

# HITACHI

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## Data Management Multilanguage Software

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for the CLA-1™ Luminometer  
Version 2.5

# User Manual



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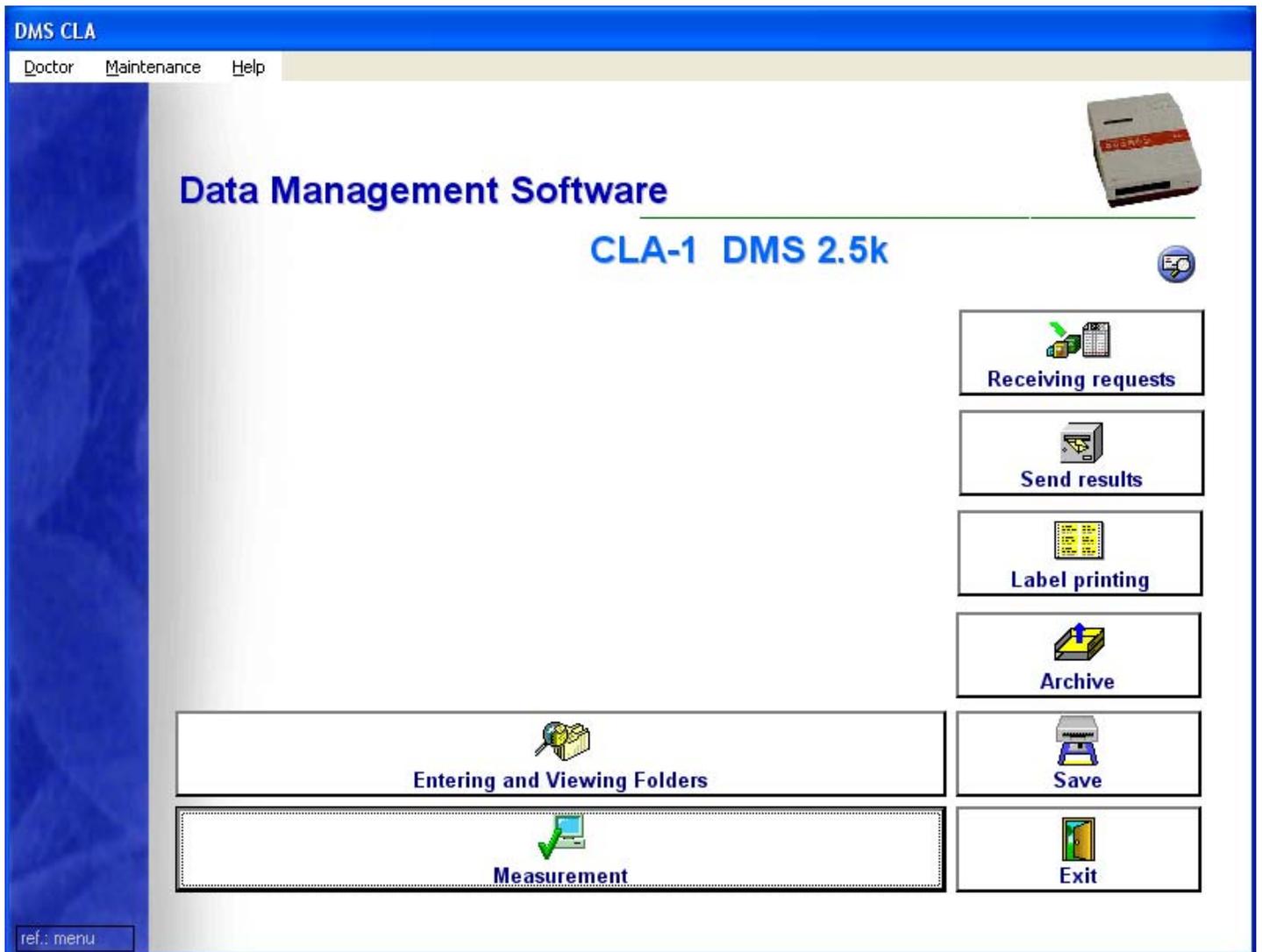
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# Data Management Software for the CLA-1™ Luminometer



**Main Menu**

## Label printing

Button on the main menu:



Printing Barcode Labels

### Labels of folders to be measured

Number of folders:18

Look for #:

Look for name :

Read serum tubes n°:

Accession number	Name	Type	Status
1101069401I4		CLA Atopy	To be meas
1101071601I4		CLA Atopy	To be meas
1101113601L1		CLA Atopy	To be meas
1101183701N1		CLA Inhala	To be meas
1101232101L1		R CLA Atopy	To be meas
1101232501N1		CLA Inhala	To be meas
1101242101I4		CLA Atopy	To be meas
1101242301I4		CLA Atopy	To be meas
1101279801L1		CLA Atopy	To be meas
1130253301I4		U CLA Atopy	To be meas
1130266201I4		CLA Atopy	To be meas
1130271901L1		CLA Atopy	To be meas
1130293101L1		CLA Atopy	To be meas
1130294201I4		CLA Atopy	To be meas
1130302801I4		CLA Atopy	To be meas
1130323101N1		CLA Inhala	To be meas

A4 labels, print from line n°:

 **Print selected folders.....**  **Print only one folder**

 **Print all folders to be processed** 

ref.: FrmEtq

->Start with n°:  Select the line and click on F2

Only patient accession numbers to be measured are displayed here.

Pette bar code labels can be used when starting measurements. The characters on the bar code label include the patient accession number and the type of pette panel to be measured.

Patient accession numbers are sorted in sequential order by the DMS application.

There are three ways for printing pette bar code labels:

- Select specific patient numbers by using the bar code reader (read bar code labels on patient serum tubes then, Print selected folders.)
- Print a single label (Print only one folder)
- Print all labels (Print all folders to be processed).

A line number can be used to specify printing on a specific line of the label sheet (for economy, where label sheets are already started).

## Entering and Viewing Folders

Button on the main menu:



This module displays all folders stored in the database (to be measured, measured, archived).

**Folders**

Display folders :

- To be measured
- Measured
- Archived

Look for :

by patient accession#:

by patient name:

Print all reports: tick the box and click here ----->

Buttons: New, Delete, Modify, Print, View result, Export, Close

Accession #	First Name	Last Name	Measurement date	Panel	Status	Doctors
9796B4			09/03/2004	CLA.DP	Done	
9796B4			09/03/2004	CLA.DP	Done	
9794Y3			09/03/2004	Hungarian Inhalant I	Done	
9793Z3			09/03/2004	CLA-TOP	Done	
1130230401N1	C		11/03/2004	Universal Panel 20	Done	
12345654G1	D			Childrens Atopic	Done	
1129467701L1	P		11/03/2004	CLA Atopy 20	Done	
44422211	T		13/02/2004	Childrens Atopic	Done	
111888J2	T		09/03/2004	IgG Panel 36	Done	
666644J2	T		09/03/2004	IgG Panel 36	Done	
777555H4	T		09/03/2004	CLA Atopy 20 L	Done	
888222Y1	T		09/03/2004	Extended Food	Done	
666111J2	T		13/02/2004	IgG Panel 36	Done	
445566I1	T		09/03/2004	Childrens Atopic	Done	
556644I1	T		13/02/2004	Childrens Atopic	Done	
446655E1	T		09/03/2004	Brasil General	Done	
887799E1	T		13/02/2004	Brasil General	Done	
24567892E1	T			Brasil General	Done	12345
101010Z3	T		09/03/2004	CLA-TOP	Done	
101010Y1	T		13/02/2004	Extended Food	Done	
101010I1	T		13/02/2004	Childrens Atopic	Done	

ref.: Da\_tab

The selector below displays folders depending on status (to be measured, measured or archived):

Display folders :

- To be measured
- Measured
- Archived



The "New" button allows the operator to create a new patient to measure. See next page.

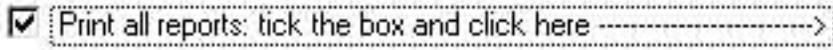
Look for :

by patient number:

by patient name:

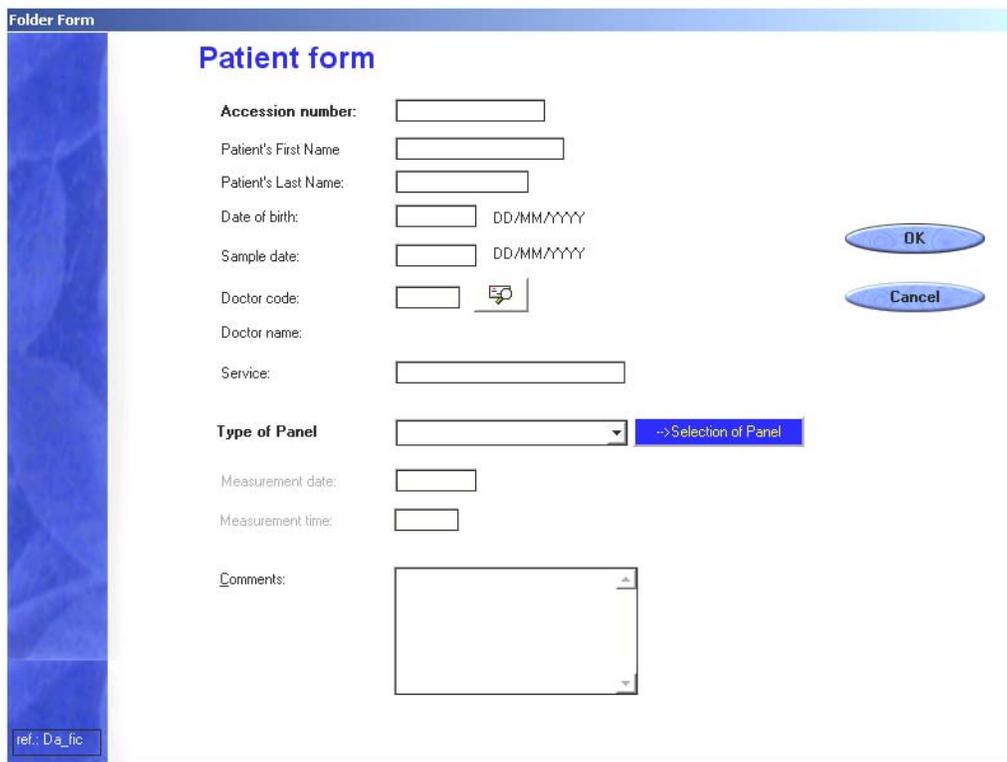
Search command (by patient number or patient name).

Print all results:



After measurements, this command allows the operator to print all results of the day.

To add patient folders to be measured manually, click on the “New” button of the previous screen display:



The operator has to input data manually (through keyboard). Only the patient accession number, and pette type are required fields.

Patient numbers can include letters, digits, special characters like: - (dash character), or \_ (underscore character).

It is recommended that the **Space** character, \* (star), / (slash), and \ (backslash) are not used in the patient number format.



## Display an Analysis Report

Button from the main menu: Select “Entering and Viewing Folders”



On the Display folders: select the “Measured” option:



The button “View Result” is accessible only for “Measured” and “Archived” folders.

Select a patient and click on “View Result.” The following results are displayed:

Analysis Report			
		LU	Class
P	Positive Procedural Control	>300	PASS
N	Blanking Control	8	PASS
1	Acacia	0	0
2	Ash, White	0	0
3	Beech	0	0
4	BirchAlderMx	0	0
5	BoxElder,Mpl	1	0
6	Cedar, Mtn	6	0
7	Cottnwd,East	6	0
8	Elm, White	2	0
9	Meiалеuca	1	0
10	Mulberry Mix	0	0
11	Oak, White	10	0
12	Pine Mix	>300	4
13	Privet	>300	4
14	Sycamore, Am	56	1
15	Wint/Hck/Pcn	4	0
16	Bahia Grass	2	0
17	BermudaGrass	1	0
18	Cocklebur	12	0/1
19	Eng Plantain	0	0
20	Lamb's Qtrs	0	0
21	MarshldrMix	1	0
22	Pigweed	10	0
23	Ragwd, Short	7	0
24	Sheep Sorrel	4	0
25	TimothyGrass	15	0/1
26	Waterhemp	12	0/1
27	Cat	5	0
28	Dog	19	0/1
29	CockroachMix	11	0
30	Housedust	17	0/1
31	Mite,faeinae	10	0
32	Alternaria	6	0
33	Aspergillus	4	0
34	Candida	1	0
35	Cladosporium	6	0
36	Penicillium	0	0

**SE Inhalant 81407**

Accession number:  
006-6--H3

Patient's name:  
[Empty field]

Measurement date:  
10/08/2003

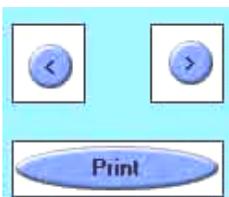
Class : Lumens  
 4 Very High ..... > to 243  
 3 High ..... 143 to 242  
 2 Moderate ..... 66 to 142  
 1 Low ..... 27 to 65  
 0/1 very low ..... 12 to 26  
 0 Undetectable < to 11

[Left Arrow] [Right Arrow]

[Print]

[Image Icon]

ref.: Results



Arrow keys: Allows the previous or next patient Analysis Report to be displayed.

Send to the printer.

## Measurement

Before measuring, be sure Luminometer(s) are configured correctly. Refer to the DMS 2.5 Installation Guide and the CLA-1 manual.

Button on the main menu: Select “Measurement”

A screenshot of the "Measurement" software interface. The window title is "Measurement". The main heading is "Folders to be processed". Below this, there are three lines of instructions: "1. Test the communication (inactivate printer)", "2. Enter your accession numbers and check them", and "3. Click on Start". The interface features four columns of input fields, each headed by a "Luminometer" button (Luminometer 1, 2, 3, and 4). Each column has five numbered input fields (1-5). Below the input fields are four buttons: "Testing comm.", "Check n\*", "Start", and "Close". At the bottom, there is a "Delete above selections" button with a trash can icon, followed by four empty text input fields. The bottom left corner of the window shows "ref.: Mes\_tab".

1 – Click and place the cursor into the first field under the “*Luminometer 1*” button. **Note: Up to four luminometers can be installed with DMS 2.5 full version.**

2 – The bar code reader can be used to read the bar code labels on the back of the pettes. The patient accession number can also be entered through the keyboard or by clicking on the “Luminometer” button (see next page). **Note: Select luminometers and measurement positions sequentially, do NOT randomized or operational errors may result.**

3 – Verify that all patient numbers are in the work list by clicking on the “Check N<sup>o</sup>” button.

4 – Test RS232 communication between the PC and luminometers, before measuring. Click on the « Testing comm. » button and follow instructions displayed on the TESTCOM windows to disable the Luminometer printers.

5 – To start measuring, the Luminometer printer must be disabled, then click on “Start” button. The Luminometer’s doors will open automatically. Insert your rack and then press on “OK” on the message “Insert a rack into luminometer x.” **Note: Do not press any buttons on the Luminometer(s) while measuring; allow the DMS application to control the CLA-1 luminometer.**

## Patient selection:

You can also manually select the patients to be measured. For each Luminometer, click on selected “Luminometer” button to display all patients to be measured on the “Folders to be measured” window:

Accession number	Name	Type	Status
1101069401I4		CLA Atopy	To be measu
1101071601I4		CLA Atopy	To be measu
1101113601L1		CLA Atopy	To be measu
1101183701N1		CLA Inhala	To be measu
1101232101L1		CLA Atopy	To be measu
1101232501N1		CLA Inhala	To be measu
1101242101I4		CLA Atopy	To be measu
1101242301I4		CLA Atopy	To be measu
1101279801L1		CLA Atopy	To be measu
1130253301I4		CLA Atopy	To be measu
1130266201I4		CLA Atopy	To be measu
1130271901L1		CLA Atopy	To be measu
1130293101L1		CLA Atopy	To be measu
1130294201I4		CLA Atopy	To be measu
1130302801I4		CLA Atopy	To be measu
1130323101N1		CLA Inhala	To be measu
1130370701N1		CLA Inhala	To be measu
1130426101N1		CLA Inhala	To be measu

Select a maximum of 5 patients sequentially with the left button of the mouse or select different patients by keeping the “Ctrl” key pressed and clicking the left button of the mouse on the patients you wish to measure. Then click on “Select line and click here” button.

Selected patients are displayed in the list “Folders selected”. Press on “OK” to validate your selection. Selected patients are now displayed in their respective positions:

When the measurements are finished, the software will request if the operator wants to see the measured results, in order to verify that the "Positive Control" is correct.

A warning message indicates to the operator if the positive control is incorrect (less than 243 LU). A warning message indicates to the operator if the negative control is incorrect (greater than 33 LU) or greater than 69 LU for OPTIGEN®.

If a low positive control is encountered, the patient panels must be re-measured.

Analysis Report		
	LU	Class
P Positive Procedural Control	>300	PASS
N Blanking Control	8	PASS
1 Acacia	0	0
2 Ash, White	0	0
3 Beech	0	0
4 BirchAlderMx	0	0
5 BoxElder,Mpl	1	0
6 Cedar, Mtn	6	0
7 Cottnwd,East	6	0
8 Elm, White	2	0
9 Melaleuca	1	0
10 Mulberry Mix	0	0
11 Oak, White	10	0
12 Pine Mix	>300	4
13 Privet	>300	4
14 Sycamore, Am	56	1
15 Wlnt,Hck,Pcn	4	0
16 Bahia Grass	2	0
17 BermudaGrass	1	0
18 Cocklebur	12	0/1
19 Eng Plantain	0	0
20 Lamb's Qtrs	0	0
21 MarsheldrMix	1	0
22 Pigweed	10	0
23 Ragwd, Short	7	0
24 Sheep Sorrel	4	0
25 TimothyGrass	15	0/1
26 Waterhemp	12	0/1
27 Cat	5	0
28 Dog	19	0/1
29 CockroachMix	11	0
30 Housedust	17	0/1
31 Mite,faerinae	10	0
32 Alternaria	6	0
33 Aspergillus	4	0
34 Candida	1	0
35 Cladosporium	6	0
36 Penicillium	0	0

**SE Inhalant 81407**

Accession number:

Patient's name:

Measurement date:

Class : Lumens  
 4 Very High ..... > to 243  
 3 High ..... 143 to 242  
 2 Moderate ..... 66 to 142  
 1 Low ..... 27 to 65  
 0/1 very low ..... 12 to 26  
 0 Undetectable < to 11

ref.: Results

Note: There is not an « equivocal » class (12-26 lumens) for the panel « Universal Panel 20 ».

Press on the "EXIT" button to view the next result.

## How To “Send results” To LIS or Network

Button on the main menu: Select “Send results”



Patient folders are sent to the host computer by using a shared directory on the network.



The access path and the filename of the result file are defined in the maintenance menu (see “System configuration” page 15). **Note: Result files are overwritten each time a new file is sent to the LIS or Network destination.**

Results are recorded in an ASCII text file format.

Patient folders are automatically archived.

## How To “Receive requests” From LIS or Network

Button on the main menu:



By clicking on this button, the software will open and read the work list sent by the Host computer.



The access path and the filename of the work list file sent by the LIS or Network are defined in the maintenance menu (see “System configuration” page 15).

## Archive

Patient folders can be also archived manually, when results do not have to be sent to the LIS or Network destination (see example below).



Archiving Folders

**Folders to be archived** Look for # :

Accession number	Name	Type	Status
12345654G1		Childrens	Measured
24567892E1		Brasil Gen	Measured
00001Z3		CLA-TOP	Measured
111888J2		IgG Panel	Measured
444222I1		Childrens	Measured
666111J2		IgG Panel	Measured
888222Y1		Extended F	Measured
445566I1		Childrens	Measured
556644I1		Childrens	Measured
446655E1		Brasil Gen	Measured
887799E1		Brasil Gen	Measured
777555H4		CLA Atopy	Measured
6666444J2		IgG Panel	Measured
0002Y3		Hungarian	Measured
0003B4		CLA. DP	Measured
656565Z3		CLA-TOP	Measured
988998Y3		Hungarian	Measured
9898981B4		CLA. DP	Measured
101010Z3		CLA-TOP	Measured
121212B4		CLA. DP	Measured
101010Y1		Extended F	Measured
101010I1		Childrens	Measured
131313Y3		Hungarian	Measured
9797Y3		Hungarian	Measured
9796B4		CLA. DP	Measured
9795B4		CLA. DP	Measured

Archive selected folders

Archive all folders

ref.: Arch\_tab

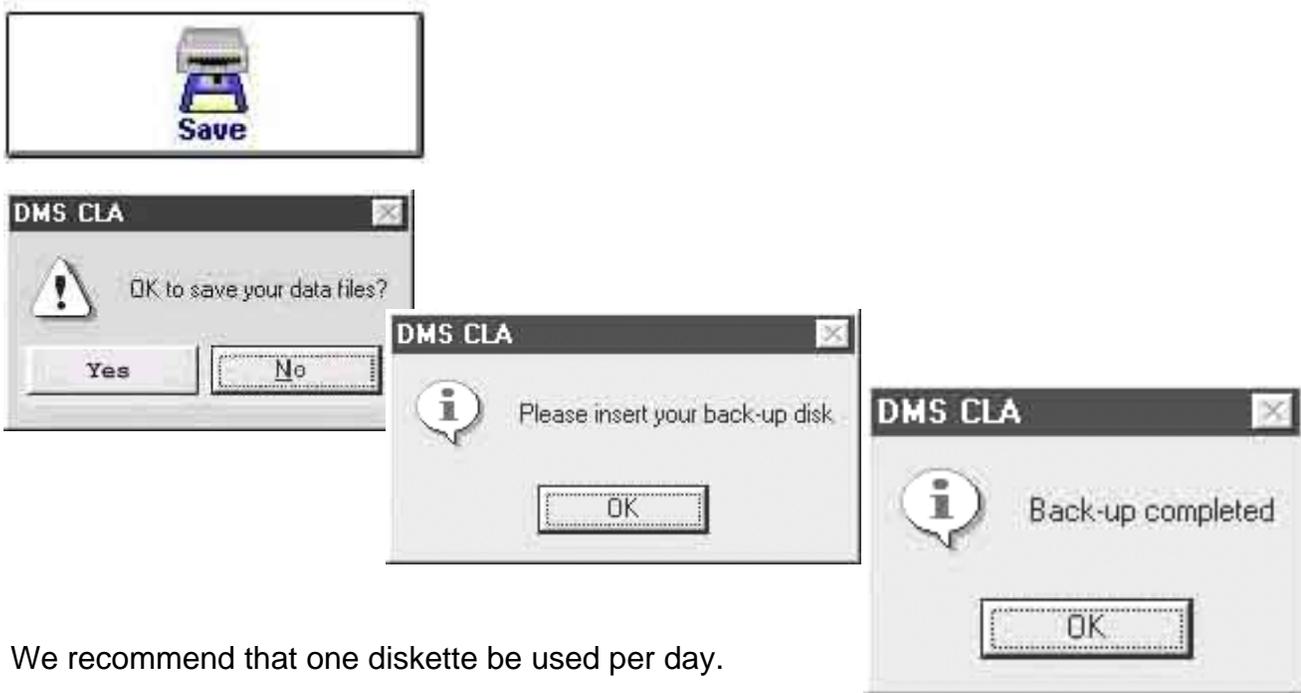
Archive all patients by clicking on the button "Archive all folders" or select some patients by maintaining the "Ctrl" key pressed and click with the left button of the mouse on patients you wish to archive then click on the button "Archive selected folders".

## Saving Data

To avoid problems, we recommend data to be saved:

- 1 – after reception of the work list from the LIS or Network.
- 2 – after measurements.

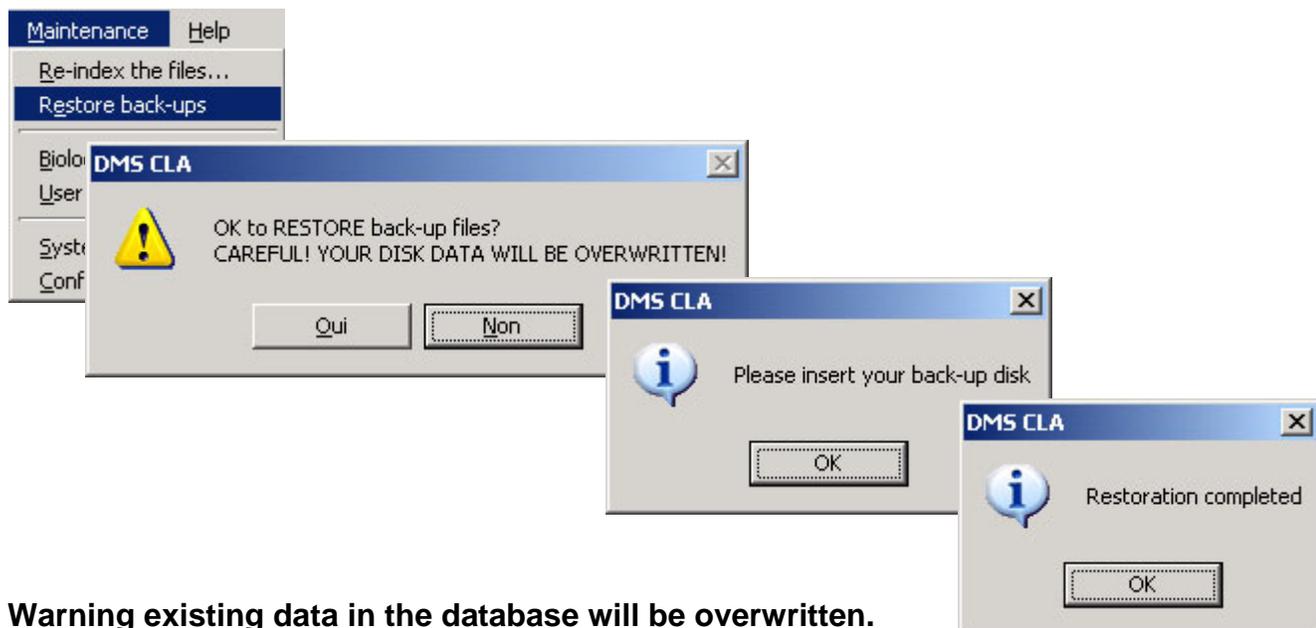
Click on the “Save” button and follow instructions.



We recommend that one diskette be used per day.

## Restoring Data

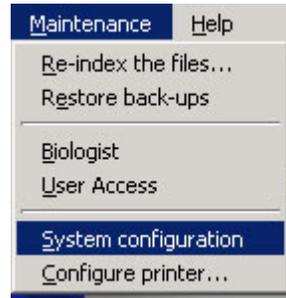
This option enables data to be restored from a floppy disk. Follow instructions.



**Warning existing data in the database will be overwritten.**

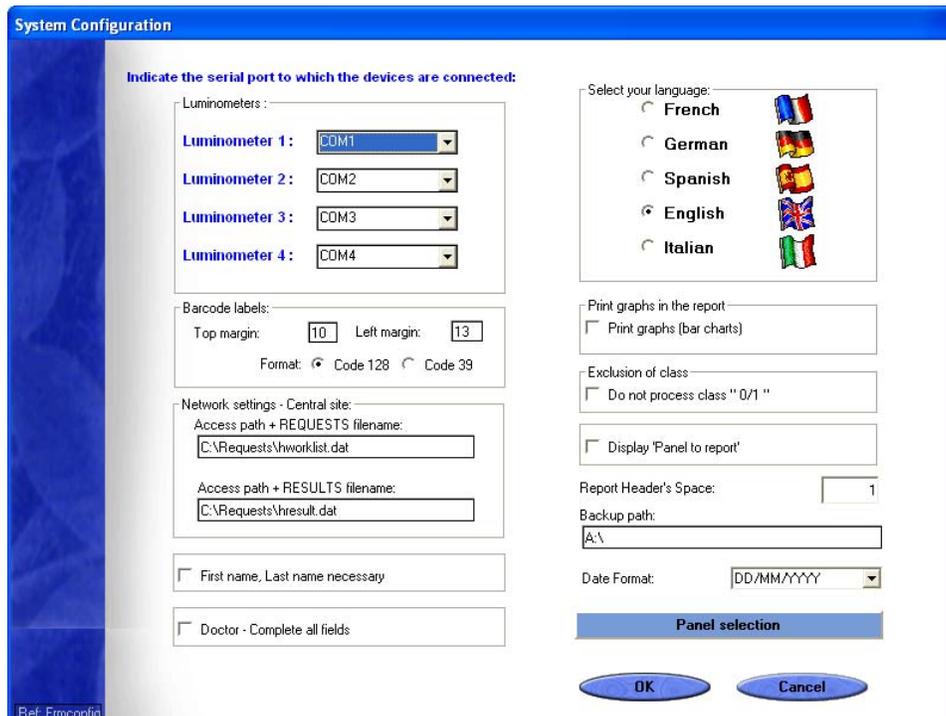
## System Configuration

From the main menu:



Configuration of the system:

- Specify how many Luminometers are used and on which serial ports they are connected,
- Specify the software language (French, German, Spanish, English or Italian),
- Specify if horizontal histograms must be printed on result report.
- Specify if the class « 0/1 » 12-26 lumens must be performed. (Not available with Universal Panel 20)
- If LIS (i.e. LIS or Network) connection is installed, specify the network paths for reading the working list (Request filename) and storing results (Results filename). Validate your selection by clicking on “OK” button
- Specify the Date format (“DD/MM/YYYY”, “MM/DD/YYYY”).
- Specify the option “First name, last name necessary” if required when creating or modifying folder.
- Specify the option “Doctor – complete all fields”, if all fields should be given when creating or modifying any doctor file.

A screenshot of the 'System Configuration' dialog box. The dialog has a blue title bar and a light blue background. It is divided into several sections:

- Indicate the serial port to which the devices are connected:** This section contains four dropdown menus labeled 'Luminometer 1' through 'Luminometer 4', each with 'COM1' through 'COM4' selected.
- Barcode labels:** This section has two input fields for 'Top margin' (value 10) and 'Left margin' (value 13). Below them is a 'Format' section with radio buttons for 'Code 128' (selected) and 'Code 39'.
- Network settings - Central site:** This section has two text input fields: 'Access path + REQUESTS filename:' with the value 'C:\Requests\hworklist.dat' and 'Access path + RESULTS filename:' with the value 'C:\Requests\hresult.dat'.
- Below the network settings are two checkboxes: 'First name, Last name necessary' and 'Doctor - Complete all fields', both of which are currently unchecked.
- Select your language:** This section has radio buttons for 'French', 'German', 'Spanish', 'English' (selected), and 'Italian'. Each radio button is accompanied by a small flag icon.
- Print graphs in the report:** This section has a checkbox for 'Print graphs (bar charts)' which is unchecked.
- Exclusion of class:** This section has a checkbox for 'Do not process class " 0/1 "' which is unchecked.
- Display 'Panel to report':** This section has a checkbox which is unchecked.
- Report Header's Space:** This section has a small input field with the value '1'.
- Backup path:** This section has a text input field with the value 'A:\'.
- Date Format:** This section has a dropdown menu with 'DD/MM/YYYY' selected.
- At the bottom of the dialog is a 'Panel selection' button, and below that are 'OK' and 'Cancel' buttons.

## Panel Selection

In the previous screen display (ref. FrmConfig) the “Panel selection” button allows access to the control panel in which you can activate or deactivate panels.

In the column “Used”, indicate “Yes” or “No”. Only activated panels will appear on the Patient form (ref Da\_fic).

**Panel selection**

**Panel selection**

Date of last modification (mm/dd/yyyy): **04/19/2005**

Time of last modification: **12:56**

Panel database version: **2.3**

Panel Code:

Name of panel:

Number of allergens:  DMS Code:

Panel n°	Name	DMS code	activated
81276E	Alimenticio	A1	No
81305E	Analitico Brasil IgG	B1	No
81320E	ASEAN Allergy I	C1	No
81253E	Brasil Comp IgE	D1	No
81179E	Brasil General	E1	No
81277E	Brasil Geral A	F1	No
81278E	Brasil Geral I	G1	No
81345E	Canarian Panel	H1	No
81365E	Childrens Atopic	I1	No
81275E	CLA Allergy Test Scr	J1	No
81239E	CLA Allergy Test Std	K1	No
81285E	CLA Atopy 20	L1	No
81335E	CLA Essential 20	M1	No
81286E	CLA Inhalation 20	N1	No
81287E	CLA Nahrung 20	O1	No
81300E	CLA DP	P1	No
xxxxxE	CLA-1 Control Panel	Q1	No
81330E	CLA-TOP	R1	No
81382E	Hungarian Inhalant I	S1	No
81284E	Combinado Argentin	T1	No
81315E	DAVOS Panel	U1	No
81402E	Eastern 81402	V1	No
81274E	Enviro Mold IgG	W1	No

Allergen n°	Allergens
1	Bean, White
2	Cabbage Mix
3	Carrot
4	Pea
5	Pepper, Green
6	Squash Mix
7	Tomato
8	Almond
9	Peanut
10	Walnut
11	Avocado
12	Apple
13	Banana
14	Citrus Mix
15	Peach
16	Strawberry
17	Chocolate
18	Yeast, Bakers
19	Oat
20	Wheat
21	Corn
22	Potato
23	Rice
24	Soybean
25	Shellfish Mix
26	Shrimp
27	Tuna

ref.: Pip\_fic

**OK** **Cancel**

Validate your selection by clicking on the “OK” button.