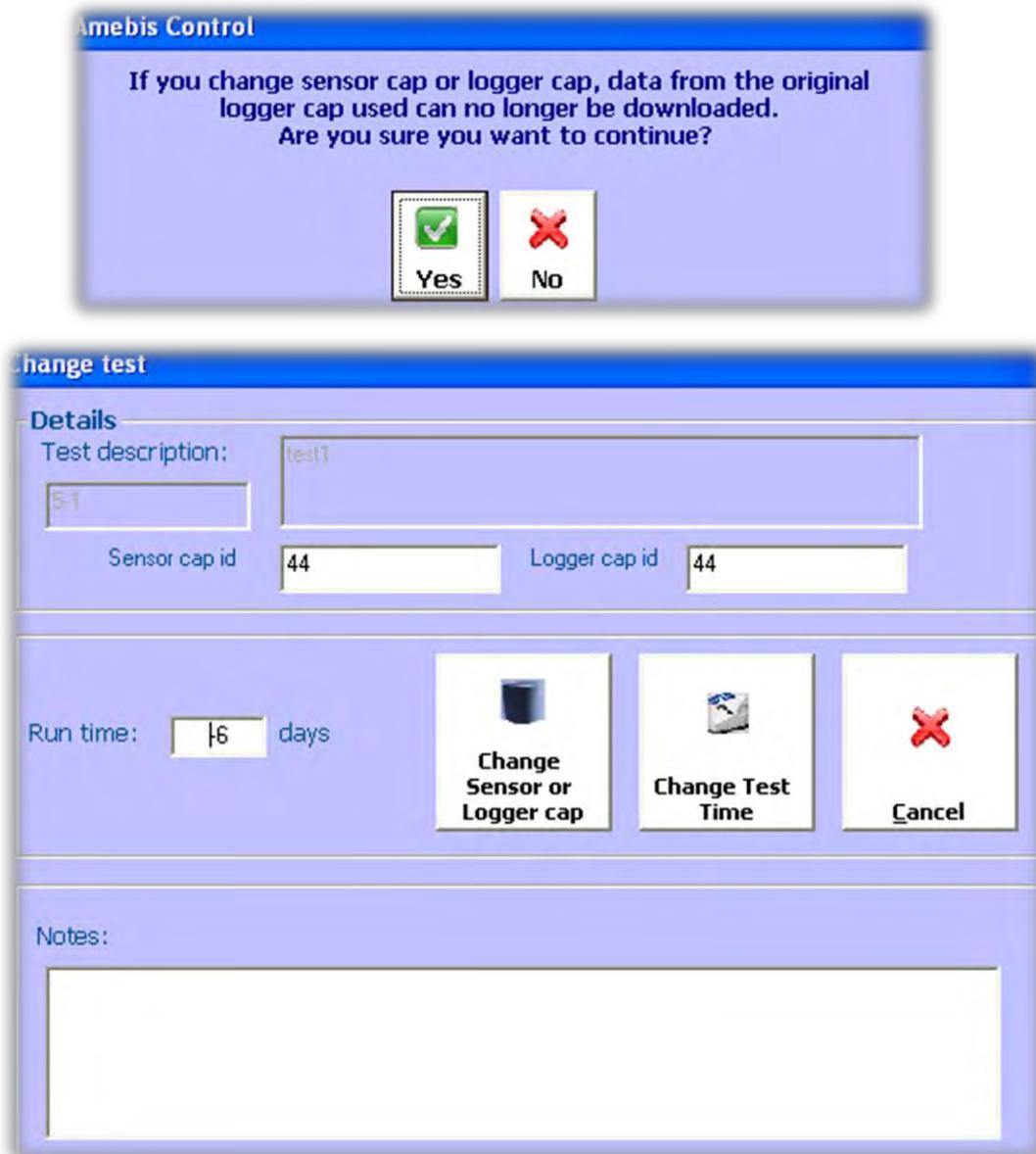
Allows the following to be performed for a test:
- Change the end date
- Change the sensor cap or logger cap

To perform either of the above choose the test on the Home Screen and click 'Change'. The 'Change' dialog box opens and the user has the choice of changing the test duration by clicking 'Change Test Time' or changing the sensor cap or logger cap by clicking 'Change Cap or Logger'.

Follow the on screen instruction to perform either function.

It is important to note that if a sensor cap or logger cap is changed then data for the original logger cap cannot be downloaded to the Control Software.

If the initial logger cap contains data for download then this data should first be downloaded by a 'Manual Download' or by using the 'logger cap' function before the 'Change Test' is executed.

11. Download Messages

Click the 'Download Messages' on the main screen to view details of all attempted Manual and Automatic Downloads.

| Result	Date and Time	Manual or Automatic
▶ 1-2battery will not last test duration Tests: 1-1, 1-2, have oos results	23/12/2009 13:56	Manual
Tests: 1-1, 1-2, downloaded with no problems	23/12/2009 13:10	Automatic
1-2battery will not last test duration Tests: 1-1, 1-2, downloaded with no problems	23/12/2009 12:46	Manual
1-2battery will not last test duration Tests: 1-2, downloaded with no problems	23/12/2009 12:41	Manual
Tests: 1-1, downloaded with no problems	23/12/2009 12:38	Manual
1-1Error 513a: Problem communicating with basestation	23/12/2009 12:36	Manual
Download was cancelled by user amebisadmin	23/12/2009 12:34	Manual
Download was cancelled by user	23/12/2009 12:34	Automatic

Now viewing messages from: 16/12/2009 ▾ to: 23/12/2009 ▾   Search by date   Close

The message box shows if the attempted downloads were successful and if not the problems encountered.
Messages can filtered by date if required.

12. Test Status

Test status

The following tests are near or at their end date

Description	Test Id	Due end date
▶ test4	4-1	15/12/2009
test1	5-1	15/12/2009

Close

Clicking the 'Test Status' button on the main screen opens a table of tests for which the run time has expired but the tests have not yet been ended and tests due to end within the next 24 hours.

?

13. Logger Cap Status

Logger cap status

Logger caps nearing capacity; please download data

Test Id	Description	Days Left

Close
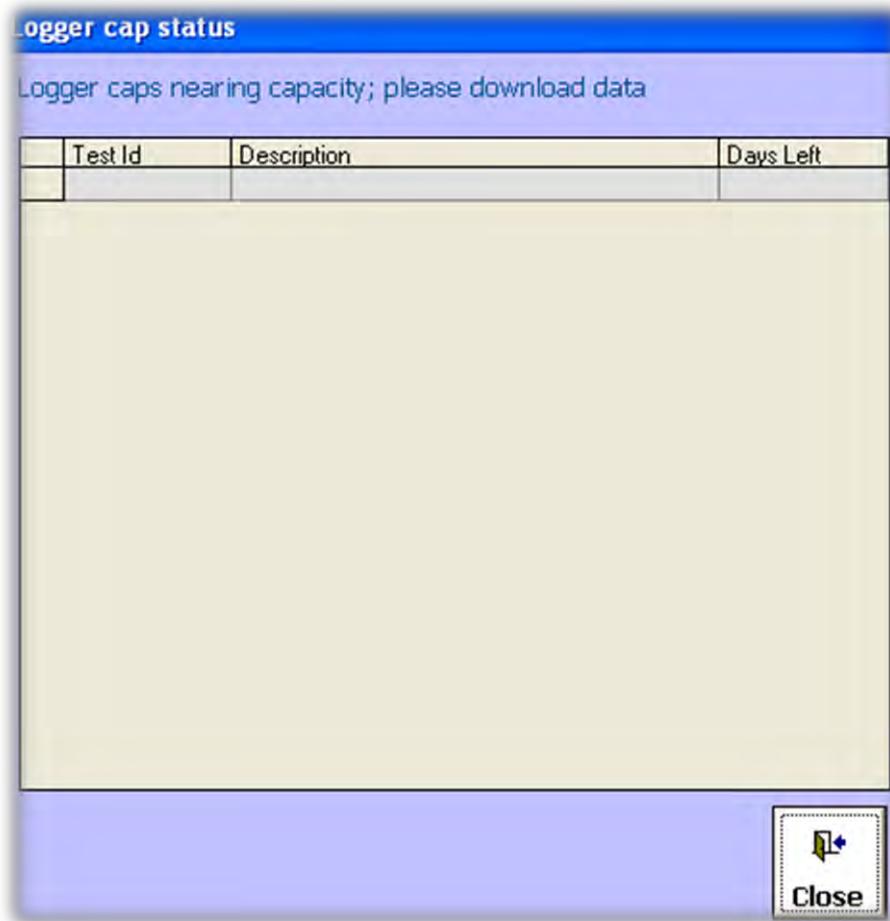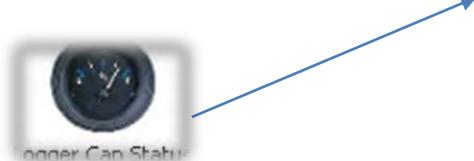
Clicking the 'Logger Cap Status' button on the Home Screen opens a table of tests whose logger cap memory is nearly full. Logger caps can store 8,000 readings and must be reset or changed before their memory is full. This table will list the logger caps well in advance of the memory being full and the entry will remain until the test is ended or logger cap changed.

Logger Cap Status

14. Back-up

Backup Database

Clicking the 'Backup' button on the main screen performs a backup of the database.

The backup file is date stamped and is stored in the directory designated by the user in Settings.

An automatic backup is performed every 24 hours at a time designated by the user (see section 16).

15. Calibration

The 'Calibration' button on the main screen opens the Rotronic HW4 software which is required to calibrate the sensor caps.
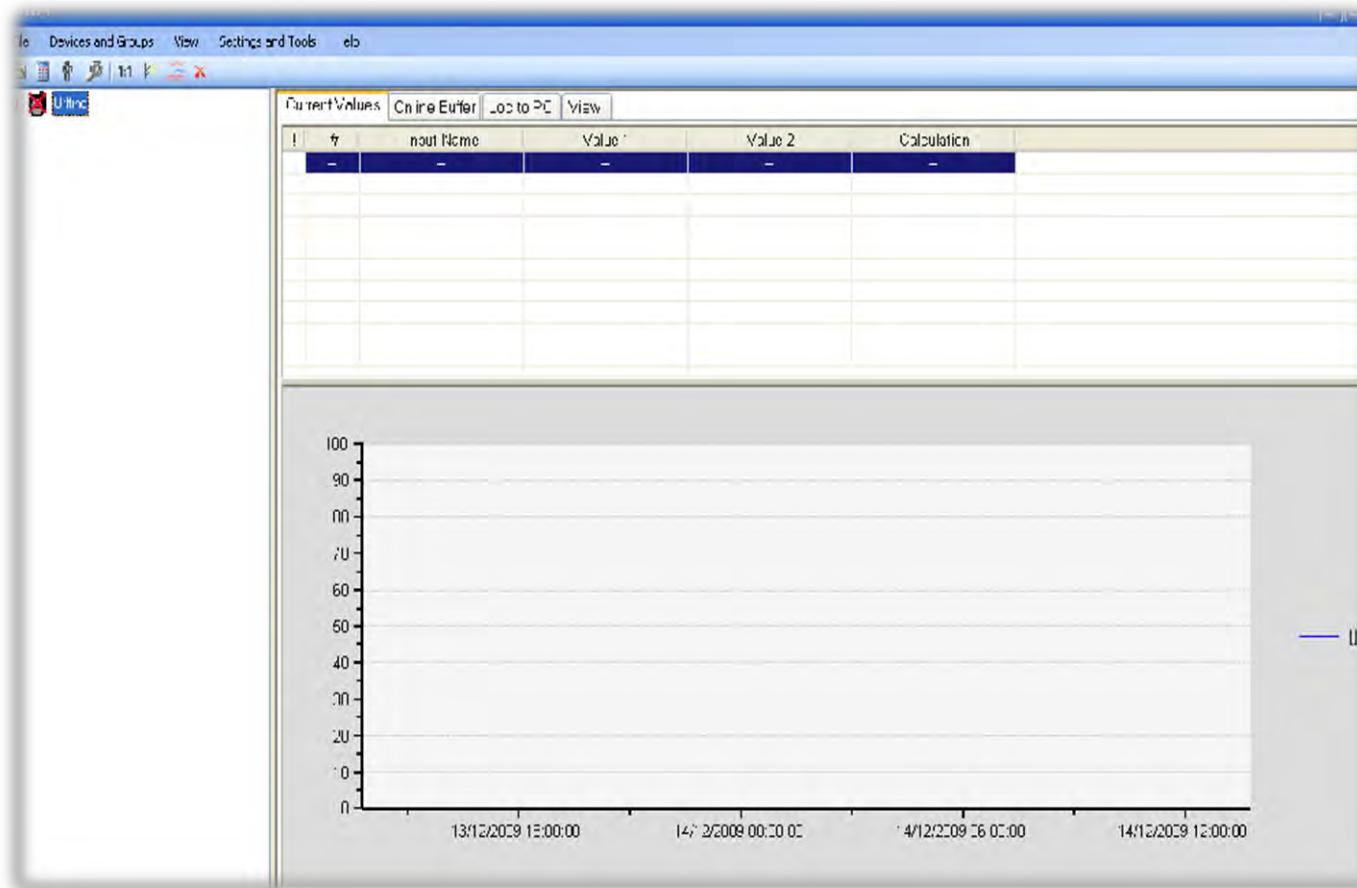
Please consult the Rotronic manual for guidance on the use of the HW4 software.

16. Settings

The 'Settings' button on the main screen opens the 'Settings' screen through which all conditions for running and controlling the software are set up.

Active Run Conditions

Set reporting email address

Restore database from back-up

Time Automatic Downloads commence

Date of last automatic download

Change time for automatic Downloads

Change time for Automatic Backups

Time Automatic backup performed

Displays the Audit Trail.

Opens security function to control user access.

Number of active runs on the system

Number of active tests on the system

Check if Remote station and Basestation are on-line.

Opens the Administration Reports screen.

Opens the "create Run Condition" dialog box.

Current back-up location.

Set backup location

Date last backup took place

Run numbers which never contained initiated tests.

Run Condition Description	Station ID	Lw Temp ºC	Up Temp ºC	RH Req	Lw RH %	Up RH %	Interval (mins)	Auto Download	Ramp Up
Norwich	1	20	22.6	Yes	20.1	80	5	Yes	1

Audit Trail
Check Station
Security
Active runs: 2
Active tests: 2

New
Admin Reports
Current Backup Location
Set Backup Location
C:\amebiscsv

Email Address
Restore

Download time: 11:00
Last auto download: 13/12/2009
Back-up time: 22:22:00
Last back-up: 08/12/2009 14:08:49

Save Download Time
Save Backup Time
Unused Runs

17. Security

The security screen can be accessed by clicking 'Security' on the 'Settings' screen which is accessed by clicking the 'Settings' button on the home screen. The security functionality allows you to manage the users and their access level to the Amebis Control Software.
There are three access levels allowed:
Administrator; has full access to the software
User; has full access to software except for functionality controlled via the 'Settings' button on main screen
Reports; can view reports only
Users can be edited, deleted and added.

Add a user. Usernames must be unique and the user groups are
1 Administrator - Full access
2 User - Access to all functions except settings
3. Reports – Can view reports only
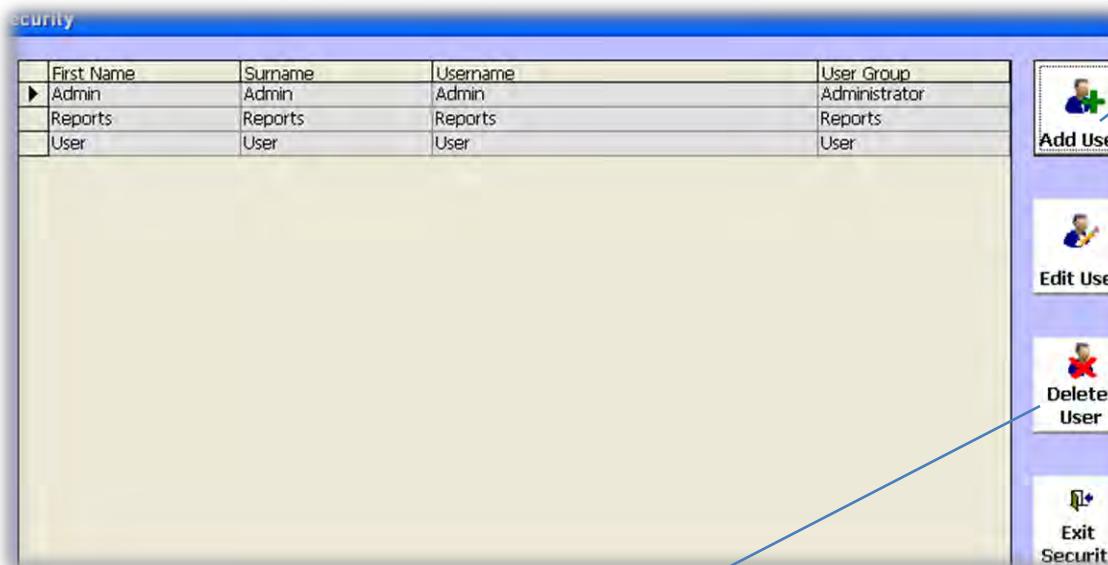
Delete a user. You delete a user from the system. Once deleted they will have no access.
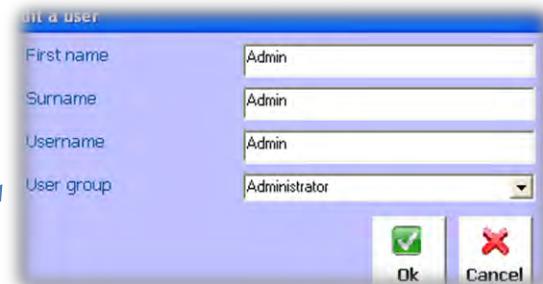
Edit a user. You can change the details for a user .

18. Audit Trail

The 'Audit Trail' can be accessed by clicking 'Audit Trial' on the 'Setting' screen which is accessed by clicking the 'Settings' button on the home screen.

The Audit Trail details the date, username and action performed. An action can be any of the following:

- User logs on and off the software – shows username
- User sets up a run. – shows run number
- Automatic downloads – shows test numbers
- User manually downloads data. – shows test numbers
- User ends tests. – shows test numbers
- When user is set-up, edited or deleted from system
- Test is changed – shows test number
- Test Ends – shows test number

The automatically generated audit trail of all sql actions can be viewed by clicking here.

The 'Audit Trial' can be printed if required.

19. Administration Reports

The 'Admin Reports' can be access by clicking 'Admin Reports' on the 'Setting' screen which is accessed by clicking the 'Settings' button on the home screen.
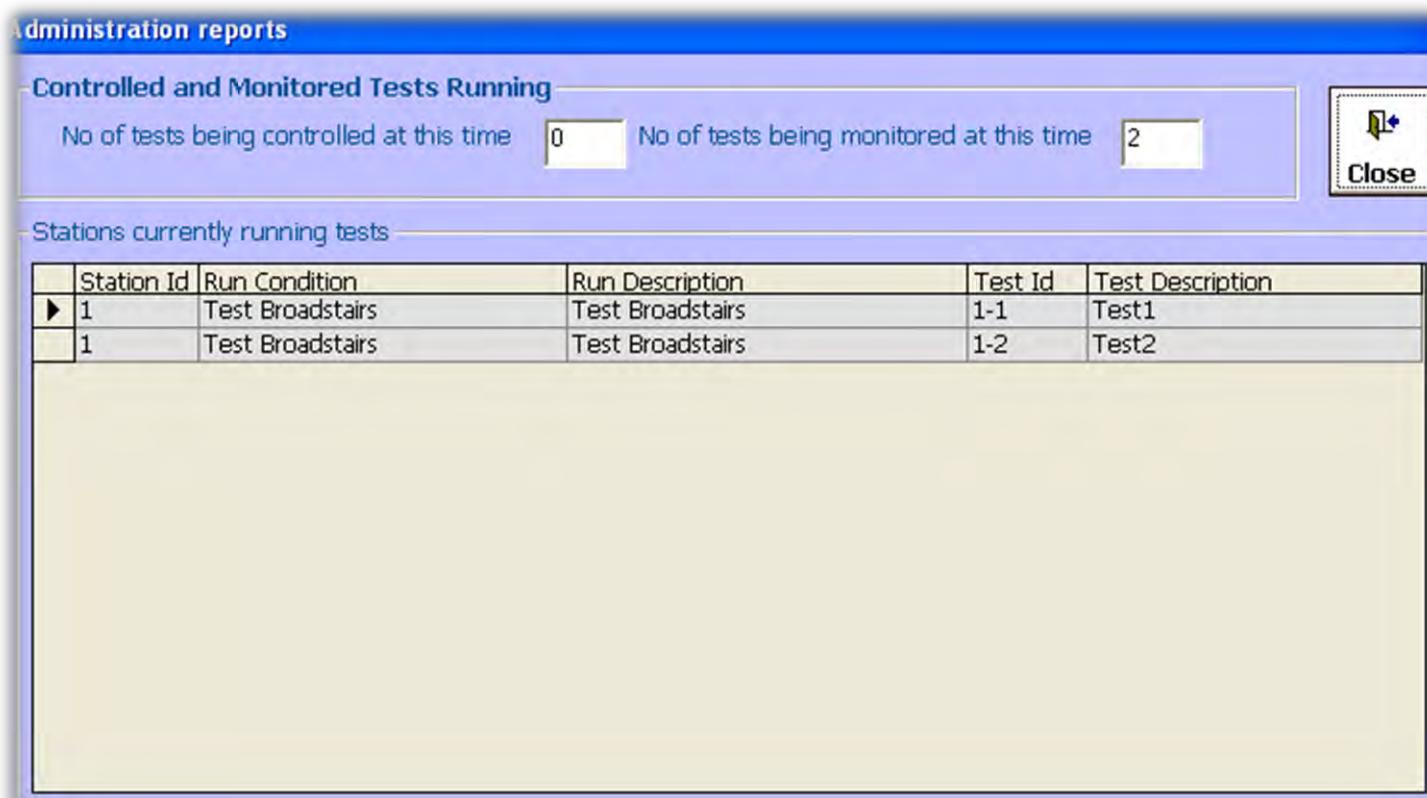
This screen details the number of tests currently being controlled and monitored on the system and provides details of active tests linked to the run conditions.

20. Logger Cap Function
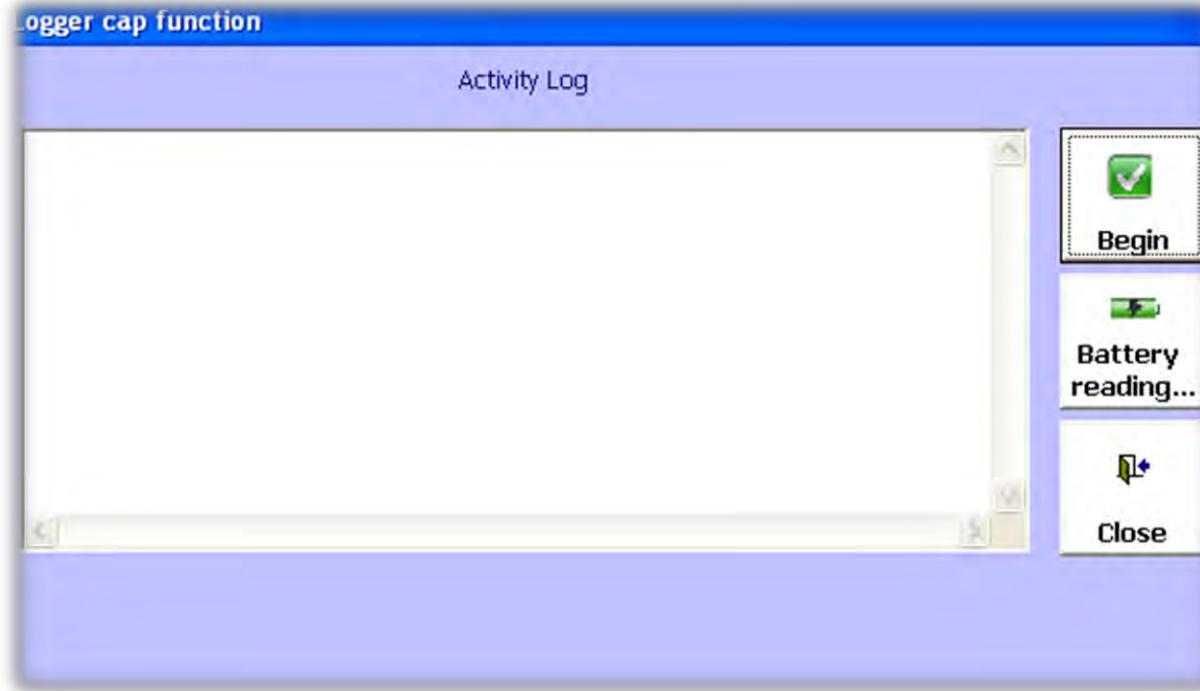
This is accessed by clicking 'logger cap' on the home screen.

Logger Cap

A logger cap must be docked on the basestation in order to use the 'Logger Cap Function'.

The following can be performed with the 'Logger Cap Function':

•Check the battery level of the docked logger cap

•Download data on a logger cap

•Reset logger cap to factory settings and ready for next test

21. Reports

Reports

All of the data collected for a test and all reports are accessed by clicking 'Reports' on the main screen. This opens the 'Reports' screen which lists all of the runs initiated. By highlighting and clicking a run the 'Summary Reports' screen is opened.

This screen contains a list of all the tests initiated as part of this run. The screen also contains two buttons called 'Run Details' and 'Test Details'. These screens provide summary details on the run and test such as limits, minimum and maximum temperature and humidity readings, averages etc.

The data collected for a test can be presented in graphical or tabulated format. Out of Specification results obtained for a test can be displayed by clicking 'Out of Specification' button on the 'Test Readings' screen.

The tabulated data can be exported by pressing the export button. The graphical and tabulated data can also be printed.

21.1. Reports

Reports

Runs - double click a run to go to the reports.................

Id	Run description	Start date	End date	Total tests	Active tests	Run condition	Rh requ...	
2	Topchem 25-60	03/07/2008 11:3	03/12/20	1	1	25 60	Yes	

View the specific details for each test in the run. Double clicking the arrow beside a test will open the table of results for the test (seen on next page).

Summary Reports

un Description Test Broadstairs   Run Details   Test Details

	Test	Test Description	Due End Date	Status	Last Download	OOS
▶	1-1	Test1	27/12/2009	Controlled	23/12/2009	Yes
	1-2	Test2	27/12/2009	Controlled	23/12/2009	Yes

Displays details for this test

Displays details for this run

Displays the graph of results

Displays a table of results

Allows printing of the screen details

Closes this screen

Graph   Table   Print   Close

21.2. Graph

The graph represents the data collected for a test.

The top of the graph details the temperature and humidity limits

Graph

| Run Description | tester123 | | Test Description | 66 |
| Test ID | 17 - 1 | Due End Date | 28/01/2010 | Run Conditions | Norwich1 |

Limits   Lower Temp ºC   20.2   Upper Temp ºC   59.8   Lower RH %   20.4   Upper RH %   73.2

Graph is displaying data from: 21/11/2009 16:17:03   To: 23/11/2009 15:22:03

From ☑ 11/12/2009 ▾   To: ☑ 11/12/2009 ▾   Filter by Date   Show All   Table   Print   Close

| From date for data filtering | To date for data filtering | Filter by chosen dates | Remove the filter | Show results table | Print the graph | Close this screen |

21.3. Run and Test Details

Mean Kinetic Temperature.

Number of readings expected since the test was initiated.

Number of readings downloaded for the test.

Number of readings expected in the database to the last download

21.4. Test Readings

Filters to display out of specification data, click again and all data shown.

Display the graph

Export the readings. The exported file is stored in the C:\amebiscsv folder on the hard disk of the laptop

Print the readings

Close this screen

Readings can be sorted by clicking the column headers

Test Readings

Field	Value
un Description	Test Broadstairs
est Description	Test1
ue End Date	27/12/2009
est ID	1-1
un Condition	Test Broadstairs
tatus	Controlled

imits

wer T ºC	20	Lower RH %	20
pper T ºC	50	Upper RH %	80

Out of Spec | Graph | Export | Print | Close

Date/Time	Temperature ºC	Relative Humidity %
23/12/2009 14:42:07	18.5	50.2
23/12/2009 14:37:07	18.4	50.1
23/12/2009 14:32:07	18.3	50.2
23/12/2009 14:27:07	18.2	50.2
23/12/2009 14:22:07	18.0	50.2
23/12/2009 14:17:07	18.0	50.2
23/12/2009 14:12:07	17.9	50.2
23/12/2009 14:07:07	17.8	50.3
23/12/2009 14:02:07	17.7	50.3
23/12/2009 13:57:07	17.7	50.3
23/12/2009 13:52:07	17.7	50.2
23/12/2009 13:47:07	17.7	50.1
23/12/2009 13:42:07	17.7	49.9
23/12/2009 13:37:07	17.8	49.9
23/12/2009 13:32:07	17.8	49.9
23/12/2009 13:27:07	17.9	50.0
23/12/2009 13:22:07	17.9	50.0
23/12/2009 13:17:07	18.0	50.0
23/12/2009 13:12:07	18.0	50.1
23/12/2009 13:07:07	18.1	50.0
23/12/2009 13:02:07	18.1	49.9
23/12/2009 12:57:07	18.1	49.8
23/12/2009 12:52:07	18.1	49.8
23/12/2009 12:47:07	18.1	50.1

22. Logon/Off Quit

To use the Amebis Control Software except for the 'Reports' functionality requires the user to log on. The first time a user logs on will require input and confirmation of a password.

Subsequently you will be asked to enter your Username and Password to access Amebis Control Software. During logging on you may change your password. Amebis Control Software automatically logs out after 30 minutes unless cancelled. All automatic functions can continue without being logged on.

23. Glossary of Terms

STS – Amebis Stability Test System
An Amebis product used to provide controlled environments for use in pharmaceutical stability studies. The product will provide a means by which the temperature and humidity in those environments can be monitored, collected, stored and transferred to a PC interface where the data can be retrieved and viewed.

MMS – Amebis Monitoring & Mapping System
A product that will be incorporated into the STS used to monitor and map environments of interest to the pharmaceutical and other life science industries.

Test
An individual unit that is initiated on the Amebis Control Software. For stability studies a unit will have a sample of the product contained within a test chamber connected to the sensor cap with an activated attached logger cap. For Monitoring and Mapping there will be no attached test chamber. If the Amebis Control Software is used as a diary for Stability Studies only then there won't be an activated logger cap attached to the test.

Run
A number of tests set up for incubation at the same environmental conditions and with the same limits on these environmental conditions.

Session
The time monitored by a run.

Run time
The time period for which an individual test's run is controlled i.e. readings are collected and compared to limits if set.

Controlled Status
A test is said to have a controlled status during the period of its run time. During the run time the data collected by the test is compared to limits if set and can be automatically downloaded via a designated remote station.

Monitoring Status
A test is said to have a monitoring status when its run time has expired. The data collected by a test with a monitoring status is not compared to limits and can only be downloaded by manual remote or direct commands at the basestation.

Download
The retrieval of data collected by the logger cap to the system database.

Remote download
A download operation in which the retrieval of data is performed from an undocked logger cap through radio frequency commands.

Automatic download
A remote download that is performed by the STS system at intervals set by the user.

Manual download
A remote download that is performed by a direct command to the system by the user.

Direct download
A download operation that involves direct connection of the logger cap to the system's basestation.

Run Condition
Target environmental conditions for a test during a run. Will also include limits on the environmental conditions and a text title for the Run Condition.

Sensor Cap
A cap, which incorporates a humidity and temperature sensor and the associated electronics that allows the environment to be monitored.

Logger cap

A device that connects to the sensor cap and collects and stores the temperature and humidity readings taken by the sensor in the sensor cap. This data is transmitted via radio frequency to the remote station or basestation components of the system from where it is transferred to the interface software. The logger cap also accepts the session settings and commands that are inputted at the interface software.

Remote station

A device that is placed in the temperature cabinets or other location where the test units are held. The remote station wirelessly communicates with the logger caps and transmits the data and information sent to it by the PC via the basestation.

Basestation

A device that is hardwire connected to the remote station and the PC on which the system's interface software is held. The basestation communicates settings that are entered into the software by the user to the logger caps and accepts the data collected by the logger cap that is transferred from the remote stations. The basestation can also accept data from logger caps without the remote stations either remotely by radio frequency or directly by connecting the logger cap to a d-sub connection on its upper surface.

Run ID

Unique number provided by database to every run which is successfully initiated.

Test ID

Unique number provided by database to every test which is successfully initiated. The first part of the number is made up of the run ID followed by a dash and two digits representing the test within the run i.e. 054-03.

Station ID

Number on every remote station and basestation which is used to communicate with logger caps associated with run conditions linked to the remote station or basestation.