

Distension of hollow organ system (V 3,0)

AstraZeneca

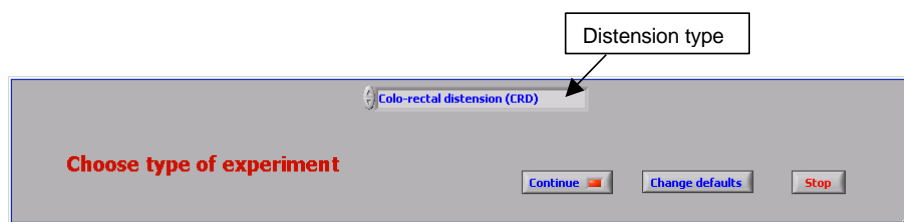


A simulation example

When the program is started the following window will be opened (Start window). As default the system is set to run in connection with a distension device. For training purposes and test of the system it is possible to run the program with no distension device connected to the computer. In such a case the program will simulate a distension device and will run all the different processes normally performed with a distension device.

Push F1 to activate the simulation milieu:

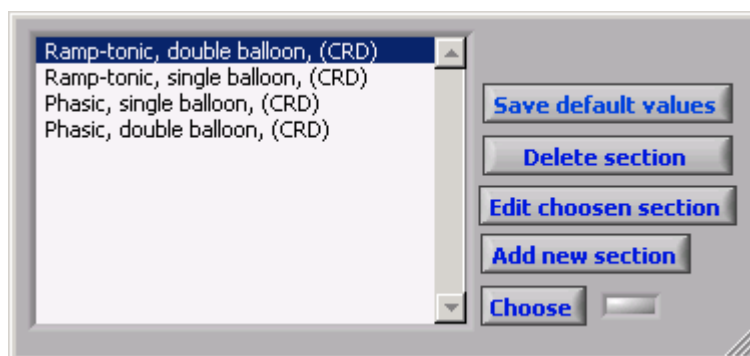
A narrow blue border will appear on the active window indicating that the stimulation milieu is active.



- | | |
|-----------------|--|
| Distension type | This function will allow you to choose different types of distensions. For each type of distension the program can save and use different sets of default values. This will make it possible to use the system in a lab with different distension experiments and different default values without need to change any parameter. |
| Change defaults | This function allows you to change the default values for each distension type. |

*Using the distension type Chose **Colo-rectal distension (CRD)** and push the **Continue** button*

The following window will be opened.



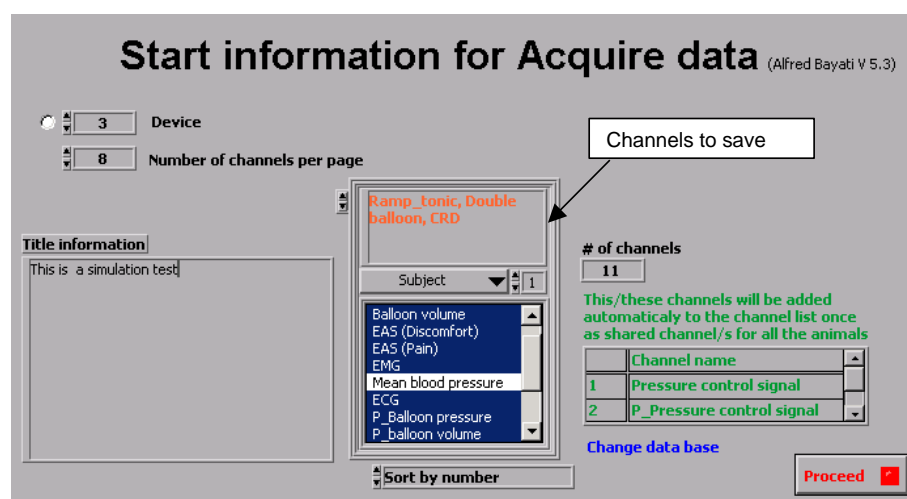
In each distension type different distension paradigms can be used. The default values for these distension paradigms can be different and are saved and used by the system automatically when one distension paradigm is chosen. The values can

be changed, new distension paradigms can be added, old distension paradigms can be deleted and the default values can be saved and printed.

Chose **Ramp-tonic, double balloon, (CRD)** and push **Choose**

This will allow you to run a ramp tonic distension with two balloons.

When the **Choose** button has been pushed a new window will open.



This window will allow you to configure your acquisition board and chose the channels you want to monitor, acquire and/or save.

Device This is the physical position of the board used to acquire data in your system. This value is set once when the system is configured and should not be changed.

Number of Channels per page A maximum number of 8 channels can be shown on the screen at any time. The total number of channels the system can acquire is set by the physical property of the AD board (in this system 64 channels). Even though up to 64 channels can be chosen at any time only 8 can be shown on the screen simultaneously. During data acquisition the user can browse through all the 64 channels using different pages with 8 channels per page.

Chose the number of channels you want to be shown on the screen at any time.

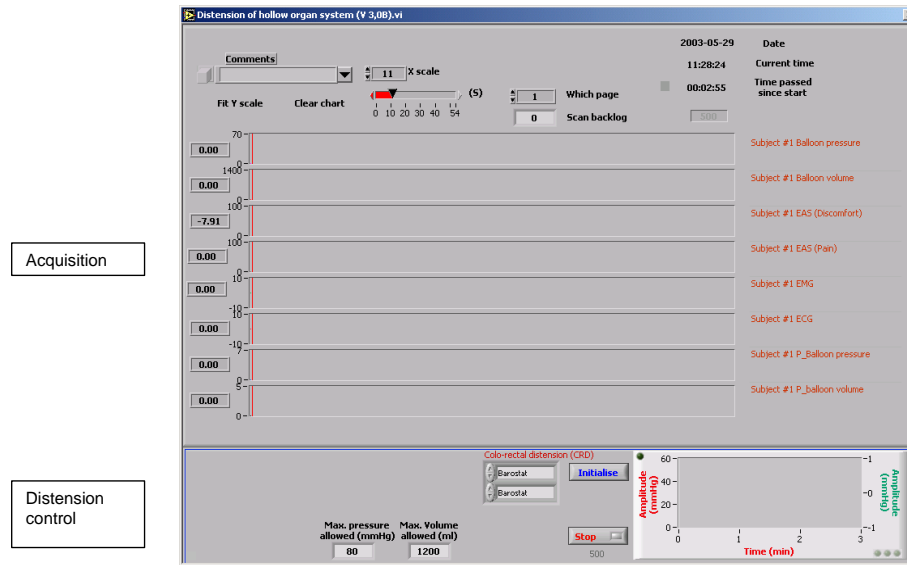
Title information Here the user can type any kind of text with no restrictions. This information will follow the saved file at all times and could give the user information about the kind of data saved in the file.

Channels to save Using the arrow heads on the left of this box the user can chose different predefined channel lists with chosen channels for acquisition and save from a data base.

- Change data base The data base with different channel lists, calibration data, system calibration procedure and graph colours can be changed with this function.
- Sorted by name The chosen channels can be acquired and saved sorted by their position number or function.

Make sure that the chosen parameters in this window is as is shown in the figure above and then click on **Proceed**

The main window of the program will now open.



This window is divided into two sub-windows.

Acquisition window starting from upper left corner:

- Comments During acquisition if the save function has been chosen the user can type different information in this box. When the button to left of this box is pushed the contents of this box will be time stamped and will be incorporated in the file with the acquired data. This information can later be used in the GrafView program where the data can be inspected and analysed. There is no limitation on the length of the text typed and the number of comments added to the data file. It is strongly recommended that this function be used as much as possible. These comments will make it very easy for the user to jump to different parts of the data file during inspection of the data.
- Fit Y scale The scale of the Y axes of the different graph windows will be automatically adjusted to the data shown.
- Clear chart All the different graph windows will be cleared. This function **dose not** affect the collected data and can be used as many times as the user wishes.
- X scale The scale of the X axes can be chosen and changed during data acquisition. This function **will not** affect the collected data. The maximum possible X axes value is calculated by the program depending on the number of channels chosen, sampling frequency and the physical memory available. In our example the maximum x scale is 54 seconds. This means that a maximum of 54 seconds

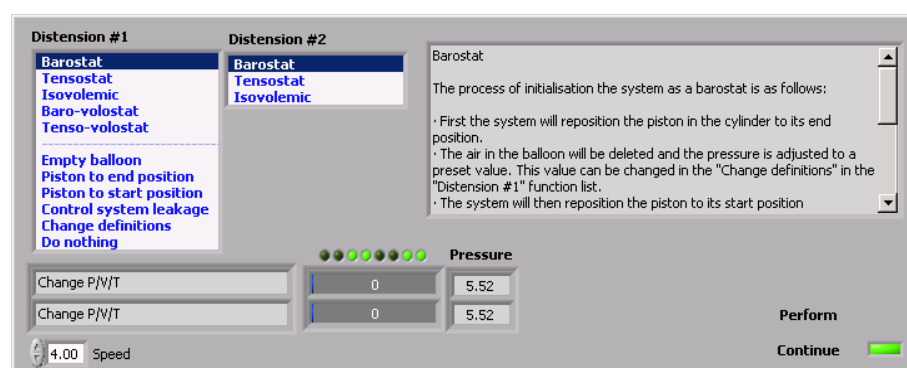
	<p>of data can be shown on the screen at each time. However X scale shows 11. This means that the user has chosen to see only eleven seconds of the data on the screen at each time.</p>
Which Page	<p>If the number of channels chosen is larger than 8 the user can browse through the different channels by changing this value. Each page can show a maximum of 8 channels.</p>
Scan backlog	<p>Acquisition part of this program uses a circular FIFO memory area. This means that data is collected by the hardware and stored in this memory. The software then saves this data 2 times per second. Some times there could be less time for the software to save the data to disk as compared to the time that the hardware has to collect data ex. when user moves the mouse or chooses Fit Y scale etc. In such a case the data will be collected in the memory and will wait for the software to save the data. This value shows how many blocks of data are waiting to be saved. There are enough place in the memory for 4000 blocks of data. If the user sees that this value is increasing constantly then the sampling rate or the number of channels should be decreased or a faster computer be used. If the number of blocks waiting in the memory exceeds 2000 the program will shutdown the presentation of data on the screen. This is done because presentation of data on the screen is a very time consuming process and in order not to lose any data it is shut down. This will give the program enough time to save data to disk and decrease the number of data blocks awaiting in the memory.</p>
Time passed Since start	<p>This is a time watch which can be used by the user. The small grey box on the left of this timer will reset the timer to zero. This function will not affect the acquired data.</p>
Graph windows	<p>This part of the window can show 1-8 graph windows depending on the number of channels chosen to acquire and save.</p>
<p>Distension control window: starting from the left side:</p>	
Max. pressure Allowed (mmHg)	<p>This is the maximum pressure allowed in the system controlled by the software which can be changed in the system data base. If the pressure in the balloon during the distension exceeds this value all valves will be opened, the pressure in the balloon will drop to zero, and the program will halt and inform the user. There is also a mechanical pressure guard for each distension system which is set at 80 mmHg. If the pressure in the balloon exceeds 80 mmHg and by some reason the software can not control it ex. the program crashes resulting in an uncontrolled infusion of air in the balloon, the power to the system will be cut off which will result in the drop of the pressure in the balloon to zero.</p>
Max. Volume Allowed (ml)	<p>This is the maximum volume allowed during a distension session. If the volume infused in the balloon exceeds this value the system will shut down, the pressure in the balloon will drop to zero and the program will alert the user. This value can be changed in the system data base.</p>
Colo.rectal	

Distension (CRD)	This shows the type of experiment chosen by the user. Each distension device can be run as a barosta, isovolemic, tensosta, baro_volostat or tenso-volostat. This is shown in the two boxes. These values will be set automatically during the initialisation process.
Initialise	Before start of a distension session the system should be initialised. No experiment can be performed without an initialisation.
Stop	This will stop a distension session.
Graph window	The distension paradigms for both distension devices will be shown in this window.

Recognise that the text colour of the **Initialise** is blue. The colour coding is as follows.

Blue colour	This function is recommended by the program as the next function to be chosen. If more than one function is in blue colour the user can chose either of them.
Green colour	This function can not be chosen at this stage or it has already been chosen.
Red colour	This function will abort the current process.

Push the **Initialise** button this will open the following window (*Initialise window*)



The system should always be initialised before each distension session. This will guarantee that the volume measured during the distension is accurate. The user can chose between different alternatives as shown in the **Function boxes**. Each distension device can have it's own function. The possible functions in the **Function box for Distension #1** are divided into two different categories. The functions bellow the dotted line, which affects both distension devices, are for manipulating the device, testing the integrity of the balloon etc. The functions above the dotted line are the functions that can be chosen to be valid during the distension session for the first distension device. Function for the second distension device can be chosen from the **Distension #2** box.

When using the system in simulation milieu and/or in vitro test the velocity of the initialisation should be changed. **Remember this should not be done when using the system in man.**

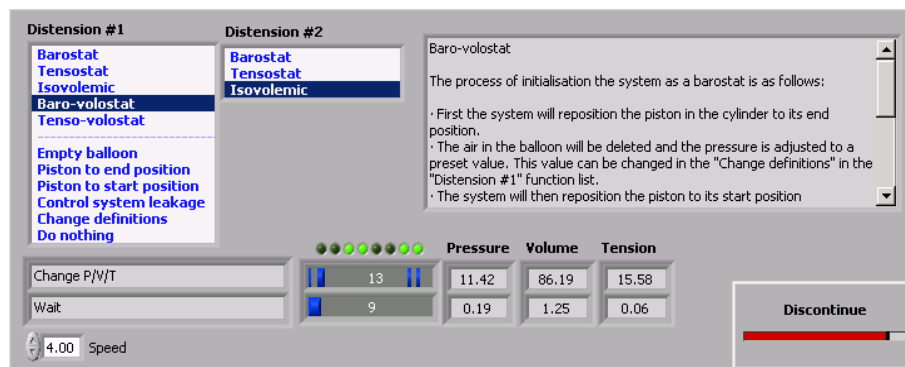
Push F1

A small digital control will be visible on the left lower part of the window with a value of 2. This is the default value which should always be used in man. However, in simulation and invitro test of the system this value should be changed to 4.

Change the speed value to 4

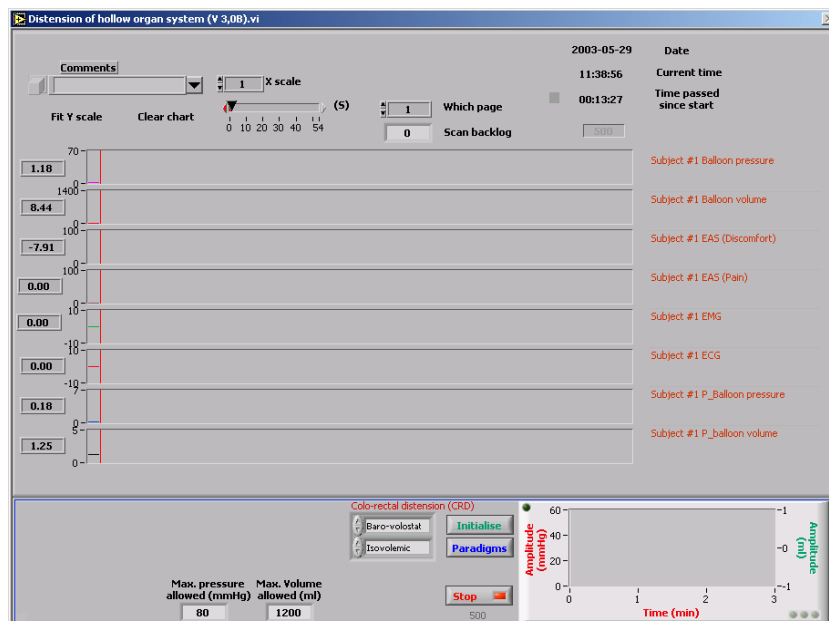
Chose **Baro-volostat** for **Distension #1** and **Isovolemic** for **Distension #2** click on **Perform**

The program will start initialising the system as shown in the figure bellow. Initialisation process can be interrupted by clicking on the **Discontinue** text.



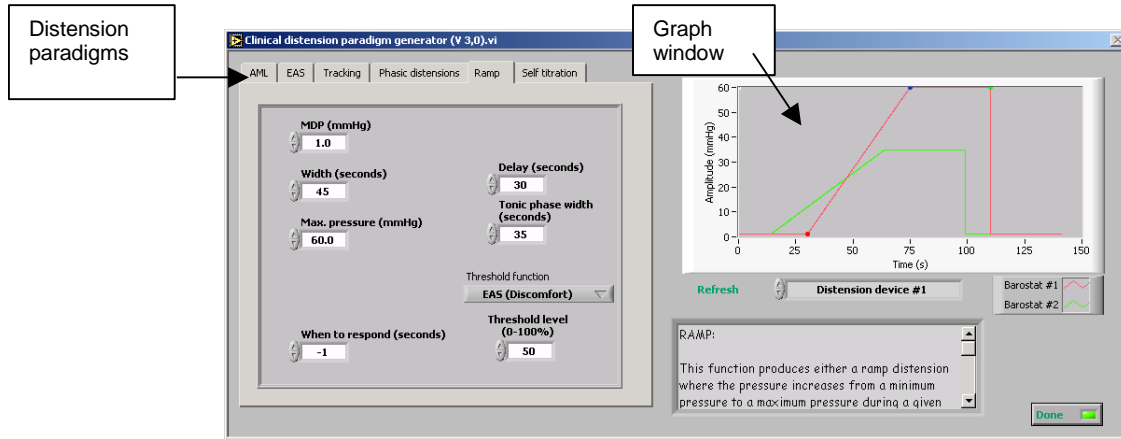
When ready click on **Continue** text which will bring you back to the main window.

Recognise that the text **Initialise** is now green and that a new button with blue text (**Paradigms**) is now visible.



Push **Paradigms** button.

A new window will open as shown bellow.



Distension paradigms

Different distension paradigms can be chosen. Each paradigm's criteria can be changed.

Graph window

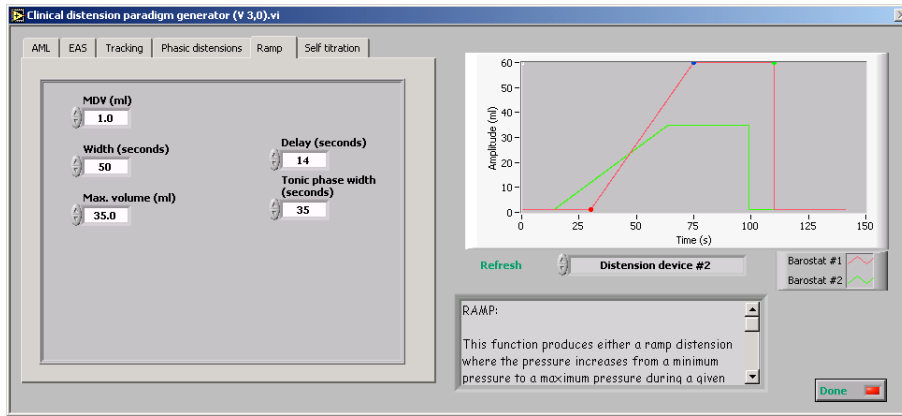
The resulting paradigm will be shown in this window. Push **Refresh** to refresh the information in this window. The red line represents the distension paradigm for the first distension device and the green line represents the distension paradigm for the second distension device.

Trigger markers

There are four colour coded triggers in the system. The red trigger identifies the beginning of a distension. The blue trigger identifies the start of the maximum pressure in the current distension. The green trigger identifies the end of the maximum pressure in the current distension. The white trigger is user defined and can be placed anywhere in the distension curve. The value **When to respond (seconds)** in the **Distension paradigm** window defines the position of this trigger related to the red trigger, i.e. a value of 15 seconds mean that this trigger is 15 seconds after the red trigger.

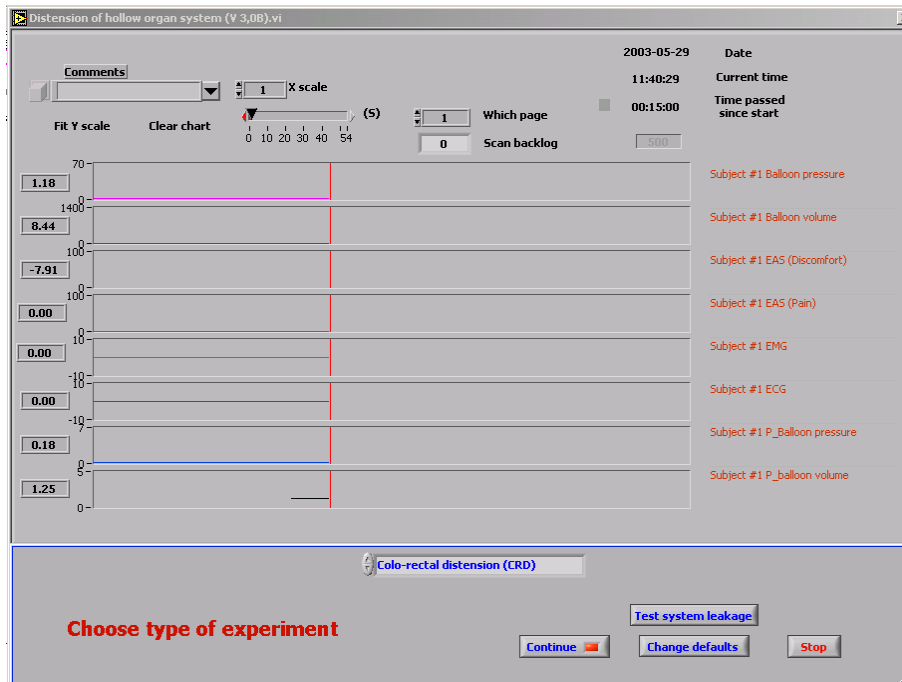
Distension System number

Chose distension device #1 or #2 and then push **Refresh** to recalculate and refresh the distension paradigms for the two distension devices.



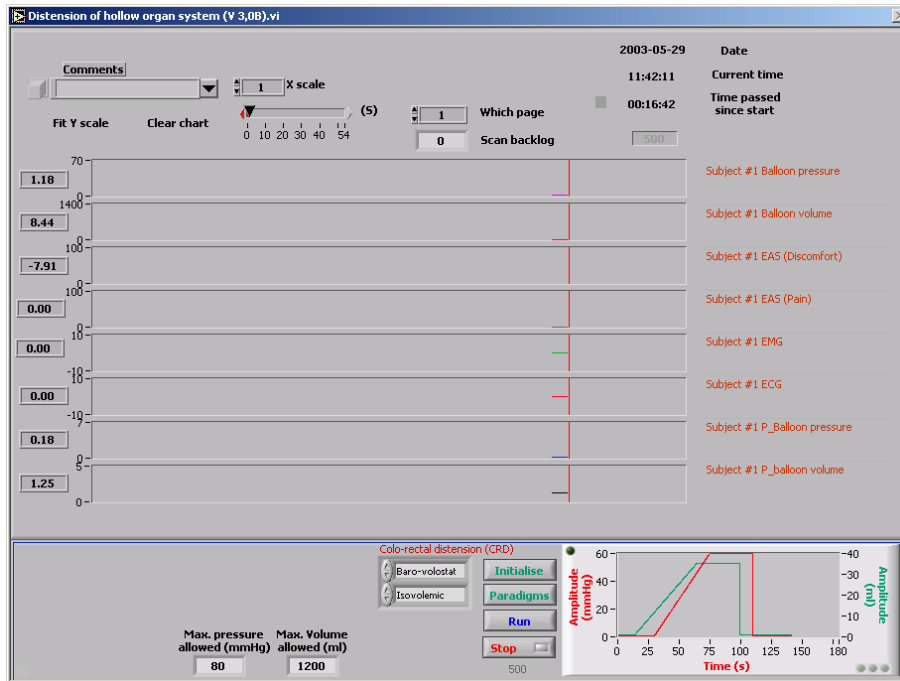
Make sure that all values, both for distension #1 and #2 are the same as the values shown in the figures above and then push **Done**.

This will change the main window as shown bellow.



Push **Continue** button

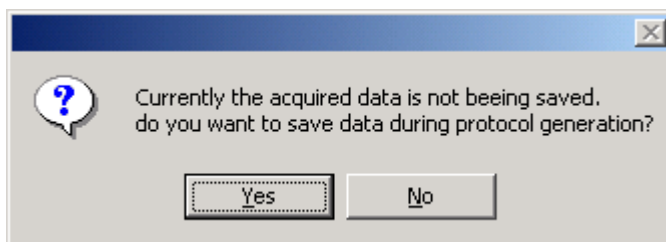
The window will be changed as shown bellow. The program will start acquiring data and shows the data on the screen. At this stage no data is being saved. A new button with blue text (**Run**) is now visible while (**Paradigms**) are now green.



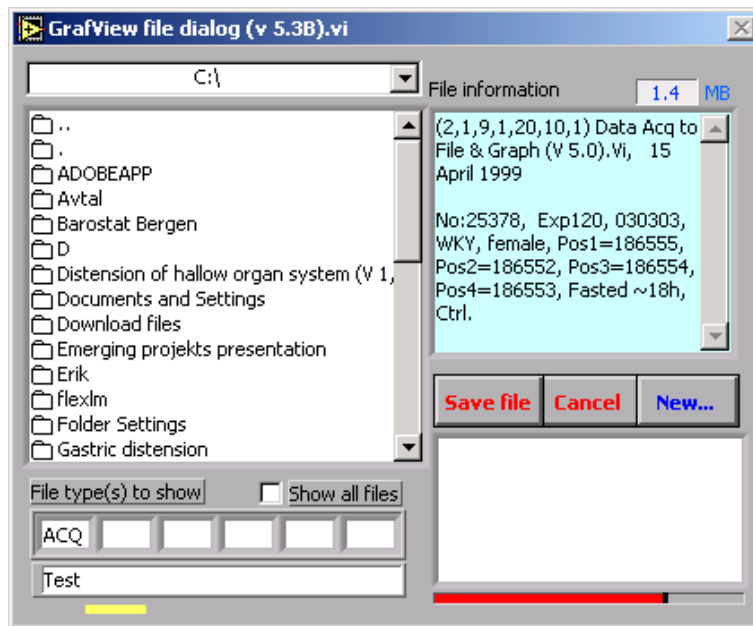
You are now ready to run the experiment.

Push the Run button

A new window will open and warn you that the data which will be collected will not be saved. You can choose to save the acquired data by choosing Yes. If you choose No the program will start running and perform the whole distension but no data will be saved.



Answer Yes.



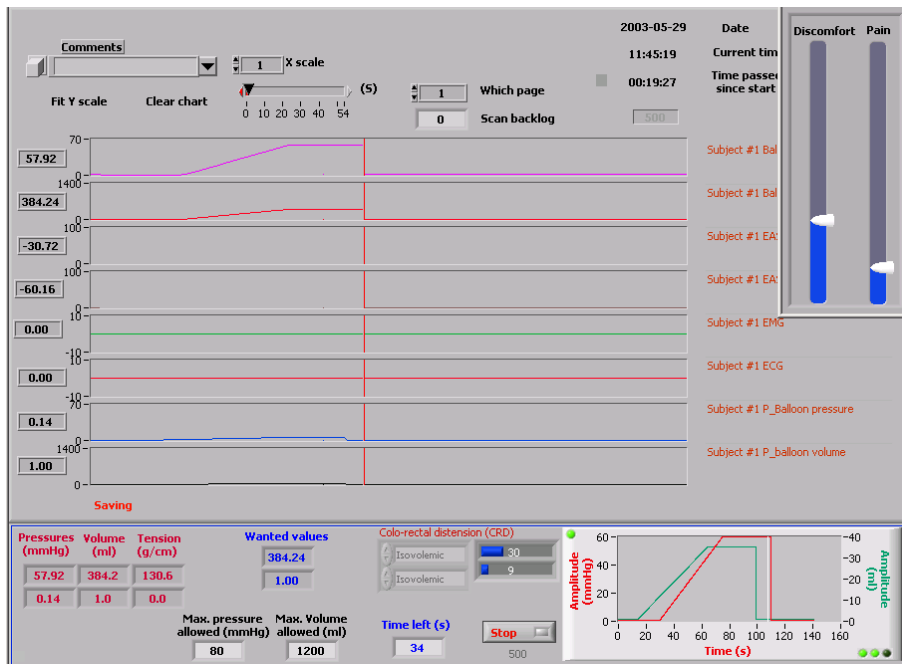
A new window will open where you can specify the address and name of the file you want the data to be save in.

Chose C:\ type **This is a test** in the small white box in the bottom left corner of the window.

Click on the **Save file** button two times

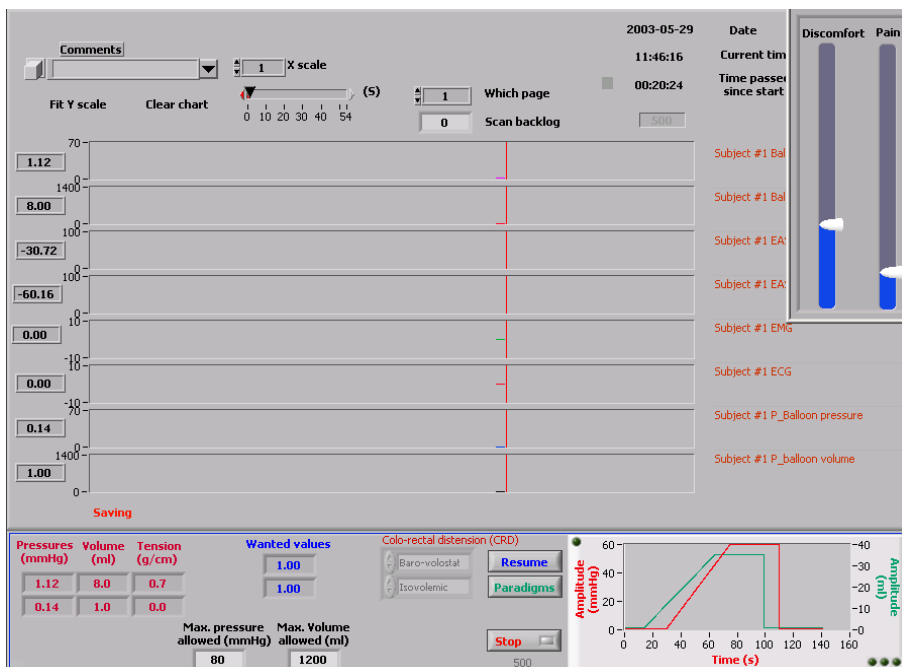
The distension session will start and you can see a white vertical cursor in the **Graph window** of the **Distension control** window of the **Main window** showing the progress of the distension (see figure bellow).

At this time a second window titled **Simulate EAS & perception panel.vi** will be superimposed on the main window. This window is activated only during simulation of a distension and will not be seen during a real distension session. With this window you can simulate the expected response of the test subject and study the reaction of the program to those responses.

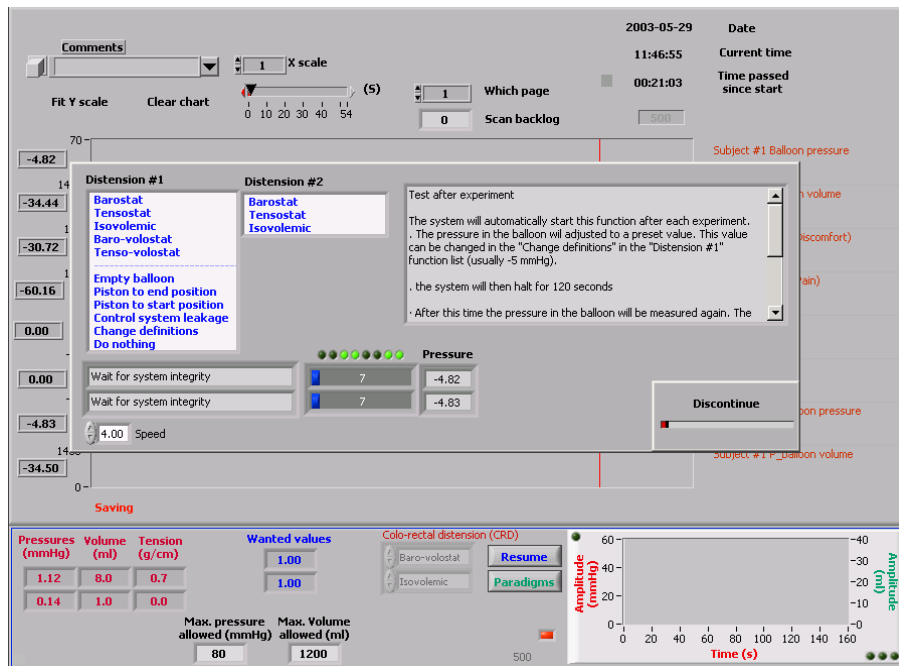


When the distension is finished the system will stop controlling the barostat while, the program is still acquiring and saving data (see figure bellow). The pressure and the volume in the balloon will not be released at this time. Here the user has two alternatives:

1) Chose a new distension paradigm or use the same paradigm and click on the **Resume** button. This will restart a new distension paradigm. As pressure and volume has not been released by the system no new initialisation is necessary.



2) Click on the **Stop** button. This will end the distension session the system will automatically activate a test sequence in which the integrity of the system is checked.



After the integrity test a new window will open accepting or rejecting the two distension devices.

Click on the **OK** button



The window will be closed and you will be back in the initialisation window.

Click on **Continue**

Initialisation window will be closed and you will be back in the start window.

End of simulation session

