

Operating Instructions

Fully-auto chemiluminescence immunoassay analyzer

Maglumi 600/800

Chapter 16

Host Result Management

16.1 Host Result Management in Overview				
16.2 Host Setup in MAGLUMI [®] software				
16.2.1 ASTM Setup dialog 16.2.2 Online icons in the MAGLUMI [®] software	2 3			
16.3 Types of possible Host Connections in MAGLUMI [®] software	4			
16.3.1 Host Query 16.3.2 How To send results to the LIS	4 5			
16.4 MAGLUMI [®] software communication format	7			
16.4.1 Inquiry Reagent Information	8			
16.4.3 Senaing test results				

16.1 Host Result Management in Overview

In this chapter, we describe the different types of HOST (also called LIS) setup and how each setup affects the processing of results. This information is only given from a user standpoint. Details about special settings or configuration of the HOST connection are located in documents external from this manual.

The MAGLUMI[®] system can be set up to communicate with the Laboratory Information System (LIS) in different configurations.

NOTE

LIS = Laboratory Information System: is a system used for computerized management of labs dedicated to chemical-clinical or microbiological analysis. This is not a feature of the MAGLUMI® software. The LIS is an external program used in most clinical institutions for centralized information processing.



The host program is not Part of the MAGLUMI® Diagnostic System. Therefore, SNIBE Co., Ltd. cannot guarantee for the safe cooperation of the MAGLUMI® software and the host software. There exist no warrantee by SNIBE Co., Ltd. Against data safety corruption by the host program.



Configuration changes for the LIS are to be accomplished only by trained authorized personnel for the MAGLUMI[®] system



For maintaining safety of the diagnostic results, it is necessary to accomplish a complete qualification test for the host connection by the user.

16.2 Host Setup in MAGLUMI® software

There are several host options in the MAGLUMI[®] software. This section describes the different access possibilities. These definitions will be needed later in this chapter.

16.2.1 ASTM Setup dialog

When the MAGLUMI $^{\otimes}$ is Host connected, certain settings must be done from the main program, using the ASTM Setup Dialog present in **<System> <Online>** (Fig.16.2-1).

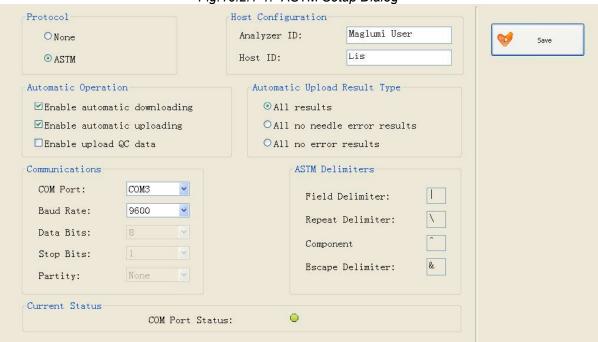


Fig.16.2.1-1: "ASTM Setup Dialog"

Analyzer ID	This field allows assigning a unique Analyzer ID to the MAGLUMI [®] .
Host ID	This field allows assigning a specific name to the host (required).
COM Port	This field specifies the serial port of the MAGLUMI [®] PC used for host communication. Host can be connected to any <u>free</u> CON port, except for COM1, which is used for the connection to the Analyzer.
Baud Rate	Specifies the Baud Rate used for transmissions between MAGLUMI [®] and the host any values from 4800 to 19200 can be chosen. MAGLUMI [®] and Host have to have matching Baud Rate speeds.
Delimiters	These fields specify the set of delimiters used for transmissions Modification is not recommended.

16.2.2 Online icons in the MAGLUMI® software

Online icons can be found in the MAGLUMI® software.

This icon can be used to upload results in [Journal] and [Valid].

16.3 Types of possible Host Connections in MAGLUMI® software

Major types of transmission between the Host and MAGLUMI[®] are the following:

Host Query

All downloading data transferred from LIS to the MAGLUMI® system PC are accomplished automatically when the samples are loaded.

In addition to this type of communication, there are many variables that are available. These will be described in user detail in this chapter.

16.3.1 Host Query

When samples are loaded on the MAGLUMI[®] and after closing the flap or within a certain period of time (approximately <1 minute), the MAGLUMI[®] automatically sends a query to the Host and the LIS responds with the job list associated to those loaded samples.

Although the Host Query has many types of possible settings, the automatic reception of the job list remains the same.

NOTE

In this configuration it is also possible to request a Query All by pressing the <Online> icon (download) from the [Report].

16.3.1.1 How to accept job lists from the LIS using Host Query

- 1. Load the barcode-labeled patient samples in accordance with chapter 15.
- 2. Wait for the job list to appear in the patient sample dialog.
- 3. Repeat steps 1 and 2 until all patient racks have been loaded.



Patient racks may not be loaded too fast. It must be ensured that the HOST allows enough time to pass between individual requests (timeout) so that the system can be kept in operation. Failure to comply with the above instructions could result in the loss of patient data.

Valid

16.3.2 How To send results to the LIS

Once the patient samples have been run and results are present, the user can send results to the Host as follows:

16.3.2.1 Results transmitted with validation on MAGLUMI® as manually sending of results

The results will be validated on the analyzer, and will be sent to the host manually from the **[Valid]**.

In this configuration, the **<Valid>** icon is used in the **[Report]** and all results that have been selected will be transferred to the **[Valid]**. The selected data will be deleted from the **[Journal]**.

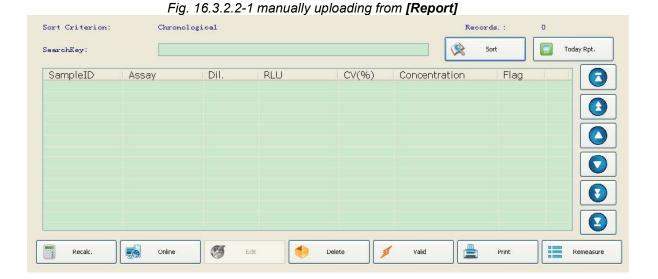
In the [Valid] the user must press the <Online> icon

(Uploading) to send all results to the Host. The transfer is completed when the status reads [Finished].

16.3.2.2 Results transmitted without validation on MAGLUMI® as manually sending of results

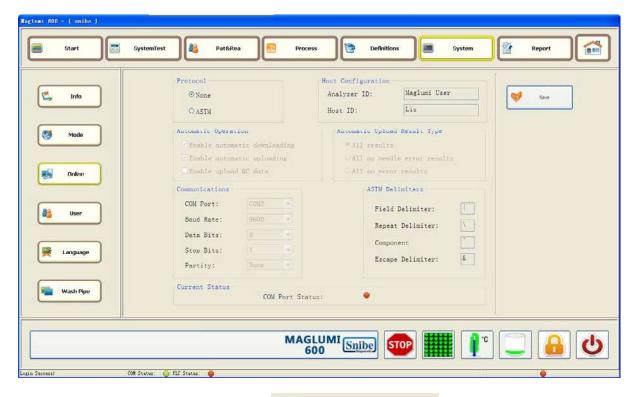
The results can not be validated on the analyzer but will instead be sent to the host manually for their validations. In this configuration,

an **<Online>** icon (Uploading) appears in the **[Journal]** (as pictured in *fig. 16.3.2-1 manually uploading from* **[Report]**).



16.3.2.3 Results transmitted without validation on MAGLUMI® as an automatic sending of results

The results can not be validated on the analyzer but will instead be sent to the host automatically for their validations.



Click the to mark a "\sqrt{" on this option to enable automatic uploading test results without validation.

If the user enable automatic uploading, there are 3 options for it:

[All results]

automatic uploading all results anyway, including those with flag of machine error, pipetting error, etc.

[All no needle error results]

automatic uploading all results, except those with flag of needle error.

[All no error results]

automatic uploading all results, except those with flag of machine error

Check the results on the Host, if any results are not transmitted correctly, manually transfer them again according to chapter **16.3.3.2**

16.4 MAGLUMI® software communication format

MAGLUMI[®] software use ASTM E1394 protocol for communication. Directory \online\log records all the communications between the software and LIS.

The content of the communication between MAGLUMI[®] software and LIS is as following:

16.4.1 Inquiry Reagent Information

Once the sample rack is inserted in to the sample area, after the barcode reader reads the barcode labeled on the sample tube, MAGLUMI® software will inquiry the LIS host for the assay need to be performed for the sample.

Communication content:

```
--><ENQ>
<--<ACK>
--><STX>
<--<ACK>
-->H\^&||PSWD|Maglumi 600||||Lis||P|E1394-97|20100323<CR>
Q|1|^1234567||ALL||||||||O<CR>
L|1|N<CR>
<--<ACK>
--><ETX>
<--<ACK>
--><EOT>
<--<ACK>
```

Symbol meaning:

Letter	means	ASCII
>	send	
<	receive	
<enq></enq>	enquiry	0x05
<ack></ack>	answer confirm	0x06
<stx></stx>	text start	0x02
<etx></etx>	text ends	0x03
<cr></cr>	home	0x0D
<eot></eot>	transmitting end	0x04

Here:

```
H|\^&||PSWD|Maglumi 600||||Lis||P|E1394-97|20100323<CR>
Q|1|^1234567||ALL||||||||O<CR>
L|1|N<CR>
```

This is a message which ASTM E1397 enquiry the assay needs to be performed for the sample. Here we take sample ID 1234567 for example.

16.4.2 LIS return the assay information

```
<--<ENQ>
-><ACK>
<--<STX>
--><ACK>
<--H|\^&||PSWD|Maglumi 600||||Lis||P|E1394-97|20100319<CR>
P|1<CR>
O|1|1234567||^^^CA125|R<CR>
O|2|1234567||^^^CA153|R<CR>
O|3|1234567||^^^CYFRA211|R<CR>
O|4|1234567||^^^FT3|R<CR>
O|5|1234567||^^^FT4|R<CR>
O|6|1234567||^^^T3|R<CR>
O|7|1234567||^^^TG|R<CR>
O|8|1234567||^^^TGA|R<CR>
L|1|N<CR>
--><ACK>
<--<ETX>
--><ACK>
<--<EOT>
-><ACK>
```

Letter meaning as the above

Here:

```
H|\^&||PSWD|Maglumi 600||||Lis||P|E1394-97|20100319<CR>
P|1<CR>
O|1|1234567||^^^CA125|R<CR>
O|2|1234567||^^^CA153|R<CR>
O|3|1234567||^^^CYFRA211|R<CR>
O|4|1234567||^^^FT3|R<CR>
O|5|1234567||^^^FT4|R<CR>
O|6|1234567||^^^T3|R<CR>
O|7|1234567||^^^TG|R<CR>
O|8|1234567||^^^TG|R<CR>
O|8|1234567||^^^TGA|R<CR>
L|1|N<CR>
```

This is a message which is returned by ASTM E1394 LIS includes the relative assay need to be performed for the sample. Here sample ID 1234567 will be performed assay: CA125, CA153, CYFRA211, FT3, FT4, T3, TG and TGA.

16.4.3 Sending test results

```
--><ENQ>
<--<ACK>
--><STX>
<--<ACK>
-->H\^&||PSWD|Maglumi 600||||Lis||P|E1394-97|20100326<CR>
P|1<CR>
O|1|1234567||^^^CYFRA211<CR>
R|1|^^^CYFRA211|0||0 to 7|N|||||20100326172956<CR>
L|1|N<CR>
<--<ACK>
--><ETX>
<--<ACK>
--><EOT>
<--<ACK>
```

Letter meaning as above,

Here:

```
H|\^&||PSWD|Maglumi 600||||Lis||P|E1394-97|20100326<CR>
P|1<CR>
O|1|1234567||^^^CYFRA211<CR>
R|1|^^^CYFRA211|0||0 to 7|N|||||20100326172956<CR>
L|1|N<CR>
```

This is a message which ASTM E1394 sending the test results to LIS. Here sample ID 1234567 performed assay CYFRA211 test result is sent to LIS.

Chapter 17 Quality Control

Chapter 17

Quality Control

17.1	Quality	Control in	overview	 2
	Quality		OVCIVICIO	_