Medtronic

POLYGRAM NET™

pH Testing Application

$$RefluxArea = (E - S + 1) * \frac{1}{f * 60} * \frac{\sum_{n=S}^{E} abs(StartThreshold - pH(n))}{E - S + 1}$$

$$= \frac{\sum_{n=S}^{E} abs(StartThreshold - pH(n)}{f * 60}$$

Reference Manual

CE 0543

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Contents

CONTENTS **2**

INTRODUCTION **5**

OVERVIEW 5

PH CALCULATIONS **6**

DEMEESTER SCORING METHOD 6
Normal Values *6*
DeMeester Scoring Parameters *7*
DeMeester Total Score *9*
Composite DeMeester Score *10*
ENHANCED COMPOSITE SCORE 10
REFLUX ITEMS–PERIOD TABLE 10
Period Table *10*
Duration of Period *11*
Reflux Index *16*
JOHNSON – DEMEESTER 19
BOIX-OCHOA SCORING METHOD 19
Boix-Ochoa Score *20*
SYMPTOM INDEX (S.I.) 20
SYMPTOM ASSOCIATION PROBABILITY (S.A.P.) 21
Calculation of Symptom Association Probability (SAP) *22*
SAP Calculation *23*
KAYE VALUE 25
DEMEESTER SCORING GRAPHS 26
Infant Graph *29*
FREQUENCY DISTRIBUTION TABLES/GRAPHS 30
pH Frequency Distribution Table *30*
pH Frequency Distribution Graph *30*
Cumulative Frequency Distribution Tables/Graphs *31*

BILE ANALYSIS **33**

BILE REFLUX – DUODENOGASTRIC REFLUX 33
ABSORBANCE VALUE – BILE REFLUX 34
ABSORBANCE THRESHOLD VALUE 34
Frequency Distribution Table Bile (Absorbance) *35*
Frequency Distribution Graph Bile *35*

HOME **36**

GENERAL 36

STUDIES **38**

STUDY MANAGER 38
Study Details *38*

Assign Patient *40*
Create New Patient *40*
Create New Study *41*
Tool Area *41*

PATIENTS **42**

PATIENT MANAGER 42
Creating New Patient *42*
Patient Details *43*
Tool Area *44*

PROTOCOL **45**

PROTOCOL MANAGER 45
Create New Protocol *45*
Protocol Details *46*
Tool Area *47*
pH — GENERAL SETTINGS 48
Tool Area *49*
ARTIFACT RULE 50
Tool Area *50*
EVENT AND SYMPTOM BUTTONS 51
System — Events and Symptoms *51*
User — Event and Symptom *52*
Tool Area *54*
ANALYSIS SETTINGS 54
Acid Reflux Analysis *54*
Alkaline Reflux Analysis *55*
Bile Reflux Analysis *56*
REPORT SETTINGS 58
pH Analysis Tables *58*
pH Analysis Graphs *59*
Diary Information *59*
Clip Out *59*
QUESTIONNAIRE SETTINGS 61
Generic Element Boxes *62*
Tool Area *62*

EQUIPMENT **63**

EQUIPMENT MANAGER 63
EQUIPMENT DETAILS 64
Tool Area *64*
INSTALLED OPTIONS 65
Tool Area *65*
pH Data Sources *66*

PERSONNEL **68**

PERSONNEL MANAGER 68

Creating New Personnel *68*
Tool Area *69*

ARCHIVES 70

ARCHIVE MANAGER 70
Create New Archive *70*
Register New Archive *71*
Export *71*
Tool Area *71*
SETUP MANAGER 72
Language *72*
Extensions *73*

REFERENCE ARTICLES 78

Service Centers *79*

Introduction

The POLYGRAM NET™ pH Testing Application software is intended to store, view and analyze pH and Bile data obtained from a 24 or 48-hour ambulatory esophageal pH monitoring study. The study is performed on patients who suffer from symptoms of reflux disorders such as heartburn, chest pain, and regurgitation. pH and Bile data are captured in the stomach and esophagus by means of a catheter or a radio transmitter capsule and a recording device. The data are then uploaded to the POLYGRAM NET™ pH Testing Application software for analysis. The results of these analyses are used to determine whether abnormal levels of acid or alkali are present.

CAUTION US law restricts this device to sale by or on the order of a physician.

CAUTION Physicians should exercise diligence in their interpretation of results from this system. It is always advisable to check analysis results against the signal tracings when a major consequence such as surgery occurs as a result of an investigation.

WARNING The device is not compatible for use in an MRI magnetic field.

Overview

The POLYGRAM NET™ Application consists of a series of views, which will help you to configure all the necessary information to conduct a study allowing you to review the acquired data, and create study reports.

The following sections of this manual will describe in detail all the pH and Bile analyses that can be made on the recorded data, and will guide you step by step through all the POLYGRAM NET™ pH Testing Application views.

pH Calculations

This section explains how the analysis parameters are calculated.

NOTE All calculated results are available for inclusion in the reports.

CAUTION The results obtained from the different scoring methods will be affected by the Protocol Settings applied —e.g., changing the Start Threshold to 5 instead of 4 will affect the result of a DeMeester score. The description of the calculations in this section uses the default protocol settings.

DeMeester Scoring Method

According to Johnson and DeMeester "Development of the 24-hour Intraesophageal pH Monitoring Composite Scoring system" journal of Clinical Gastroenterology, 1986.

"This system uses a uniform scoring unit and pH monitoring parameters taken from both the day and night-time segments of the pH recording. The score quantitates the degree of departure that a patient's reflux pattern exceeds physiologic reflux found in asymptomatic control volunteers, and directly correlates with the degree of reactive, epithelial change characteristic of reflux esophagitis."

Normal Values

The normal values used in the POLYGRAM NET™ pH Testing Application are taken from T.R. DeMeester "Prolonged Oesophageal pH Monitoring" in Gastrointestinal motility: which test?, NW. Read, ed., Wrightson Biomedical Publishing Ltd, 1989:

"A 24-hour pH composite score was obtained by adding the scores calculated for each of the six components. The composite score was considered abnormal when it exceeded the 95th percentile of the composite scores calculated from the 50 control subjects".

DeMeester Scoring Parameters

The DeMeester score is a measure of the exposure of the esophagus to pH levels below 4.00 for the total upright and supine periods, the DeMeester score is calculated based on the pH levels below 4.00 using normal (average) values. The DeMeester score is calculated on the following six parameters:

The DeMeester score is based on the following six parameters:

- Number of Refluxes for Total period
- Number of long Refluxes for Total period
- Duration of longest Reflux for Total period
- Fraction time pH </> X for Total period
- Fraction time pH </> X for Upright period
- Fraction time pH </> X for Supine period

The normal values used here are the ***mean*** and the ***standard deviation*** *(SD)* for each of the above parameters for the 50 normal subjects used.

NOTE DeMeester score is only defined for integer values of X.

"In 1974 we chose to express the 24 hour pH monitoring in the following ways (i) cumulative reflux time, expressed as the percentage of the total monitored time, the percentage of time that the patient is monitored in the upright position and the percentage of time monitored in the supine position; (ii) frequency of reflux episodes, expressed as the number of reflux episodes per 24 hours; and (iii) duration of reflux episodes, expressed as the number of episodes longer than five minutes, and the number of minutes of the longest episode (Johnson and DeMeester, 1974)... Although, we considered reporting frequency and duration parameters for both upright and supine time, experience indicated that the total 24hour period would suffice. This is because the longest reflux episode usually occurred during the supine time and because episodes of more than five minutes had a similar detrimental effect whether they occurred in the upright position or supine position. Hence, we felt that the above six parameters would adequately quantitate esophageal exposure to gastric juice." (DeMeester, 1989).

–See Fig. below for an example of a DeMeester Scoring Table.

DeMeester Scoring Table

Numerical Scoring on Acid Refluxes		Score
Number of Acid Refluxes	(refl/24 hour)	12.5
Number of Long Acid Refluxes	(refl/24 hour)	5.1
Longest Acid Reflux	(min)	5.4
Fraction Time pH below 4.00	(Total %)	8.2
Fraction Time pH below 4.00	(Upright %)	2.2
Fraction Time pH below 4.00	(Supine %)	22.4
Total score DeMeester Normals: <14.72 (95th percentile)		55.8

DeMeester Scoring on Acid Refluxes

Number of Acid Refluxes (refl/24 Hours)

This refers to the total number of acid refluxes that occurred during the procedure, normalized for a 24-hour period. That is, if the duration of the patient recording is less than 24 hours, the total number of reflux episodes is normalized so that it represents a 24-hour period.

Number of Long Acid Refluxes

This is the DeMeester score for only those refluxes which ≥ 5.0 minutes in duration (default settings). Again, the number is normalized for a 24-hour period.

$$\textbf{Normalized Value} = \frac{\text{Number of refluxes} \geq \text{than 5.0 minutes}}{\text{Duration}} * 24\text{h}$$

Longest Reflux Episode (min)

This is the DeMeester score for the longest reflux episode in minutes in the recording.

Fraction Time pH below 4.00 Total Period

The value refers to the percentage of time in which the pH value remained below 4.00 in the Total period.

Fraction Time pH below 4.00 Upright Period

The value refers to the percentage of time in which the pH value remained below 4.00 in the Upright period.

Fraction Time pH below 4.00 Supine Period

The value refers to the percentage of time in which the pH value remained below 4.00 in the Supine Period.

DeMeester Total Score

The total score is comprised of the six individual component scores. Note that the mean and standard deviation are based on the DeMeester normal patient group.

The formula for the *Component Score* is:

$$\frac{\text{Pt Value} - \text{Mean}}{\text{SD}} + 1$$

where,

Pt Value = Patient Value
Mean = Mean Value
SD = Standard Deviation

This formula is used to weigh each component of the 24 hours pH recording according to the dependability and reliability of the measurement. The composite score is comprised of the six individual component scores.

Normalization

The first two parameters must be normalized –i.e. adjusted to a 24-hour cycle– as the DeMeester score is developed for a 24-hour study.

The formula for the *Normalized Value* is:

$$\textbf{Normalized Value} = \frac{\text{Value}}{\text{Duration}} * 24\text{h}$$

Individual Score Calculation

The actual score for a parameter is calculated as the Patient Value – Mean dived by the standard deviation.

The formula for the *Individual Score* is:

$$\textbf{Individual Score} = \frac{\text{PtValue} - \text{Normal_Mean}}{\text{Normal_SD}} + 1$$

Composite DeMeester Score

The Composite DeMeester Score is the sum of the six individual scores.

Enhanced Composite Score

The enhanced composite score is a user-defined score that can be used to define your own scoring method for the analysis. The results of the scores applied to the analysis can be inserted in the report. To use this feature you need to define it in the protocol. A number of scores can be defined and each score must be assigned to an analysis.

The Mean and standard deviation values must be defined for the following items for each score:

- Number of Acid Refluxes
- Number of Long Acid Refluxes
- Longest Acid Reflux
- Fraction Time pH Below Threshold, Total
- Fraction Time pH Below Threshold, Upright
- Fraction Time pH Below Threshold, Supine

Furthermore, the Normal Value for the score must be defined.

The Enhanced Composite Score is calculated just as the DeMeester score except that the normal values (mean and SD) for the six parameters and the normal score are user configurable

Reflux Items–Period Table

The following calculation descriptions refer to items associated with acid and alkaline refluxes in the period table.

Period Table

Item	Total	Uprigt	Supine
Duration of Period (HH:MM)	21:32	09:02	12:30
Number of Acid Refluxes (#)	93	59	35
Number of Long Acid Refluxes (#)	6	1	4
Longest Acid Reflux (min)	23	7	23
Total Time pH below 4.00 (min)	143	49	93
Fraction Time pH below 4.00 (%)	11.0	9.1	12.4
Symptom Index (%)	N/a	N/a	N/a

Item	Meal	PostPr	Prone
Duration of Period (HH:MM)	01:10	07:07	00:04
Number of Acid Refluxes (#)	8	57	1
Number of Long Acid Refluxes (#)	0	4	0
Longest Acid Reflux (min)	0	23	0
Total Time pH below 4.00 (min)	1	100	0
Fraction Time pH below 4.00 (%)	0.8	23.4	5.0
Symptom Index (%)	n/a	N/a	100.0
Item	**ChestP**	**HrtBrn**	**Belch**
Duration of Period (HH:MM)	00:20	00:20	00:08
Number of Acid Refluxes (#)	9	6	1
Number of Long Acid Refluxes (#)	0	0	0
Longest Acid Reflux (min)	1	4	0
Total Time pH below 4.00 (min)	5	12	0
Fraction Time pH below 4.00 (%)	27.3	59.7	5.8
Symptom Index (%)	100.0	80.0	50.0

Duration of Period

This is the total duration of the period in hours and minutes.

CAUTION If artifact markers are found in the recording within the period specified, the accumulated time duration they represent is excluded from the "Duration of the period."

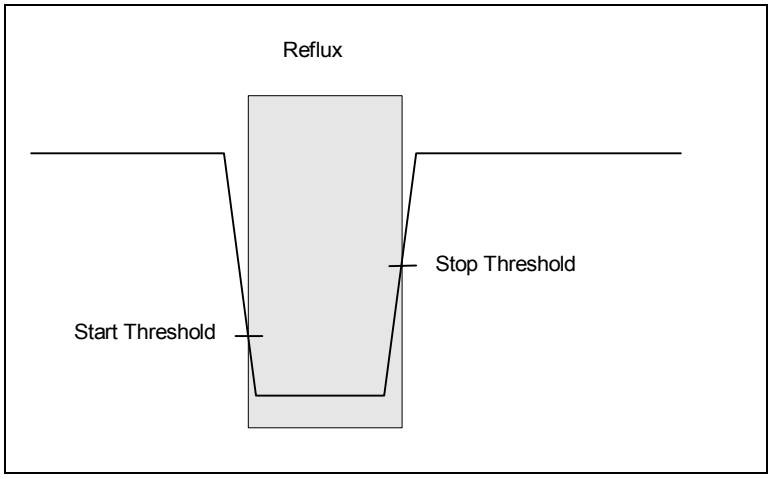
Duration of Period = Total Duration of Period – Duration of Artifact Periods

The duration of a period is define as EndTime – StartTime, and is typically reported in hours and minutes –i.e.19:18 for 19 Hours and 18 Minutes.

Start/ Stop Threshold

A Reflux is defined as present when the signal level drops/rises below/above a Start Threshold, and until the signal level raises/drops above/below the Stop Threshold. A reflux can be of Acid, Alkaline, or Bile type. Bile refluxes are only defined for optical signals.

A reflux is per definition present when a signal is below a Start Threshold at the beginning of the recording.



Acid reflux example

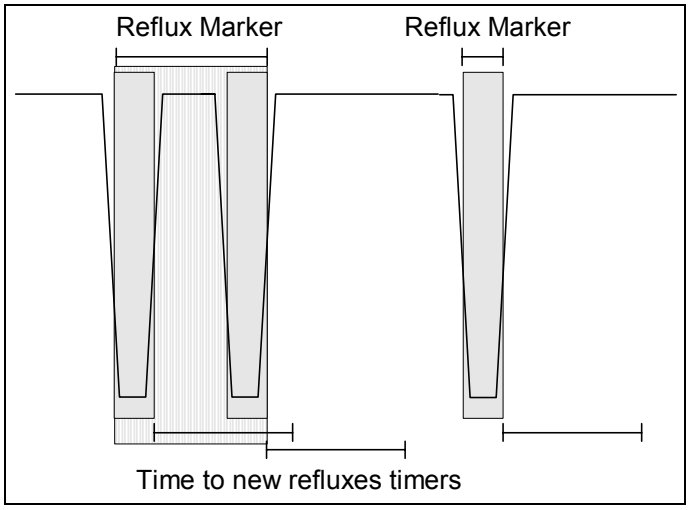
Observe the Acid Reflux example shown in the figure above. For an Alkaline Reflux the opposite picture would have been the case–i.e. a rise above a Start Threshold and then a drop below a Stop Threshold.

Disregard Refluxes Shorter than

If detected, refluxes shorter than the specified duration will be disregarded.

Time to New Reflux

When a reflux ends the *Time to new reflux* timer is started. If a reflux is identified during the *Time to new reflux* period, the first reflux marker is extended until the stop threshold is reached again. The procedure is continued until no *Time to new reflux* periods contains refluxes of the same type.



Extending the reflux marker due to Time to new reflux

Reflux Duration

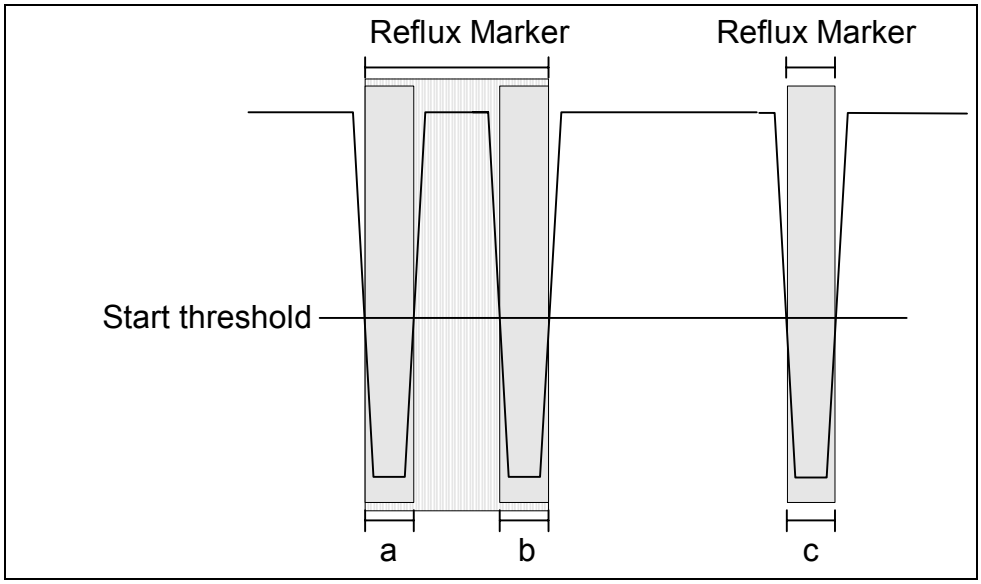
The Reflux duration is calculated as the *Reflux marker stop time - Reflux marker start time.*

Duration of Longest Reflux

The *duration of longest reflux* is found by searching for the longest duration among all reflux markers.

Time pH < X

The *Time pH < X* is calculated based on the Start threshold as X.
The T*ime pH* < X is found by measuring the time where the pH is below the start threshold over a specified period.



TotalTime pH < X = a+b+c

Fraction Time pH < X

This is the percentage of the time the pH below the threshold for each of the defined periods.

The formula for the *Percent Time pH < X* is:

$$\frac{\text{Time Signal} < \text{Threshold}}{\text{Specific Period}} * 100$$

Number of Refluxes

This is the total number of refluxes that occurred in each of the defined periods during the procedure.

Number of Long Refluxes

This is the total number of long acid refluxes that occurred in the periods during the procedure. A long reflux is a reflux that is ≥ the "long reflux" duration defined in the protocol.

Longest Reflux
This value is the duration of the longest reflux that occurred during each of the defined periods during the procedure expressed in minutes.

Total Time pH below X
This is the total time pH was below the reflux threshold during each of the defined periods. For alkaline analysis, the value indicates the total time above the start reflux threshold.

Maximum
This is the maximum pH value recorded during the Period.

Minimum
This is the minimum pH value recorded during the Period.

Mean
This is the mean pH value recorded during the Period.

Median
This is the median pH value recorded during the Period.

Reflux Area
The Reflux Area for a period is the sum of all reflux areas in the period. Refluxes are identified with Stop Threshold set equal to the Start Threshold regardless of the original Stop Threshold settings. The area of each reflux episode can be calculated as follows:

- S = Reflux Period Start Sample
- E = Reflux Period End Sample
- f = Sampling frequency (rate)

The Calculation for the *Reflux Area* is:

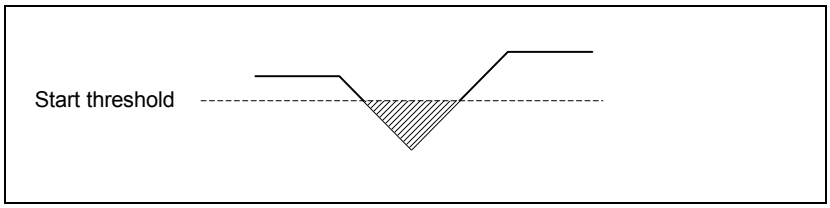
D = Duration in minutes. $= (E - S + 1)\dfrac{\frac{1}{f}}{60} = (E - S + 1)\dfrac{1}{f * 60}$

$$\text{pHMean} = \frac{\sum_{n=S}^{E} abs(StartThreshold - pH(n))}{E - S + 1}$$

RefluxArea = $D * pHmean$

Substituting D and pHmean

$$\text{Reflux Area} = (E - S + 1) * \frac{1}{f * 60} * \frac{\sum_{n=S}^{E} abs(StartThreshold - pH(n))}{E - S + 1} = \frac{\sum_{n=S}^{E} abs(StartThreshold - pH(n)}{f * 60}$$



Example of Reflux Area

Reflux Area Index

This is a way of reporting the reflux area for a given period while taking the period duration into account, and allowing comparison of the calculated reflux areas between periods of different durations.

The Reflux Area Index is calculated as the reflux area divided by the duration of that period.

The formula for the *Reflux Area Index* is:

$$RAI = \frac{refluxArea}{PeriodDuration_{inHours}} * 100 = \frac{refluxArea}{PeriodDuration_{inMinutes}} * 60 * 100$$

Number of Refluxes Longer than m Minutes

A "long" Reflux Episode is an episode, which has a duration that exceeds or matches a given value. The default value is 5 minutes.

The formula for the *Number of Refluxes ≥ than m Minutes* is:

Long reflux: *Reflux duration >= value*

After having identified all the long refluxes, the total number of long refluxes is known and is reported.

Maximum / Minimum / Median / Mean pH/Abs Value

These Values are calculated for each period.

Reflux Index

This calculation gives an idea of the frequency of the movement of gastric contents into the esophagus, regardless of the pH in the esophagus at the time that this movement occurred.

Quoting Joelsson, DeMeester, Skinner et al. 1982.

"The functional efficiency of the cardia was evaluated by calculating the number of reflux episodes per hour with the patient in the supine position. This was done by noting the duration of the time the subject was in the supine position and counting the times the pH in the esophagus dropped below 4. Obviously, only the reflux episodes that occurred while the esophageal pH was above 4 could be detected, whereas those that occurred when the pH was below 4 would go unnoticed. To correct this source of error, the number of episodes that occurred per hour while in the supine position was divided only by the time the pH was above 4. For example, if a patient had 18 reflux episodes during 8 hours spent in the supine position and the pH was above 4 for 6 of these 8 hours, then the number of calculated reflux episodes per hour would be three."

The formula for the *Reflux Index* is:

$$RI = \frac{\text{Number of Refluxes}}{(\text{Duration of Period} - \text{Time below Threshold})}$$

Oscillatory Index

It is the percentage of the investigation time that the pH is between the two boundary levels –pH 4.25 and 3.75–. The Oscillatory Index is discussed in *Vandenplas, Y.et al, Dependability of esophageal pH monitoring data in infants on cut-off limits: the Oscillatory Index. Journal of Pediatric Gastroenterology and Nutrition 11:304-9; 1990.*

- The boundary levels can be set up in Protocol Settings.

The formula for the *Oscillatory Index* is:

$$\frac{\text{Total time when (low threshold} < \text{pH} \leq \text{high threshold) (min)}}{\text{Total time for the period (min)}} * 100$$

Esophageal Clearance

This calculation gives an idea of how long each reflux actually persists taking into consideration both the average reflux time (minutes per episode), and the reflux frequency (number of episodes per hour).

The Esophageal Clearance is reported as minutes per episode. The calculation uses the reflux index as a measure of the number of refluxes that started at a time when esophageal pH was already above 4.0.

The formula for the *Esophageal Clearance* is:

$$\frac{\text{Time below/above Threshold}}{\text{Reflux Index * Period Duration}} * 60$$

The calculation for Esophageal Clearance is explained in Joelsson, DeMeester, Skinner et al. 1982:

"The functional efficiency of the esophageal body was evaluated by calculating the mean duration of a reflux episode. This was obtained by dividing the total time the pH was below 4 in the supine position by the total number of reflux episodes that occurred while in that position.

Only the supine position was used to avoid introducing errors from the beneficial effects of gravity on esophageal clearance in the upright position.

For example, a patient may have spent 8 hours in the supine position, and had three reflux episodes per hour while the pH was above 4.

Assuming that episodes of reflux occurred with similar frequency whether the pH was above or below 4, the total number of reflux episodes occurring while in the supine position can be calculated by multiplying the number of reflux episodes per hour occurring while the pH was above 4 by the total time the subject spent in the supine position.

In our example, this patient would be 24 reflux episodes while in the supine position.

To calculate the mean duration of a reflux episode, the total time the pH was below 4 in the supine position is divided by the total number of reflux episodes while in the supine position.

In our Example this would be 5 minutes per reflux episode (120 minutes / 24 reflux episodes = 5 minutes per episode).”

If the pH threshold level is specified as pH 4.0, then “tr” is the time pH is below 4.0.

NOTE If a reflux is defined as " start when pH < 4.0” and “end when pH >5.0” the **tr** is still only the time the pH is below 4.0.

Fraction Time pH below X

This is the percentage of each of the defined periods that pH was below the start reflux threshold. It is calculated in the following way:

The formula for *Fraction Time pH below X* is:

$$\frac{tr * 100}{p}$$

where,

tr = time pH below specified threshold level (min)
p = period length (min)

For alkaline analyses, the value indicates the percentage above the reflux threshold.

Meal Periods

Meal Periods can be Included / Ignored in the Period Table. –When Ignore is selected in Protocol Analyses Settings, All Meal Periods will be excluded from the analyses.

Johnson – DeMeester

The Johnson–DeMeester score is calculated just as the DeMeester score except for the used mean and SD values which are different. A normal score is a score below 22.

The following table is from Johnson LF and DeMeester TR. "Twenty-four hour pH monitoring of the distal esophagus." A quantitative meassure of gastroesophageal reflux, Am J Gastroentrol 62:325-332,1974.

Parameters Mean ± SD	Asymptomatic Control (N=15)	Normal Values	Symptomatic Patients with Abnormal Values (N=38)
Recumbent Period	0.286% ± 0.467	< 1.2%	82
Total Period	1.478% ± 1.381	<< 4.2 %	78
No. Episodes ≥ 5	0.6 ± 1.241	≤ 3	74
Longest Episode	3.866 ± 2.689	< 9.2	74
Upright Period	2.33% ± 1.975	< 6.3%	63
Total Episodes	20.6 ± 14.773	< 50	50

Boix-Ochoa Scoring Method

This score is described in José Boix-Ochoa, "Pediatric Aspects of 24-hour pH Monitoring" in esophageal Disorders: Pathophisiology and Therapy, ed. T.R. DeMeester and D.B. Skinner, Raven Press, N.Y., 1985.

"If we compare the two patterns of adults and children, we can see several important factors. First, the total period is almost the same. Second, the mean values between the seated and supine position in the child are not different, but they are in the adult. The adult is an upright refluxer; the child is not. Third, in the group of normals and in all other groups, the longest percent time of the reflux for the three positions was the prone position. This position influences enormously the final score in the pediatric group. The study of the tracings in this position shows that there are usually less refluxes but they are much longer."

Boix-Ochoa Score

Total Score = 37.8, Boix-Ochoa normals less than 11.99 (95th percentile).

–See figure below for an illustration of the Boix-Ochoa Scoring Table .

Boix-Ochoa Components		Mean	Standard Deviation
1.	Number of Acid Refluxes	10.6	8.2
2.	Number of Long Acid Refluxes	1.73	2.05
3.	Longest Acid reflux	8.07	7.19
4.	Fraction of Total Time pH below 4.00	1.86	1.60
5.	Fraction of Upright Time pH below 4.00	0.8	1.3
6.	Fraction of Supine time pH below 4.00	1.59	2.9
7.	Fraction of Prone time pH below 4.00	3.28	3.5

Boix-Ochoa Scoring on Acid Refluxes

All of the parameters shown in the table above are the same as in the DeMeester Score with the following two exceptions:

- The Boix-Ochoa score is developed for infant/pediatric usage.
- The percentage for pH values below 4.00 is included for the prone position as well as for the upright and supine positions.

Symptom Index (S.I.)

The Symptom Index is discussed in G.J. Weiner, J.E. Richeter, et al. 1988:

"We developed a numerical scale to quantify the percent association between symptoms and pH < 4 -- the symptom index (SI). ... the SI gives clinically relevant information regarding the role of acid reflux and patient's symptoms.

A patient was considered to have GER if any of three parameters for percent time with pH < 4 (upright, recumbent or total) exceeded two standard deviations from the mean derived from 20 asymptomatic volunteers (8 men, 12 women, mean age 31 yrs) previously studied in our laboratory.

To provide a numerical value for the association of patient's symptoms with esophageal acid exposure, we derived a symptom index. For each symptom un-

der question (chief complaint, heartburn, chest pain), we defined SI as the number of times the symptom occurred when pH was < 4, divided by the total number of times the symptom was reported. The quotient was then multiplied by 100 to give the percentage of symptom episodes that correlated with GER.

The formula for *Symptom Index* is:

$$\frac{sr * 100}{S}$$

where,

sr = number of correlated symptoms with acid reflux episodes
s = total number of symptoms

The Symptom Index is calculated for each symptom (e.g. chest pain, heartburn, belching). For example, the following Period Table shows that the symptom index for the symptom chest pain (ChPain) was 100%. This means all of the symptoms listed in the symptom boxes occurred at a time when the pH was less than 4.00.

NOTE When calculating the Symptom Index the program automatically includes a fixed time period of two minutes before and after each symptom in the symptom period to be considered."

Ref.: *Lam HGT, Breumelhof R, Roelofs JMM, vanBerge-Henegouwen GP, Smout AJPM. What is the optimal time window in symptom analysis of 24-hour esophageal pressure and pH data? Dig Dls Sci 1994:39; 402-209-.*

Symptom Association Probability (S.A.P.)

The symptom association probability is discussed in B.L.A.M. Weusten, J.J.M. Roelofs et al. "The Symptom-Association Probability: An Improved Method for Symptom Analysis of 24-Hour Esophageal pH Data" (Gastroenterology 1994; 107:1741-1745):

"The SAP is a single, simple, quantitative measure of the strength of the association between symptoms and reflux episodes that is devoid of the disadvantages inherent to previously used methods. The current most frequently used parameter in the symptom index (SI) defines as the percentage of reflux-related symptom episodes. However, this parameter does not take into account the total number of reflux episodes. Hence, in patients with frequent gastroesophageal reflux, a high SI may well be caused by random associations between reflux and symptoms."

"In the Symptom Association Probability, a contingency table is used, as proposed by Orr (22). In this table, the frequency of occurrence of all four possible combinations (asymptomatic and symptomatic 2-min episodes with and without reflux) is recorded. We have recently shown that in the symptom analysis of 24-h esophageal pH data, a time window beginning 2 minutes before the onset of the symptom event and ending at its onset provides optimal results (16). Accordingly, in this study the total recording period was divided into 2-min periods that were analyzed for the occurrence of reflux. Using the Fisher Exact test, significant differences in proportions of reflux-positive 2-min periods can be detected. Although a statistically significant result does not prove a casual relationship, the SAP provides objective information on the probability that observed associations in time between reflux and symptoms occur by chance. For instance, in case of a SAP>95%, the probability that the observed associations occurred by chance is less than 5%."

Calculation of Symptom Association Probability (SAP)

"First, the 24-h esophageal pH signal was divided into consecutive 2-min periods. Thereafter, all 2-min periods (on average 704 in number) were evaluated for the occurrence of gastroesophageal reflux. A 2-min period was considered to be reflux-positive, if either a fall in pH of more than 4 lasting 5 seconds or more, or a fall in pH of more than 1 pH unit (within 5 seconds) had occurred during that period. Likewise, all 2-min periods preceding the onset of symptom episodes were analysed for the presence of reflux, and classified as reflux-positive or reflux-negative. Subsequently, a contingency table was constructed, containing 4 fields: one field containing the number of symptomatic reflux-positive 2-min periods (S+R+), one field containing the number of asymptomatic reflux-positive 2-min periods (S-R+), one with symptomatic 2-min periods without reflux events (S+R-), and one field with the number of asymptomatic 2-min periods without reflux events (S-R-)."

*"The Fisher Exact test was then applied to calculate the probability (**P** value) that the observed association between reflux and symptoms occurred by chance (17). The Symptom Association Probability was calculated as (**1.0 - P) x 100%**. In contrast to the Chi Square test, application of the Fisher Exact test is also justified in case of low numbers in one of the four fields (17). Significant SAP values were only considered when symptom episodes showed more associations with reflux than could be expected by chance, i.e. when the proportion of reflux-positivity in the 2-min periods preceding the symptom was higher than that in the total recorded 2-min periods. Significant SAP values (suggesting reflux-induced symptoms) were prevented in patients in whom symptom episodes coincided less often than could be expected to occur by chance. This was done by assigning the value 1 to P (resulting in a SAP of 0) when the proportions of reflux-positive pre-symptom periods was lower than the proportion of reflux-positive periods in general."*

Numbers 16, 17 and 22 correspond to the following references:

16. Johnson LF, DeMeester TR:
Development of the 24-Hour Intraesophageal pH Monitoring Composite Scoring System. J Clin Gastroenterol, 1986;8 Suppl 1: pp 52-58.
17. Johnson, LF:
24-hour pH monitoring in the study of gastroesophageal reflux. J Clin Gastroenterol, Dec 1980, 2(4), pp 387-399.
22. Meyers, WF, Roberts CG, Johnson DG, Herbst JJ:
Value of tests for evaluation of gastroesophageal reflux in children, J Pediatric Surg, Oct 1985, 20(5), pp 515-520.

SAP Calculation

The Symptom Association Probability has two components: the ***Contingency Table*** and the ***Fisher Exact*** test. The Fisher Exact test uses the values from the Contingency Table as input. The Symptom Association Probability calculation is furthermore done on the raw signal with artifacts in it.

1. A contingency table is calculated
2. The Fisher Exact test is applied to the contingency table to obtain a P value
3. SAP=(1-P)*100

Contingency Table

The contingency table consists of four values:

(S+, R+), (S+, R-), (S-, R+), (S-, R-)

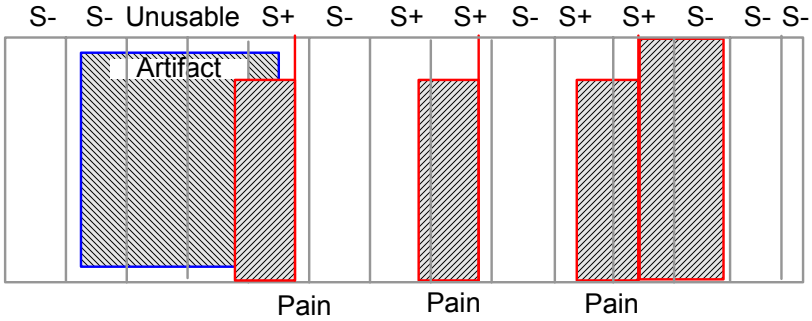
	+	–	
+	**S+R+**	**S–R+**	**(R+) Total**
–	**S+R–**	**S–R–**	**(R–) Total**
	(S+) Total	**S– Total**	**(RS) Total**

Calculation of (RS) Total

(RS) Total is the total number of segments including partial segments in the period.

Calculation of (S+) Total

1. All symptoms in the period are extended to t1 seconds before the start time and t2 seconds after the end time. The new intervals may overlap. (Default values t1=120 seconds, t2= 0 seconds)
2. All segments in the period that overlap with extended symptom intervals are counted in (S+) Total. Segments overlapping several symptom intervals are only counted once.



Calculation of S+. (S+) Total = 6

Calculation of S+R+

This calculation is done for each period type. 2-min segments are defined as occurring two minutes before the start time of each marker associated with the period. These segments are symptom related.

S+R+ is the total number of symptom related segments, which have a reflux as defined above.

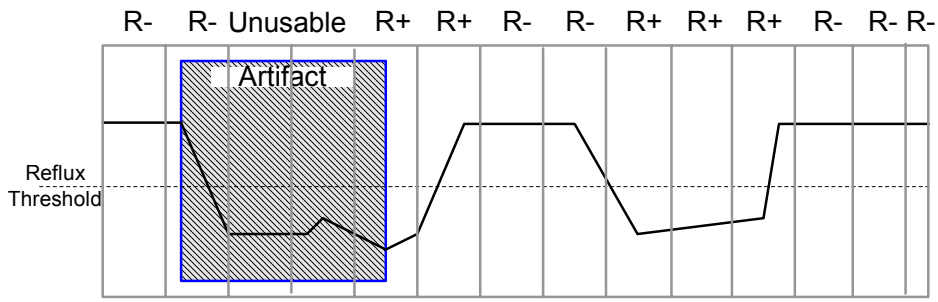
Calculation of S+R-

This calculation is done for each period type. 2-min segments are defined as occurring two minutes before the start time of each symptom marker associated with the period. These segments are symptom related.

S+R- is the total number of symptom related segments minus **S+R+**

Calculation of (R+) Total

All segments with reflux are counted as (R+) Total



Calculation of (R+) Total = 5

Calculation of S-R+

The total period is divided into 2-min segments. These segments are not symptom related.

S-R+ is the total number of non-symptom related segments that has a reflux as defined above.

Calculation of S-R-

The total period is divided into 2-min segments. These segments are not symptom related.

S-R- is the total number of non-symptom related segments minus **S-R+.**

Formula for Calculation of *SAP*.

$$P = \frac{(a+b)!(c+d)!(a+c)!(b+d)!}{a!b!c!d!(a+b+c+d)!}$$

where, **P =** probability factor

a = S+R+
b = S-R+
c = S+R-
d = S-R-

Kaye Value

The Kaye Score Method is described in M.D. Kaye, "Postprandial gastro-oesophageal reflux in healthy people", in *Gut*, 1977:

The aim of this study was to determine whether or not the normal lower oesophageal sphincter remains continuously competent under physiological conditions, and thereby to provide a more solid basis for the definition of the incompetence of the

lower oesophageal sphincter; and to devise a test applicable to the investigation of physiological and pharmaceutical influences upon its competence…

With the pH electrode in place, the subject ate a standard meal consisting of a glass of orange juice, two scrambled eggs, two slices of buttered toast, and a cup of coffee. After ingestion of the meal, he lay supine on a bed with one or two pillows for three hours, during which pH was recorded continuously. Smoking was not permitted….

Periods of time during which oesophageal pH was between 5 and 4, 4 and 3, 3 and 2, and 2 and 1 were measured for each hour of a recording, and for the total recorded time. Each period at a given pH level was then expressed as a percentage of the recording time.

A crude scoring system was devised in order to approximate the amount of reflux in each subject. For periods between 5 and 4, 4 and 3, 3 and 2, and 2 and 1, multiplication factors of 1,2,3, and 4 respectively, were applied."

The **Kaye Score** is calculated as follows:

1. The % of time pH is between 5 and 4 is multiplied by 1
2. The % of time pH is between 4 and 3 is multiplied by 2
3. The % of time pH is between 3 and 2 is multiplied by 3
4. The % of time pH is between 2 and 1 is multiplied by 4
5. The products are summed together, and the total value is presented as the Kaye Score.

DeMeester Scoring Graphs

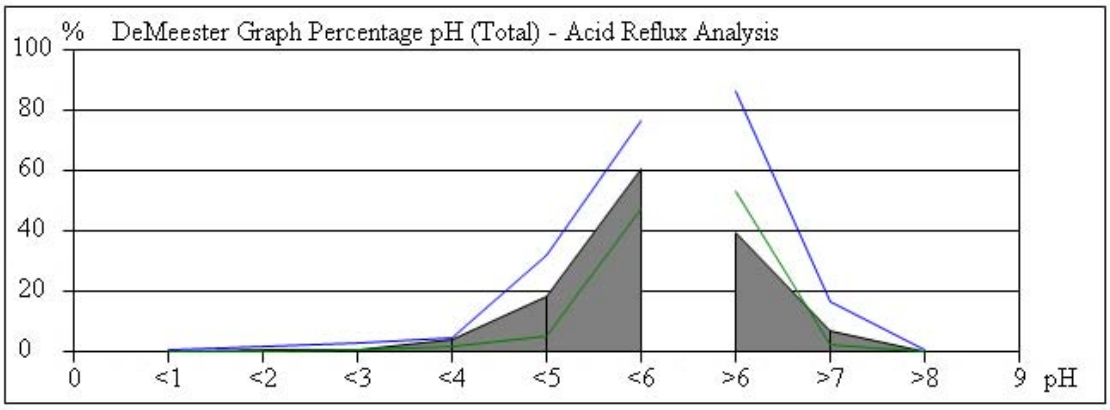
This is simply a way of graphically presenting the DeMeester normals and patient values for each of the relevant parameters on a single graph.

The calculations for these parameters are made and displayed on a single graph for all the acid reflux threshold levels (pH < 1, pH < 2, pH < 3, etc. to pH < 6) as well as for all alkaline reflux threshold levels (pH > 6, pH > 7, pH > 8). This forms the x-axis.

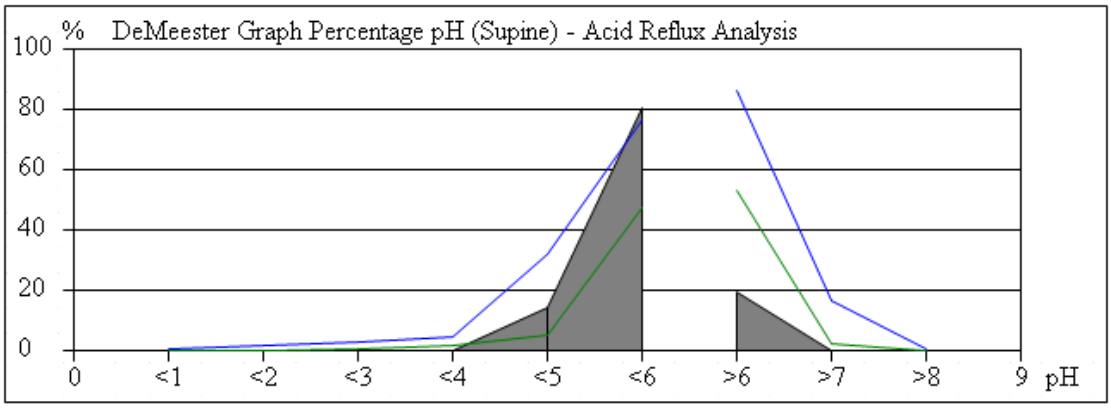
For each of the standard DeMeester parameters, there is one graph depicting the DeMeester normals and patient values. The values for the parameter form the y-axis. This gives a total of seven DeMeester graphs available, one for each of the six parameters and one for the total score.

The following DeMeester graphs are available:

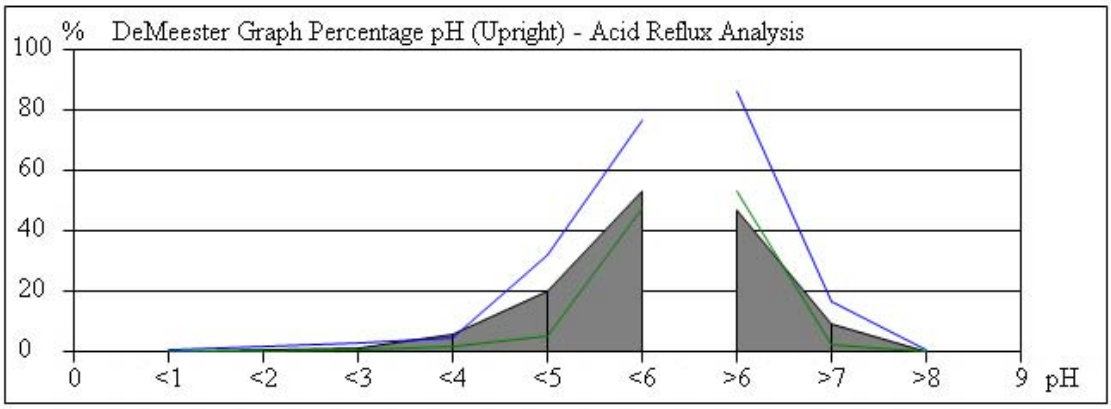
- Percent time pH < x (acid) or > y (alkaline) TOTAL
- Percent time pH < x (acid) or > y (alkaline) SUPINE
- Percent time pH < x (acid) or > y (alkaline) UPRIGHT
- No. Reflux Episodes
- No. Episodes > 5.0 Minutes
- Duration of Longest
- Composite DeMeester Score



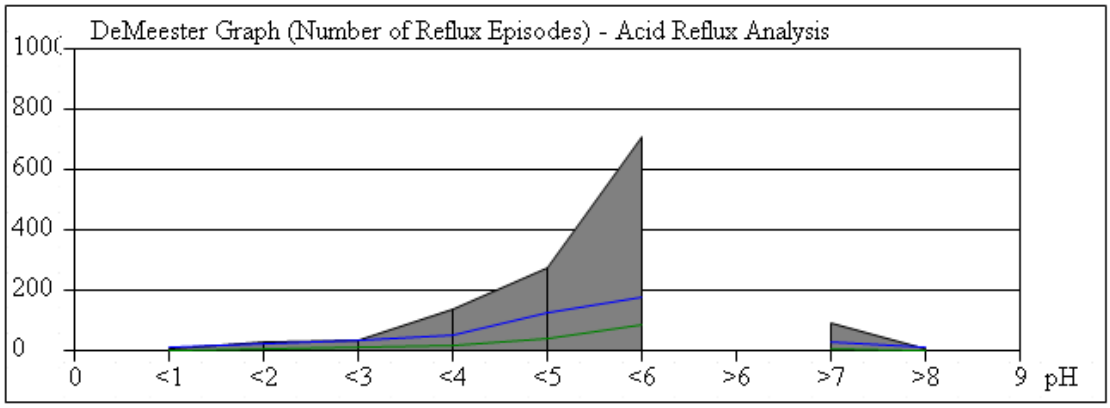
DeMeester Graph % pH Total Period



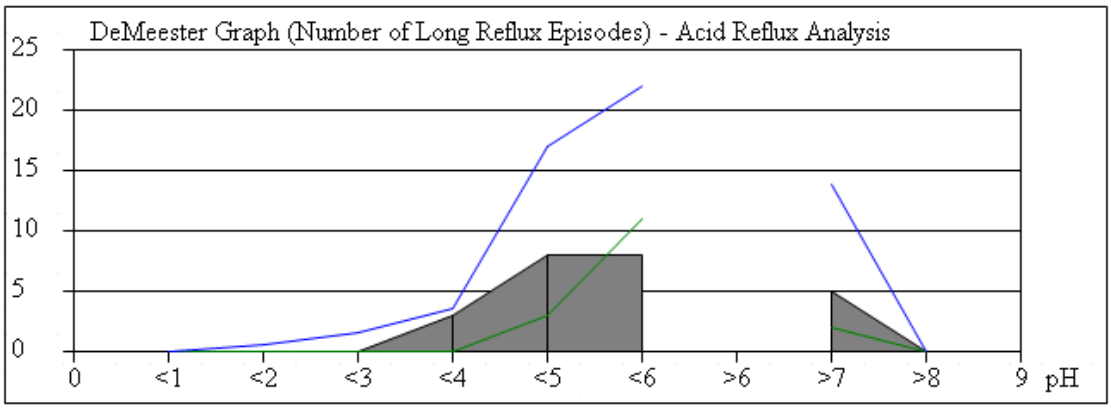
DeMeester Graph % pH Supine Period



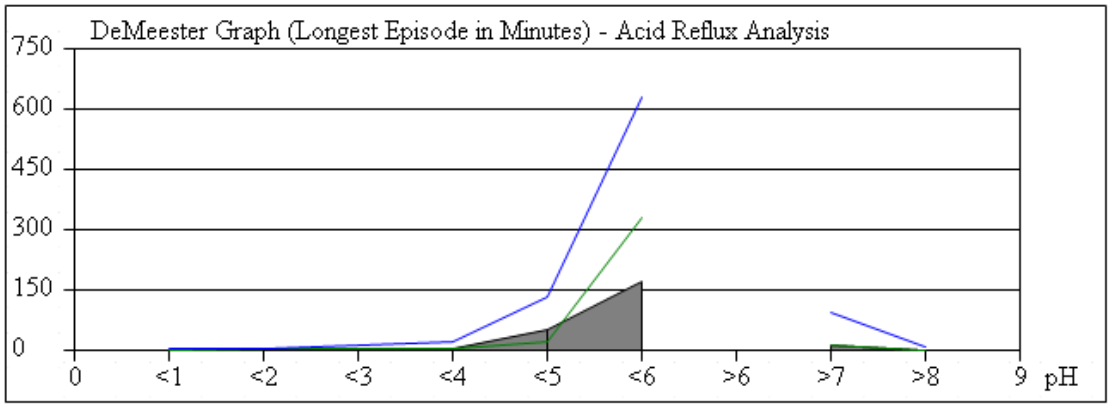
DeMeester Graph Percentage pH Upright Period



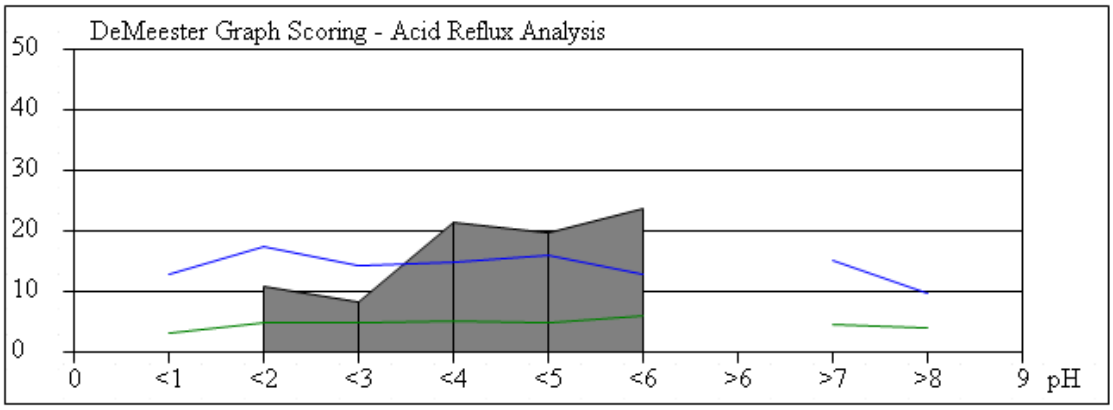
DeMeester Graph Number of Reflux Episodes



DeMeester Graph – Episode (# Longest and # Long)



DeMeester Graph Longest Episodes in Minutes

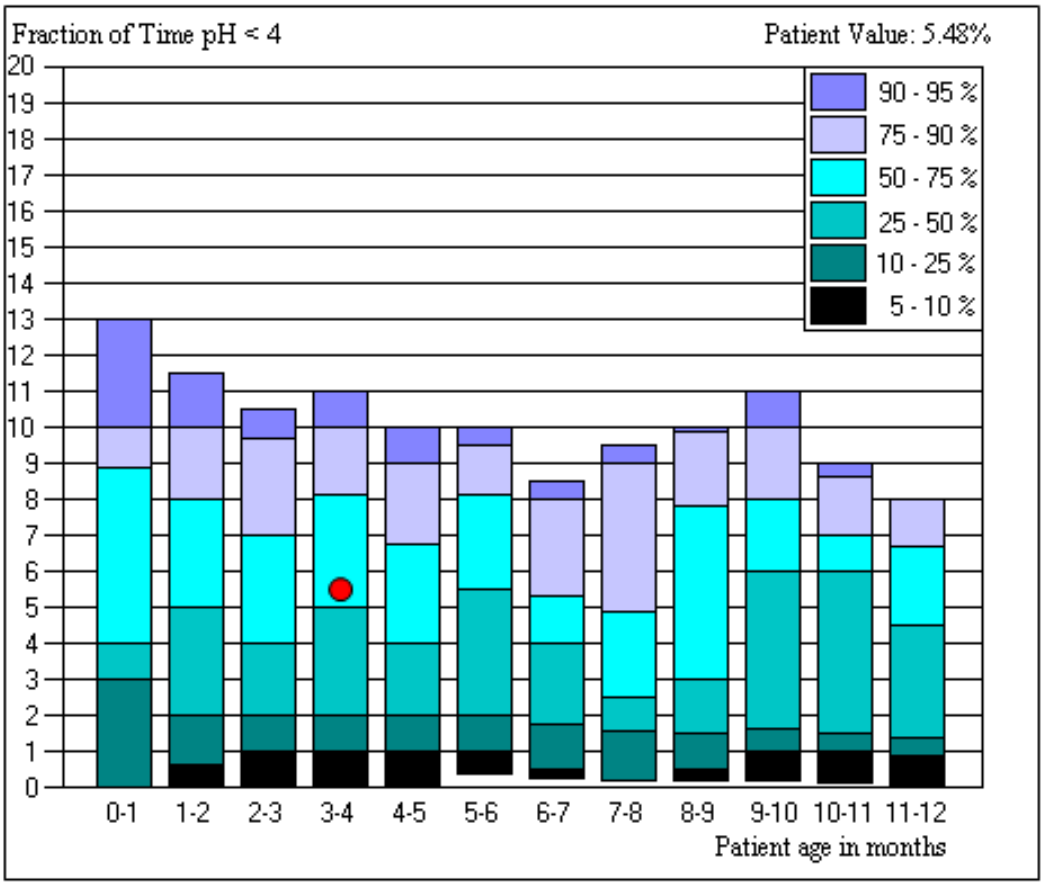


DeMeester Scoring Graph

Infant Graph

The purpose of percentile graphs for Infant Normals is to make it possible to compare patient data with normal data. This will indicate whether or not, the infant patient, up to one year of age, has a normal percentage total time pH < 4.00. The percentile graph shows the patient value in relation to the normal values.

Infant Graph - Acid Reflux Analysis



The percentile graphs for Infant Normals are described in Yvan Vanden-plas et al, "Gastroesophageal Reflux, as Measured by 24-hour pH Monitoring, in 509 Healthy Infants Screen for Risk of Sudden Infant Death Syndrome" in Pediatrics, Vol. 88, No. 4, October 1991.

Frequency Distribution Tables/Graphs

pH Frequency Distribution Table

The legal range [low;high[for the sampled values is divided into high-low integer ranges i.e. [low;low+1[,[low+1;low+2[,…,[high-1,high[and all the sampled values are sorted into these bins. The total number of samples is hereafter known and each bin is then reported displaying the size of the bin as a percentage of the total number of samples. The legal range for pH is per definition set to [0;8[.

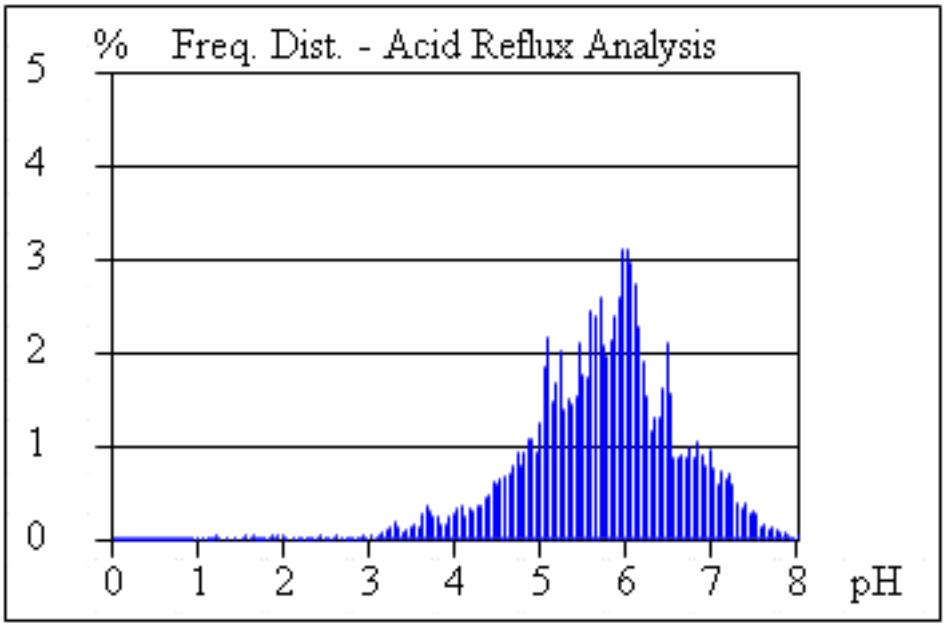
Frequency Distribution Table - Acid Reflux Analysis

pH	%
0-1	0.0
1-2	0.3
2-3	0.3
3-4	3.5
4-5	14.2
5-6	42.3
6-7	32.6
7-8	6.8

pH Frequency Distribution Graph

The legal range for pH values is divided into 256 bins and the sampled values are then sorted into these bins. The total number of samples is hereafter known and each bin is then plotted displaying the size of the bin as a percentage of the total number of samples.

The Frequency Distribution graphs display the percentage of time that the pH remained at certain levels for the total recording, and for the various periods. These distribution graphs are convenient for determining at what levels the recorded patient values remained for the major portion of the period. They are exactly like the Cumulative Percent Time graph, with one exception. In the frequency distribution graphs, the percentages represent times the pH remained at particular values, rather than below certain levels. The figure below shows the Frequency Distribution Graph for the total period.



Frequency Distribution Graph

Graph

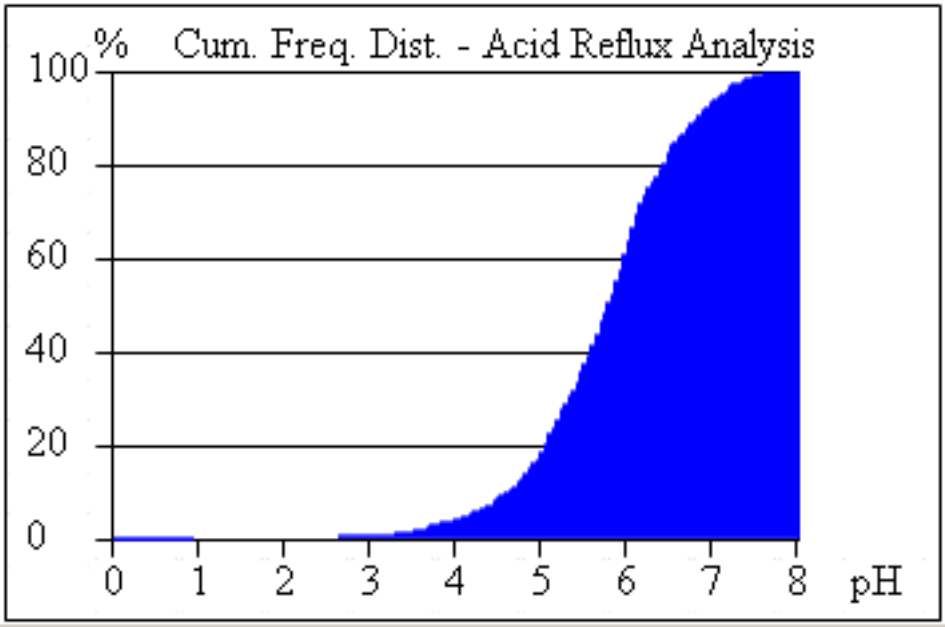
The horizontal axis (x-axis) on the bottom of the graph represents the percentages. Therefore, the filled area representing the patient data shows what percent of the time the pH remained at each of the pH levels.

Cumulative Frequency Distribution Tables/Graphs

The Cumulative Frequency Distribution graphs correspond to the cumulative frequency distribution table. These graphs display the percent of the time that the pH remained below certain levels for the total recording and for the various periods. They are cumulative because the percent time the pH remains below each level, it includes all the levels below it –e.g. the percent time the pH was below 6 includes the percent time below 5, 4, and so on.

The Cumulative Frequency Distribution Tables/Graphs are constructed in the same way as their counterpart in the Frequency Distribution Table/Graphs except that the displayed value consists of the cumulative value–i.e. for table with 3 bins; bin1, bin2 and bin3 the value displayed for bin1 is bin1, for bin2 (bin1 + bin2) and for bin3 (bin1+bin2+bin3).

Graph



Table

Cumulative Frequency Distribution Table - Acid Reflux Analysis

pH	%
0-1	0.0
1-2	0.4
2-3	0.7
3-4	4.2
4-5	18.4
5-6	60.7
6-7	93.2
7-8	100.0

Bile Analysis

Bile Reflux – Duodenogastric Reflux

"Importance of Bile Reflux in Barrett's Esophagus",
Michael F. Vaezi and Joel E. Richter, Barett's esophagus series, #4, Volume XlX Number 8.

"Although reflux of duodenal contents is commonly referred to as bile reflux, it pancreating enzymes) into the stomach, is important to remember that such refluxate contains more than just bile. Furthermore, the term "alkaline reflux" is often used interchangeably, suggesting than pH above 7 represents the reflux of duodenal contents into the lower esophagus. However, recent studies have questioned the accuracy of pH monitoring under these circumstances and suggest that the term "alkaline reflux" is a misnomer. Therefore, "duodenogastroesophageal reflux" (DGER) may be a more appropriate term, representing the retrograde reflux of duodenal contents (bile and pancreatic enzymes) into the stomach, with subsequent reflux into the esophagus. This is a normal phenomenon, occurring usually at night, and when excessive may produce symptoms or mucosal injury (13)."

"Does Duodenal Juice Reflux into the Esophagus of Patients with Complicated GERD ? Evaluation of Fiberoptic Sensors for Bilirubin" Kauer, DeMeester et al, The American Journal of Surgery, Vol. 169, Jan. 1995

"In conclusion, the Bilitec 2000 is a very useful and complementary tool to esophageal pH monitoring in the investigation of patients with foregut symptoms. Our results show that reflux of duodenal juice in addition to gastric juice does occur in patients with severe GERD, that gastroesophageal reflux can occur at normal esophageal pH levels, and in some patients may go unnoticed when esophageal pH monitoring is performed in isolation. The combination of pH and bilirubin esophageal monitoring will further our understanding and improve our care of patients with gastroesophageal reflux disease."

Absorbance Value – Bile Reflux

Bilirubin, the major pigment of bile, can indicate a bile reflux based on the assumption that bilirubin levels will mirror other bile constituents in gastric and esophageal refluxate. Using bilirubin as a marker, the time of gastroesophageal exposure to duodenal contents can be measured.

Bilirubin absorbance is measured with a fiberoptic system. The obtained absorbance value describes the degree to which the sample under study has absorbed the light emitted. The absorbance value is directly proportional (linear correlation) to the bilirubin concentration.

An absorbance value of 1 corresponds to an absorbance of 100%, i.e. 100% of the light is absorbed. An absorbance factor of 0.2 indicates that 20% is absorbed and so on.

"Long-Term Ambulatory Enteregostric Reflux Monitoring, Validation of a New Fiberoptic Technique", Paolo Bechi et al, Digestive Disease and Sciences, Vol. 38, No 7 (July 1993).

"Before discussing in vivo results, the following features must be underlined: (1) the great variability of bilirubin concentration in bile (20-800 mg/dl, 0.34-13.68 mmol/liter); (2) the great variability of bile concentration in refluxate; (3) the upper limit of the useful working range of the fiberoptic system (100 μmol/liter bilirubin concentration in bile), which corresponds to high reflux values; and (4) the lack of homogeneity of the gastric content in which both mucus and solid particles are suspended.

The fiberoptic system is able to accurately measure the contact time between the refluxate and gastric and/or esophageal mucusa. In contrast, for all the above mentioned reasons, although absorbance values could numerically express bilirubin concentration, they can only allow and approximate quantitative assessment of the overall bile reflux concentration."

Absorbance Threshold Value

Different studies have identified an absorbance threshold value beyond which bilirubin reflux was considered to take place–see example below. This threshold value is 0.14 absorbance units below which values could be accounted for by scattering effects caused by gastric contents (i.e. suspended particles and mucus). However, recent publications have indicated that a higher threshold should be used.

Bile reflux is discuss in P.Bechi, “Fiberoptic measurement of “alkaline” gastro-esophageal reflux: technical aspects and clinical indications”, in Diseases of the Esophagus (1994) 7 131-138.

“As well as for acid reflux for which an arbitrary threshold value was indicated in pH=4, bile-containing refluxes were considered to occur whenever the absorbance signal raised above 0.14 absorbance units. The latter conventional threshold value was selected because the combination of scattered particles in the gastric juice and background noise can determine an absorbance of 0.14 max.”

Frequency Distribution Table Bile (Absorbance)

The bins for a Bile Frequency Distribution Table are:
[0.00;0.14[,[0.14;0.20[,[0.20;0.30[,[0.30;0.40[,…,[0.70;0.80[

–See pH table above

Frequency Distribution Graph Bile

The legal range for Bile [0.0;0.8[values is divided into 256 bins and the sampled values are then sorted into these bins. The total number of samples is hereafter known and each bin is then plotted displaying the size of the bin as a percentage of the total number of samples.

–See pH Graph above.

Home

General

From the Home page, you can either create a new study based on the available ***Routine Protocols*** that appear in the View Selection Area, or open a study already in progress from the list of ***Ongoing Studies*** in the View Area.

The list of ***Ongoing Studies*** can be sorted out by:

- Created
- Patient Name
- Study Type
- Study ID

Ongoing Study: To access an Ongoing Study**,** locate its entry and ***Click.***

Routine Protocol: Create a New Study by using a Routine Protocol available from the View Selection Area and ***Click***.

Both options will take you to the ***Study Details*** view. —See *Study Details*, under the Studies section.

Studies

Study Manager

The Study Manager provides an overview of all the studies performed in the system.

To focus on a particular list of studies, you can filter the View by clicking on the ***View*** header. From the box that appears, choose one of the options and ***Click***.

- All Studies
- Completed Studies
- Ongoing Studies

The View can also be sorted out by:

- Created
- Patient Name
- Patient ID
- Study Type
- Study ID
- Comment

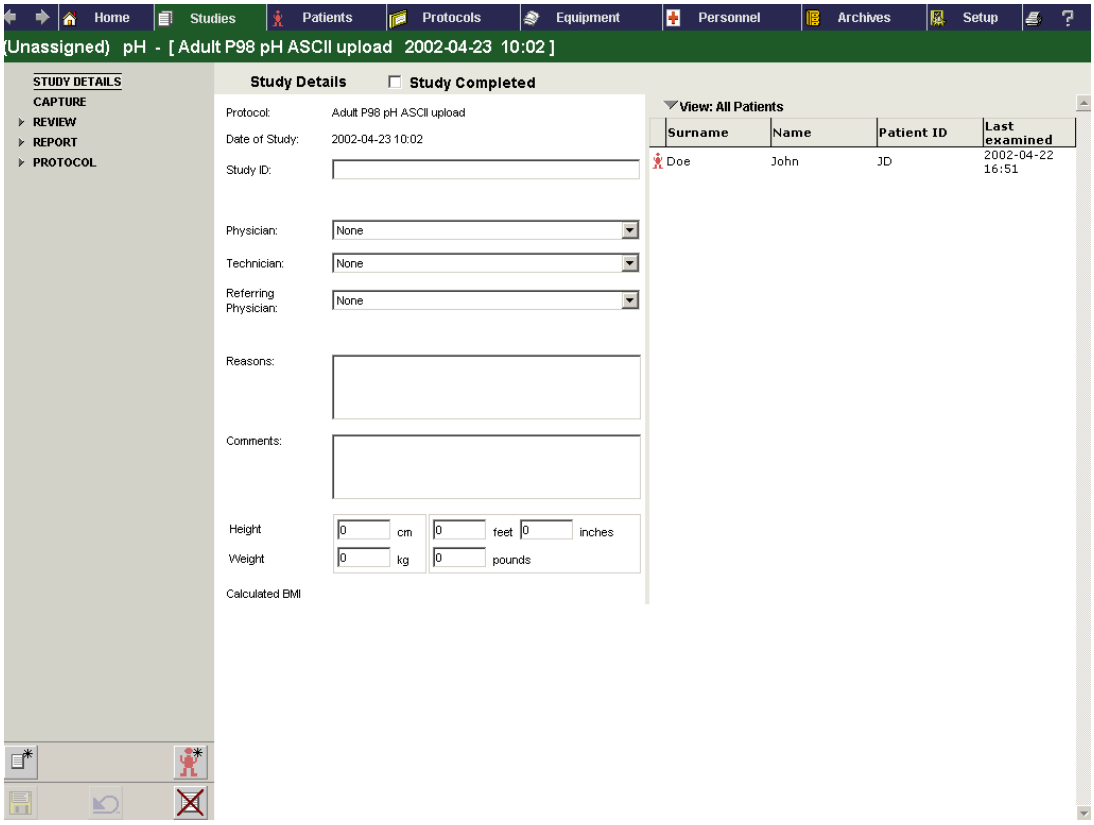
You can delete a study directly from the list by right-clicking the selected entry, and then clicking on the ***Delete Study*** box.

To access a Study, locate its entry and ***Click***.

Study Details

The ***Study Details*** page will be displayed allowing you to edit the details of a Study. The ***All Patients*** list that appears in the same view will give you an overview of all the patients in the system. The ***All Patients*** list can be sorted out by:

- Surname
- Name
- Patient ID
- Last Examination Date



Study Details

The following information will be shown on the Study Details page:

- Protocol Name
- Date of Study

The following information can be entered in the Study Details page:

- Date of Study
- Study ID
- Physician
- Technician
- Referring Physician
- Reasons
- Comments
- Height
- Weight

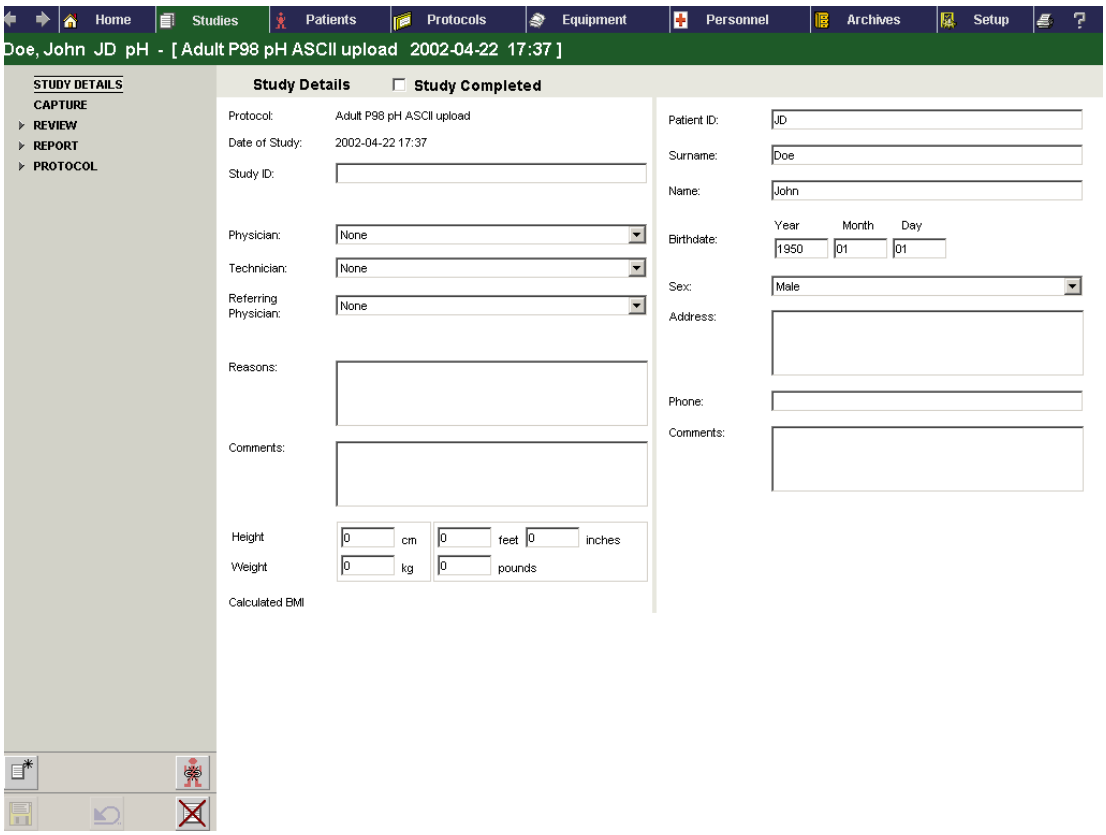
Assign Patient

From the ***All Patients*** list, you can now assign a patient to the study by clicking the corresponding entry. The Patient Details page for that specific patient will be displayed.

Create New Patient

You can create a New Patient by clicking the ***Create New Patient*** button in the Tool Area. The following Study Details page will be displayed allowing you to enter information on the patient:

- Patient ID
- Surname
- Name
- Date of Birth
- Sex
- Address
- Phone
- Comments



Study Details

NOTE If the study has been marked as completed, you will only be able to view its information. Clear the ***Study Completed*** option box to be able to add/modify existing information in the study.

Create New Study

To create a new Study, click the ***Create New Study*** button in the View Selection Area. A list with all the available Protocols will be displayed. Select the Protocol the Study should use and ***Click.***

The Study Details view will be displayed allowing you to enter any relevant information for the study.

From the ***All Patients*** list on the right, you can now choose an existing patient, or create a new one by clicking the ***Create New Patient*** button in the Tool Area.

Tool Area

Create New Study

Create New Patient

Un-assign Patient

Undo Changes

Save Changes

For Study Details on Medical Guidelines, and Data Upload refer to the User Guide.

Patients

Patient Manager

The ***Patient Manager*** provides an overview of all the patients registered in the system.

To focus on a particular list of patients, you can filter the View by clicking the ***View*** header. From the box that appears, choose one of the options and ***Click***.

- All Patients
- Ongoing Studies
- Male Patients
- Female Patients
- Undefined Patients
- Infants (age 0-1)
- Children (age 1-5)
- Young (age 5-15)
- Adult (age 15-45)
- Middle (age 45-70)
- Elderly (age70 +)

The View can also be sorted out by:

- Patient ID
- Surname
- Name
- Date of Birth
- Sex
- Last Examined
- Comments

You can create a New Study for a specific patient directly from the list by right-clicking on the desired entry, and then clicking on the box that appears.

To access a ***Patient Details*** page, locate its entry and ***Click***.

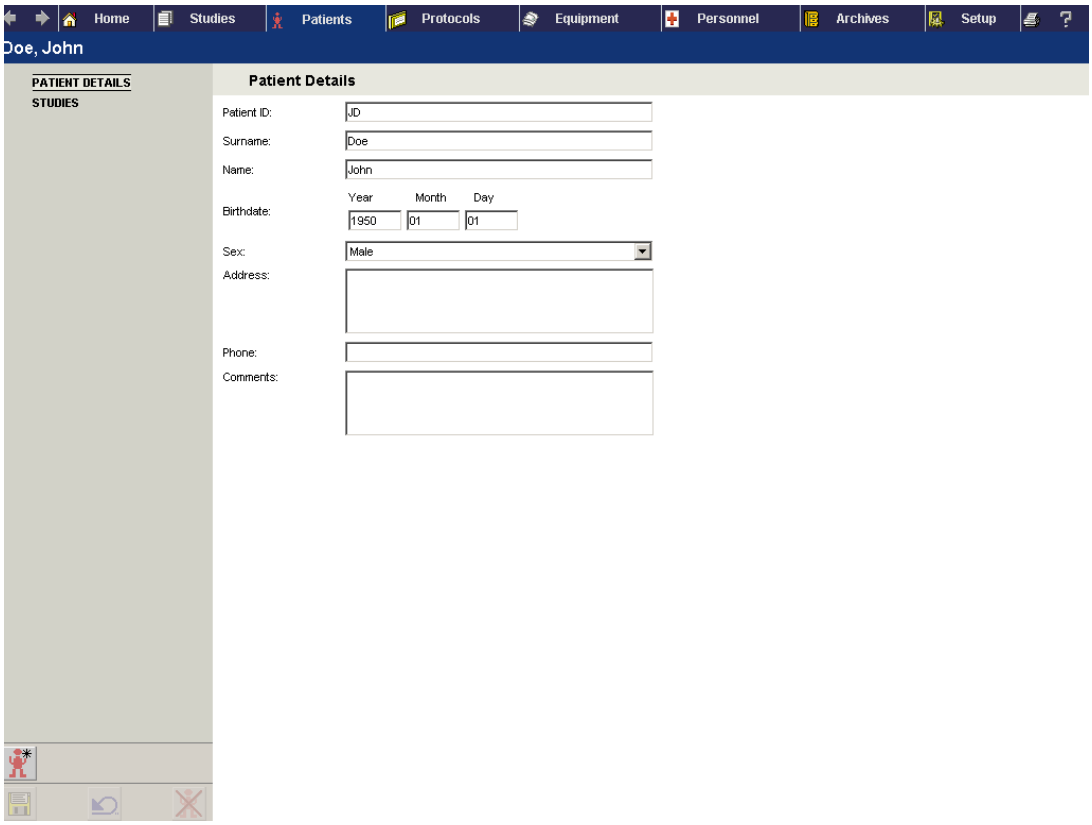
Creating New Patient

From the ***Patient Manager*** view, you can create a new patient by clicking the ***New Patient*** button in the Tool Area.

Patient Details

The ***Patient Details*** page is displayed allowing you to view and modify the following information on a particular patient.

- Patient ID
- Surname
- Name
- Date of Birth
- Sex
- Address
- Phone
- Comments



Patient Details

The above information is optional. You can leave out any fields that you do not consider relevant for the study. When you type in the date of birth, the fields will turn red until the complete date has been entered. If an invalid date is used, it will not be saved.

When modifying information on the Patient Details page, a Caution sign will be displayed warning you that the new information entered is not saved.

Tool Area

Create New Patients

Delete Patient

Undo Changes

Save Changes

NOTE Patients assigned to a study ***cannot*** be deleted.

Protocol

Protocol Manager

The Protocol Manager provides an overview of all the protocols defined in the system.

To focus on a particular list of protocols, you can filter the View by clicking the ***View*** header. From the box that appears, choose one of the options and ***Click***.

- All Protocols
- Routine Protocols

The View can also be sorted out by:

- Extension
- Protocol Name
- Routine Protocol
- Comment

Protocols can be deleted directly from the list by placing the cursor over the Protocol of your choice, right-clicking it, and then from the box that appears click the desired option.

To access the ***Protocol***, locate its entry and ***Click***.

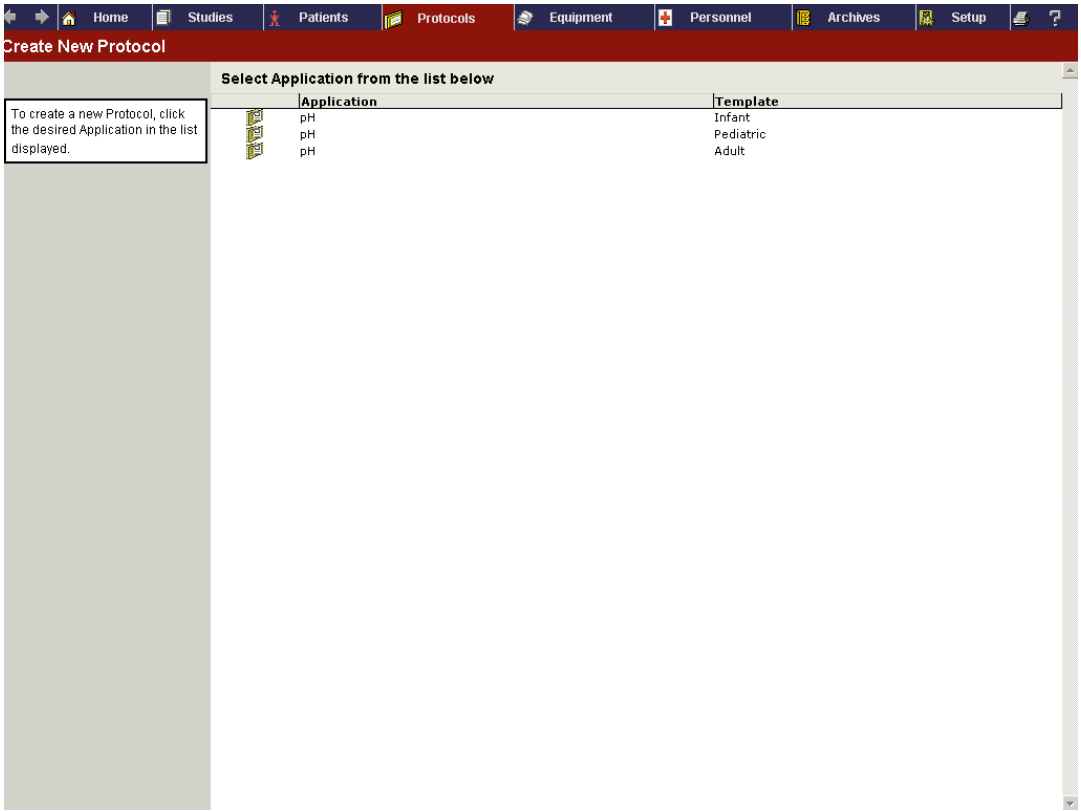
Create New Protocol

To create a new Protocol, click the ***Create New Protocol*** button from the Tool Area. The following list of available templates for pH will be displayed.

- pH Adult
- pH Pediatric
- pH Infant

NOTE The Infant Graph is only available in the Infant Template.

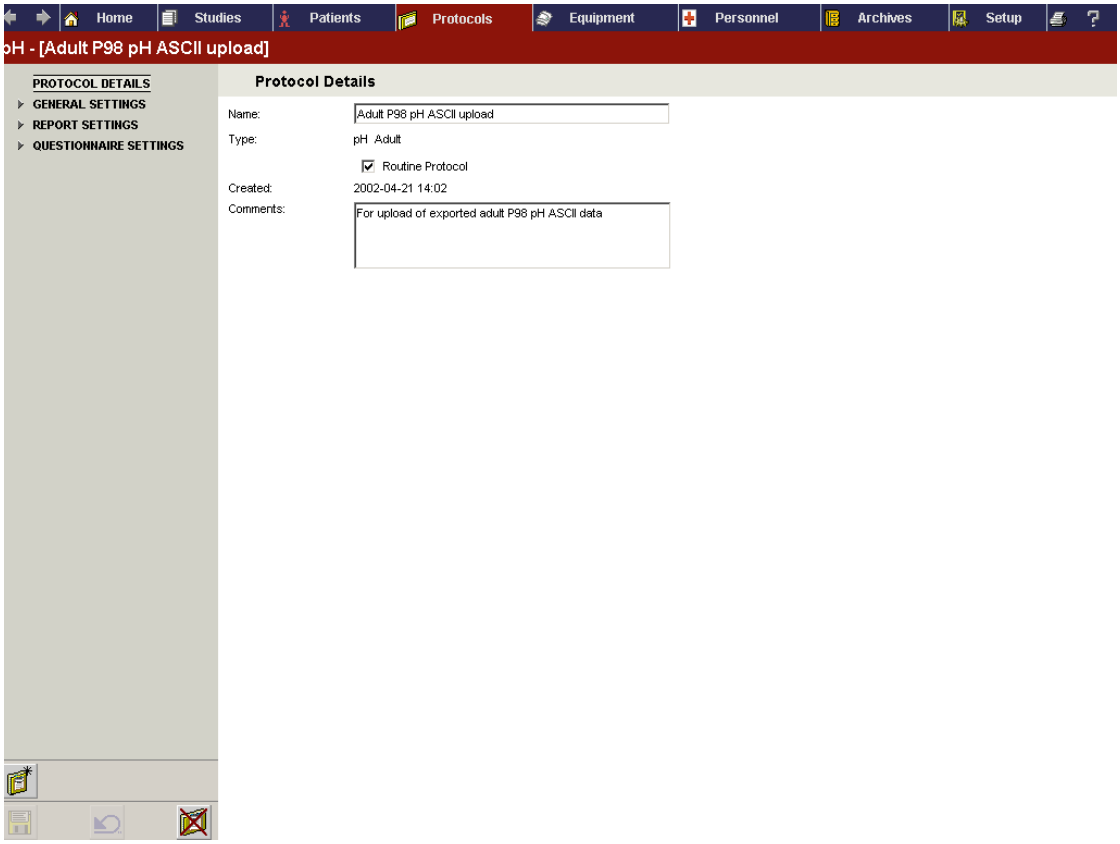
Click the Template you would like to use for this protocol. The pH—Protocol Details page will now be displayed.



Protocol Details

The Protocol Details page is displayed allowing you to:

- Enter the Name of the Protocol
- Check the ***Routine Protocol*** option box
- Enter comments in the ***Comments*** box



Protocol Details

When the ***Routine Protocol*** option box is selected, the protocol will appear in the list of Protocols displayed in the View Selection Area on the Home page.

Tool Area

Create New Protocol

Save Changes

Undo Changes

Delete Protocol

pH — General Settings

Through the General Settings view, you can configure a new Protocol, or modify an existing one. When a Protocol is assigned to a study, a copy of the Protocol will be made. Subsequent changes to the Protocol made in the Protocol Manager will not affect protocols copied into a study. Protocols assigned to a study can be modified from the Study Manager.

Equipment / Channel Configuration: When selecting Equipment, the channel configuration for the specific equipment will be shown. –See the *Equipment* section for details on Equipment/Devices.

You can use a specific device, or a generic pH —i.e. data can be uploaded from ***Digitrapper pH, Bravo pH Receiver***, ***MarkIII,*** and ***Bilitec 2000*** devices.

CAUTION When performing a combined pH and Bile study, make sure the pH device is always selected first in the protocol.

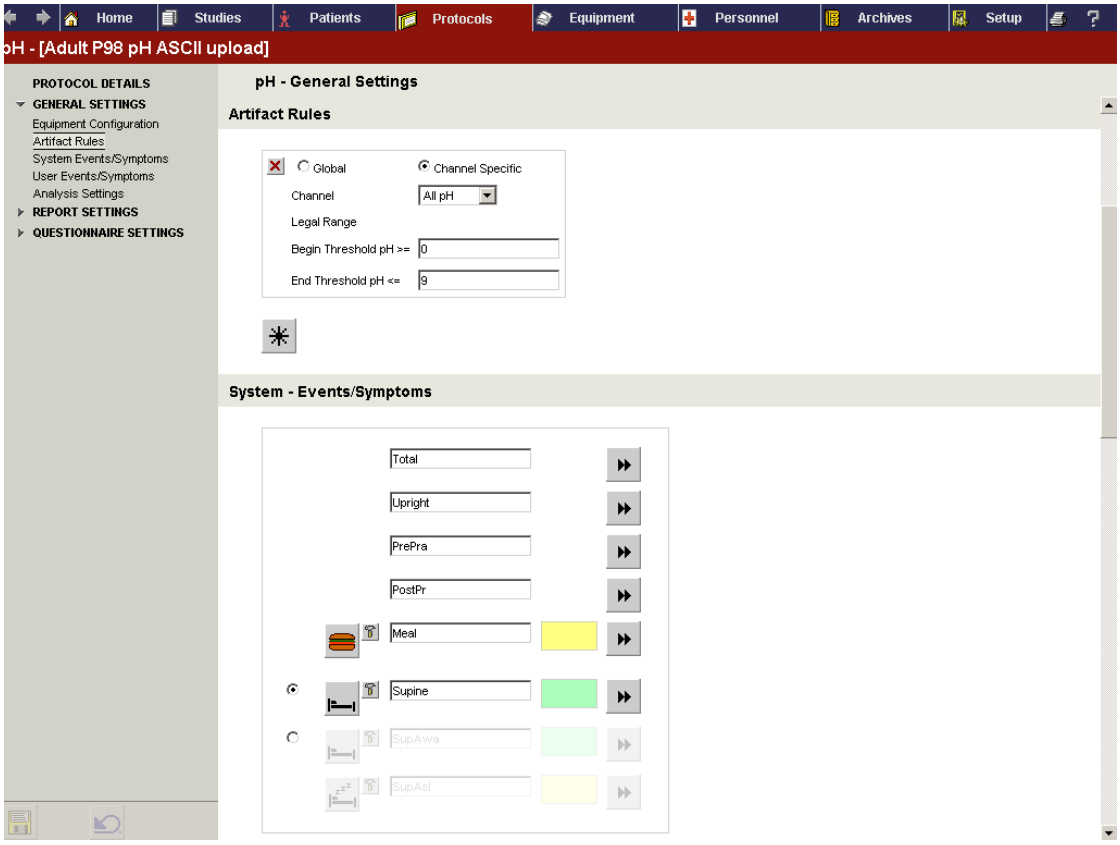
CAUTION Always upload pH data first when uploading Bile and pH data for the same study.

By clicking the asterisk, you can define the number of equipments/devices that you wish to use.

Channel Label: The channel number will appear on the box.

Color: For ease identification, a color label for each channel can be chosen by clicking the Color box and selecting a color from the pallet displayed.

Compression: Select the compression —e.g., Min/Max —for each channel by clicking the drop-down box.



Tool Area

Save Changes

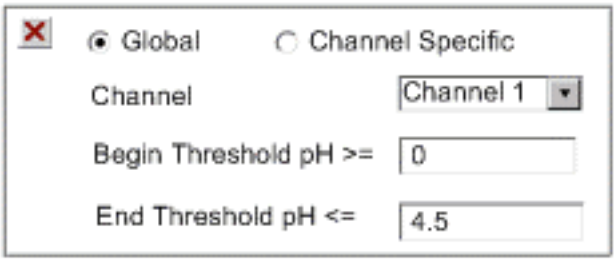
Undo Changes

Artifact Rule

The Artifact Rule defines the pH absorbance value valid range for a given channel. All values outside this Range will result in an Artifact Marker inserted. The Artifact Marker can be either Global or Channel Specific. The Begin and End Thresholds define the legal valid range.

Global: All channels selected
Channel Specific: Specific channel selected
Channel No: Select channel number.
Begin Threshold pH > = 0
End Threshold pH < = 9

NOTE Using "Any pH" in ***Channel*** will affect All pH Channels.



By Clicking the Asterisk, you can define any number of Artifact Rules you wish to include in Protocol.

NOTE Artifacts can also be marked manually by entering an artifact marker in the tracing for a given channel. They can also be added into the Diary by giving specific Start and End times.

Tool Area

Save Changes

Undo Changes

Event and Symptom Buttons

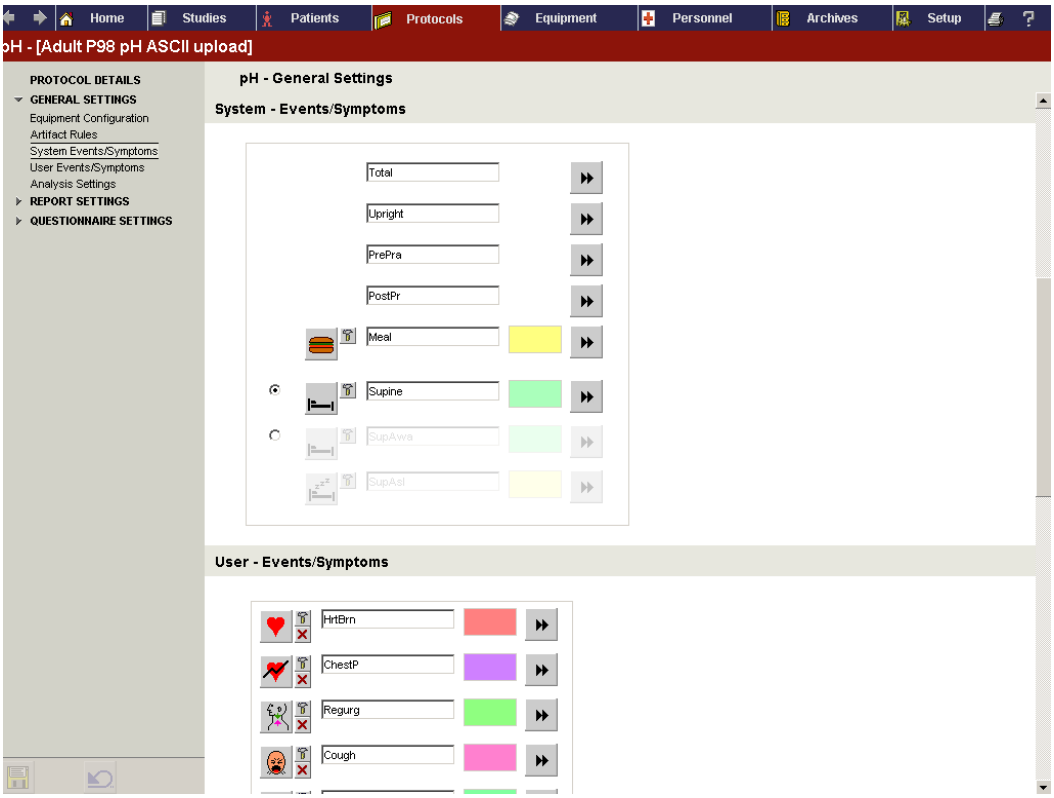
System — Events and Symptoms

The following is a list of the Events and Symptoms defined by the System:

Total = Total length of the Study
Upright = Total – Supine
Supine= Merged Period of SupineAwake and SupineAsleep
Prone=Period in Prone Position (Only for infants and pediatric usage)
Preprandial = Total – Meal – Postprandial
Meal= Meal Period

- Color labels are not user definable for Total**,** Upright, or Preprandial Periods**.**
- Total**,** Upright and Preprandial Periods are not marked as periods in the Traces.
- Periods are only used for analysis and reports.
- Artifacts are always excluded from periods.

Click the Arrow button to access the Advanced Settings Option for each Event and Symptom, allowing you to enter a description.



System-Events/Symptoms

Tools

To assign a button to an Event/Symptom, click the Assign button, and from the box displayed select a button to represent the specific Event or Symptom.

For ease identification, a color label for each Event and Symptom can be chosen by clicking the Color box and selecting a color from the palette displayed.

User — Event and Symptom

The ***Event*** and ***Symptom*** buttons are user-defined indicators that are used to show a special area of interest in the analysis.

- You can define as many Event and Symptoms buttons as you need to include in the study.

The following is an example of User-defined Events and Symptoms:

Events

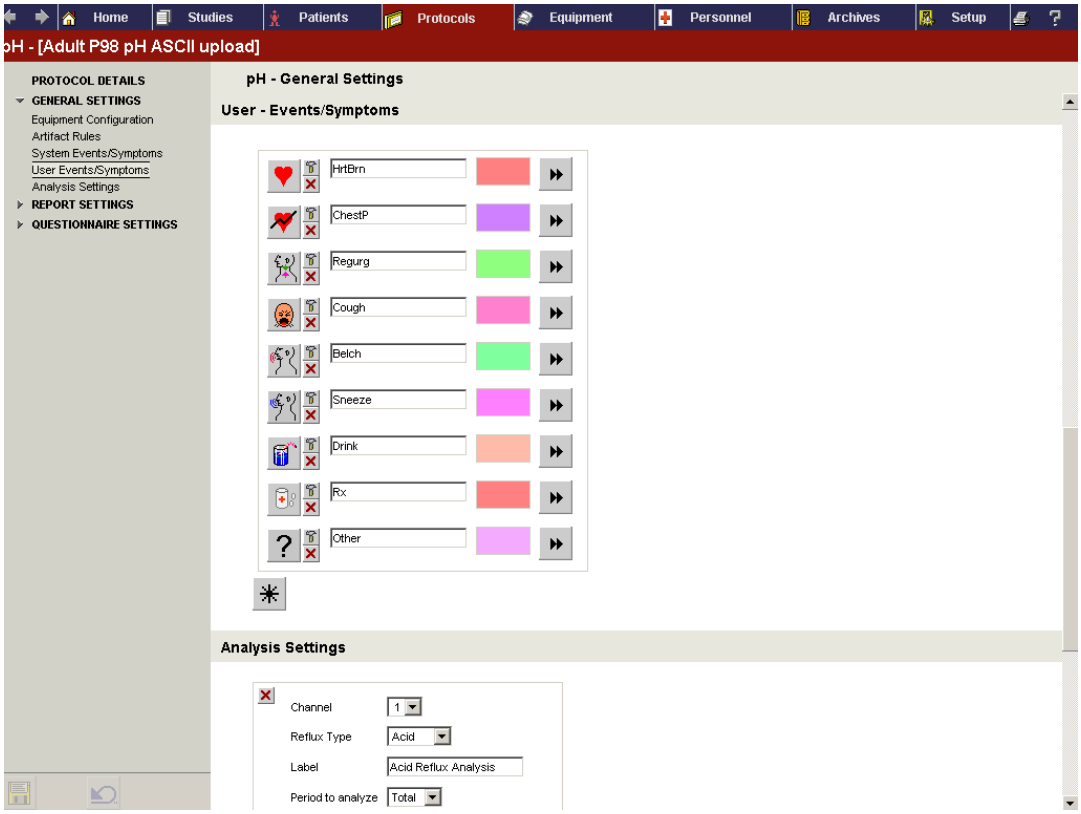
- Meal
- Smoking
- Drinking
- Sleeping

Symptoms

- Heartburn
- Chest Pain
- Regurgitation
- Belch

The order the Symptoms and Events are defined influences the default assignment of the symptom buttons in capture during the upload.

Click the Arrow button to access the Advanced Settings Option for each Event/Symptom Periods. It allows you to select between Event and Symptom, and enter its description.



User–Event/Symptoms

Tools

To assign a button to an Event/Symptom, click the Assign button, and from the box displayed select a button to represent the specific Event or Symptom.

To delete an Event or Symptom, click the Delete button.

Heartburn The name of the Event or Symptom selected appears on the Label box. You can also enter a name of your choice.

For ease identification, a color label for each Event and Symptom can be chosen by clicking the Color box and selecting a color from the palette displayed.

By Clicking the Asterisk, you can define any number of Events and Symptoms you wish to include in the Protocol.

Tool Area

Save Changes

Undo Changes

Analysis Settings

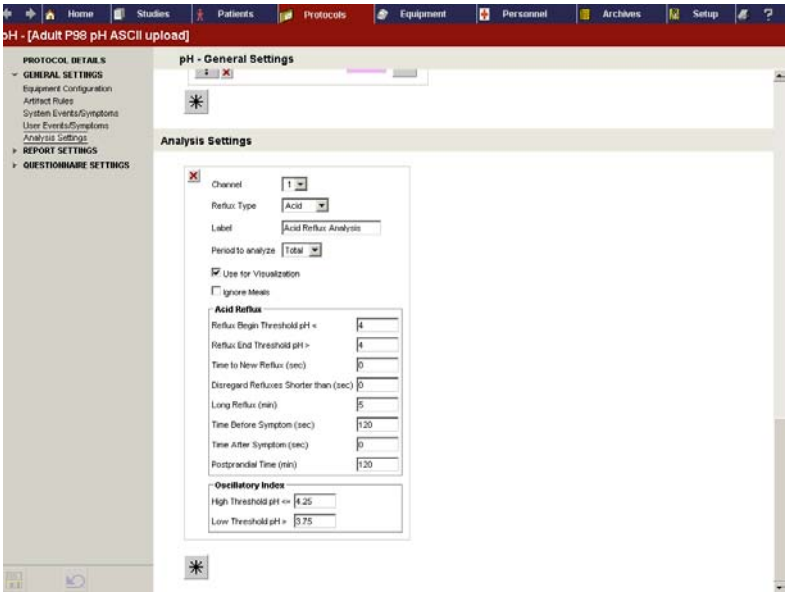
From the drop-down lists, choose the Channel number, Type of Channel and Label.

Acid Reflux Analysis

The following settings are available for the ***Acid Reflux*** analysis:

- **Use for Visualization:** Display Begin / End threshold as solid lines on traces. Only one per Channel, if more than one is selected, the first defined is used.
- **Ignore Meals:** If enabled, meal periods are subtracted from periods.
- **Reflux Begin Threshold pH<:** The pH value must drop below in order to be considered a reflux.
- **Reflux End Threshold pH >:** The maximum value the pH level can rise to without resulting in a new reflux.
- **Time to New Reflux (sec):** The minimum time between two refluxes.
- **Disregard Reflux Shorter than (sec):** The minimum length of a reflux.
- **Long Reflux min:** The minimum length of a long reflux,
- **Time before Symptom (sec):** It is used for SAP calculations.
- **Time after Symptom (sec):** It is used for SAP calculations.
- **Postprandial Time (min):** Postprandial period defined as number of minutes after a meal.
- **Oscillatory Index:** Defines the legal range for the Oscillatory Index
  - **High Threshold pH<:**
  - **Low Threshold pH >:**

  Define the]low; high[range to be considered for the Oxcillatory Index



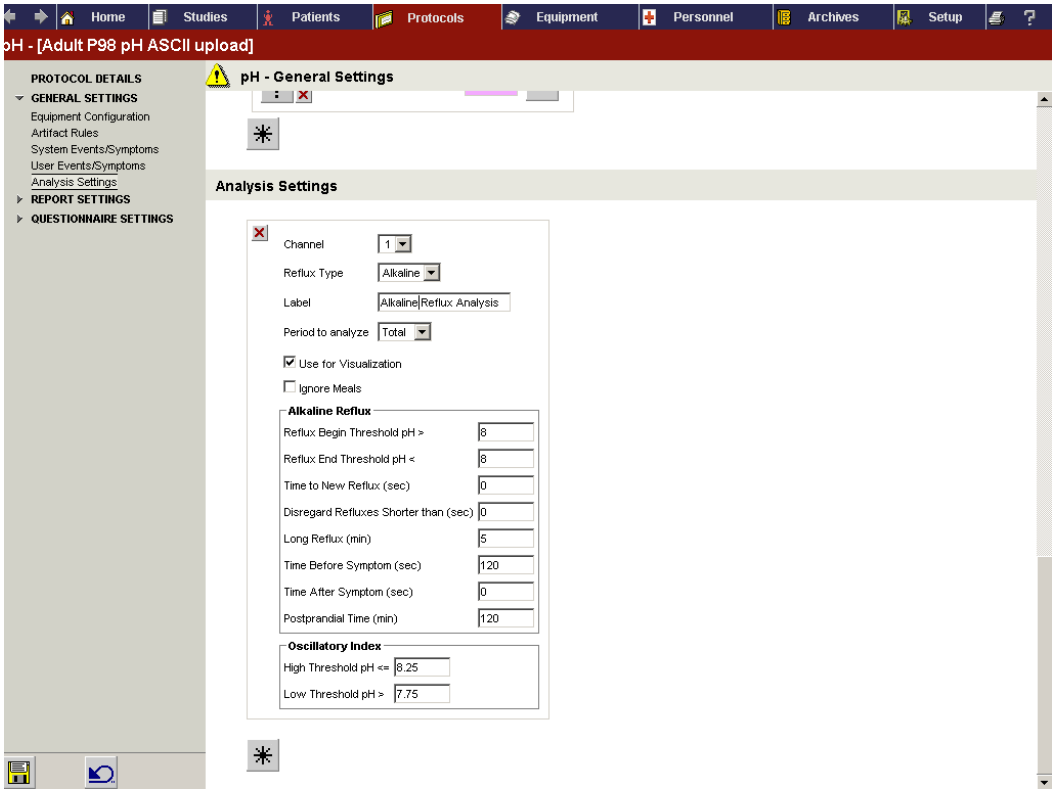
Acid Reflux Analysis Settings

Alkaline Reflux Analysis

The following settings are available for the ***Alkaline Reflux*** analysis:

- **Use for Visualization:** Display Begin / End threshold as solid lines on traces. Only one per Channel, if more than one is selected, the first defined is used.
- **Ignore Meals:** If enabled, meal periods are subtracted from periods.
- **Reflux Begin Threshold pH<:** The pH value must drop below 4.00 in order to be considered a Reflux.
- **Reflux End Threshold pH >:** The maximum value the pH level can rise to without resulting in a new reflux.
- **Time to New Reflux (sec):** The minimum time between two refluxes.
- **Disregard Reflux Shorter than (sec):** The minimum length of a reflux.
- **Long Reflux min:** The minimum length of a long reflux,
- **Time before Symptom (sec):** It is used for SAP calculations.
- **Time after Symptom (sec):** It is used for SAP calculations.
- **Postprandial Time (min):** Postprandial period defined as number of minutes after a meal.
- **Oscillatory Index:** Defines the legal range for the Oscillatory Index
  - **High Threshold pH<**
  - **Low Threshold pH >**

  Define the]low; high[range to be considered for the Oxcillatory Index



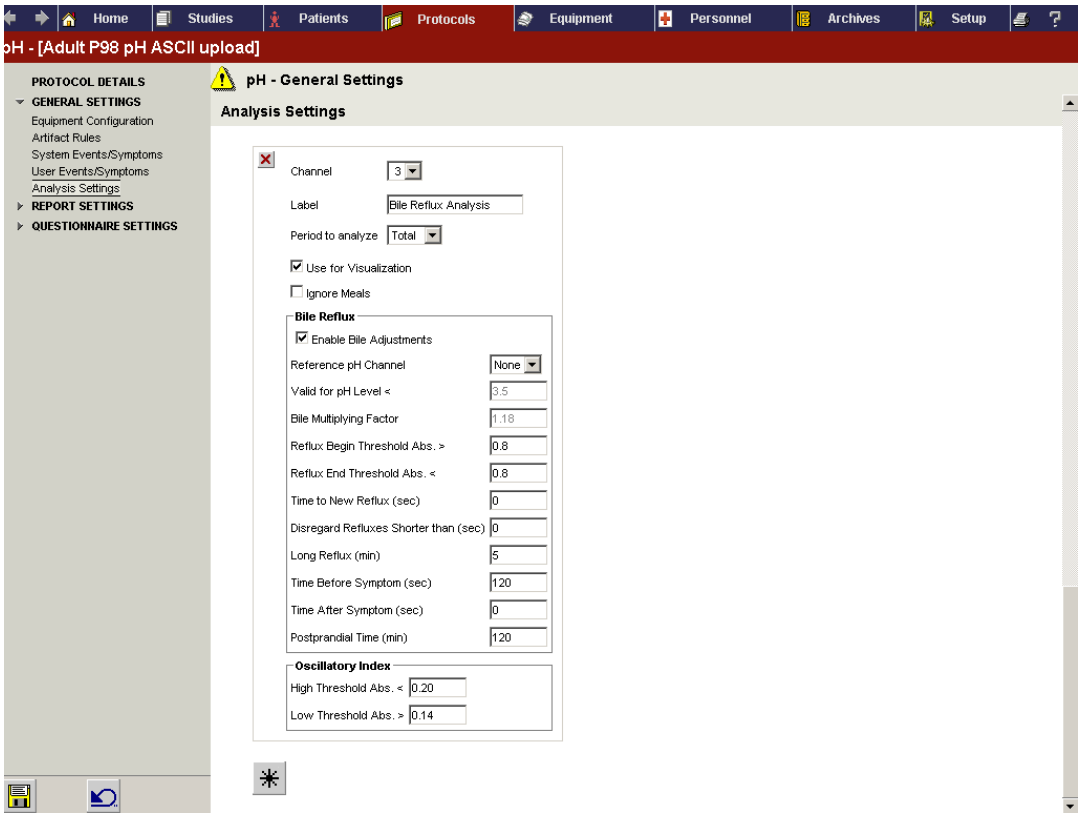
Alkaline Reflux Analysis Settings

Bile Reflux Analysis

The following settings and options are available for the ***Bile Reflux*** analysis:

- **Use for Visualization:** Display Begin / End threshold as solid lines on traces. Only one per Channel, if more than one is selected, the first defined is used.
- **Ignore Meals:** If enabled, meal periods are subtracted from periods.
- **Enable Bile Adjustment:**
  - **Reference pH Channel:** pH Channel used to control the Correction Factor (optional).
  - **Valid for pH Level<:** High Threshold for Reference pH Channel.
  - **Bile Correction Factor:** Factor to adjust bilirubin level.
- **Reflux Begin Threshold Abs<:** The maximum value the Abs level can rise to without resulting in a new reflux.
- **Reflux End Threshold Abs >:** The Abs value must drop below in order to be considered a reflux.
- **Time to New Reflux (sec):** The minimum time between two refluxes.
- **Disregard Reflux Shorter than (sec):** The minimum length of a reflux.
- **Long Reflux (min):** The minimum length of a reflux.
- **Time before Symptom (sec):** Used for SAP calculations
- **Time after Symptom (sec):** Used for SAP calculations
- **Postprandial Time (min):** Postprandial period defined as number of minutes after a meal
- **Oscillatory Index:** Defines the legal range for the Oscillatory Index
  - **High Threshold Abs<:**
  - **Low Threshold Abs>:**

Define the]low; high[range to be considered for the Oxcillatory Index



pH General Settings–Bile Reflux

Click the Arrow button to access the Advanced Settings option for the ***Acid, Alkaline*** and ***Bile*** channels.

By Clicking the Asterisk button, you can define any number of Analyses for a given channel.

By clicking the Arrow buttons, you will have access to the Adult and Pediatric/Infant templates.

Report Settings

Reports created from Protocol Details can be edited and formatted. Click ***Report*** under Report Settings in the View Selection Area.

From the drop-down list in the Tool Area, you can choose the elements that you want to include in the report. Select the element and click the Arrow button, a menu with the different options for that element will open. Select the option for it to appear in the Report.

The Elements/entries in the report can be moved about by clicking the Free-placement button in the Tool Area. When the Free-placement is Off, you can edit an entry by clicking its Edit Text icon. Use the Arrows icon to select/deselect the order of the items in the table. New columns can be added to a table by clicking the Create New icon, or entering the number in the Max Number of Columns box. To delete an entry, click its Delete icon.

Report Header: In the report header, the name of the report and hospital can be edited. An icon such as a hospital logo can also be included.

Report Content: The main report consists of results generated by the application analysis, and of user created content.

The user created contents can be moved about as the other items in the report.

The following Report Elements are available:

pH Analysis Tables

- DeMeester % Table – Total
- DeMeester % Table – Upright
- DeMeester % Table – Supine
- DeMeester Table – Episodes (Standard)
- DeMeester – Number of Long Episodes (Standard)
- DeMeester – Number of Longest Episodes (Standard)
- DeMeester Scoring Table (Standard)
- Cumulative Frequency Distribution Table
- Frequency Distribution Table
- Reflux Table
- SAP Table
- SI Table
- DeMeester Table

- DeMeester Johnson Table
- DeMeester Score
- Boix Ochoa Score
- DeMeester–Johnson Score

pH Analysis Graphs

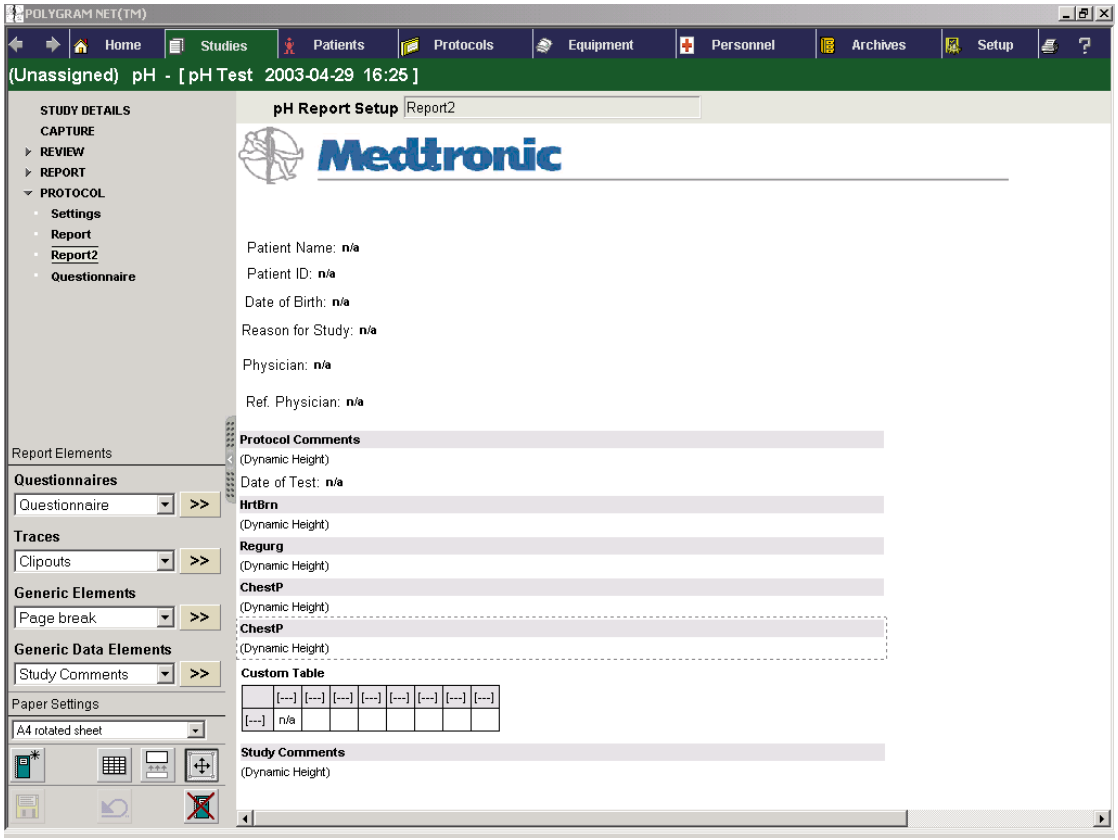
- Infant Graph
- DeMeester Graph Percentage pH – Total
- DeMeester Graph Percentage pH – Supine
- DeMeester Graph Percentage pH – Upright
- DeMeester Graph – Number of Reflux Episodes
- DeMeester Graph – Number of Long Reflux Episodes
- DeMeester Graph – Number of Longest Reflux Episodes in Minutes
- DeMeester Graph – Scoring
- Frequency Distribution Graph
- Cumulative Frequency Distribution Graph

Diary Information

- Type of Event
- Type of Symptom
- Start Date
- Start Time
- End Time

Clip Out

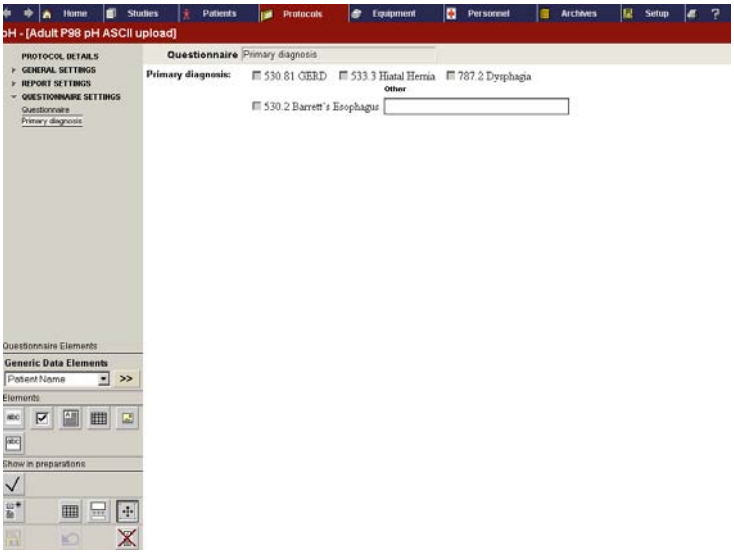
- Clip Outs can be added to the report from Capture and Review.



pH Report Setup

Questionnaire Settings

In Questionnaire Settings, a white page is displayed allowing you to create your own questionnaire form.



Questionnaire Settings

From the Tool Area, choose the elements you want to include in the questionnaire by clicking their corresponding button. The elements selected from the drop-down list are added to the page after you click the ***Double Arrow*** button.

Click the ***Free Placement*** button to be able to move the element boxes around the page. Place the mouse on the edge of the Element Box for a 4-arrow to appear allowing you to drag it to any position on the page.

You can also resize the Element Box by pulling its borders.

Click the delete button to delete a box.

Click the ***Show in Preparation*** button for the questionnaire to appear in the ***Preparation*** view.

Generic Element Boxes

The following ***Generic Element*** buttons are available in the Tool Area, and when selected, they add the following elements to the Questionnaire:

Header	Text	Comment
Grid On	Add Paper	Free Placement
Check Box	Table	Image

Tool Area

Delete Questionnaire

Create a New Questionnaire

Save Changes

Undo Changes

Equipment

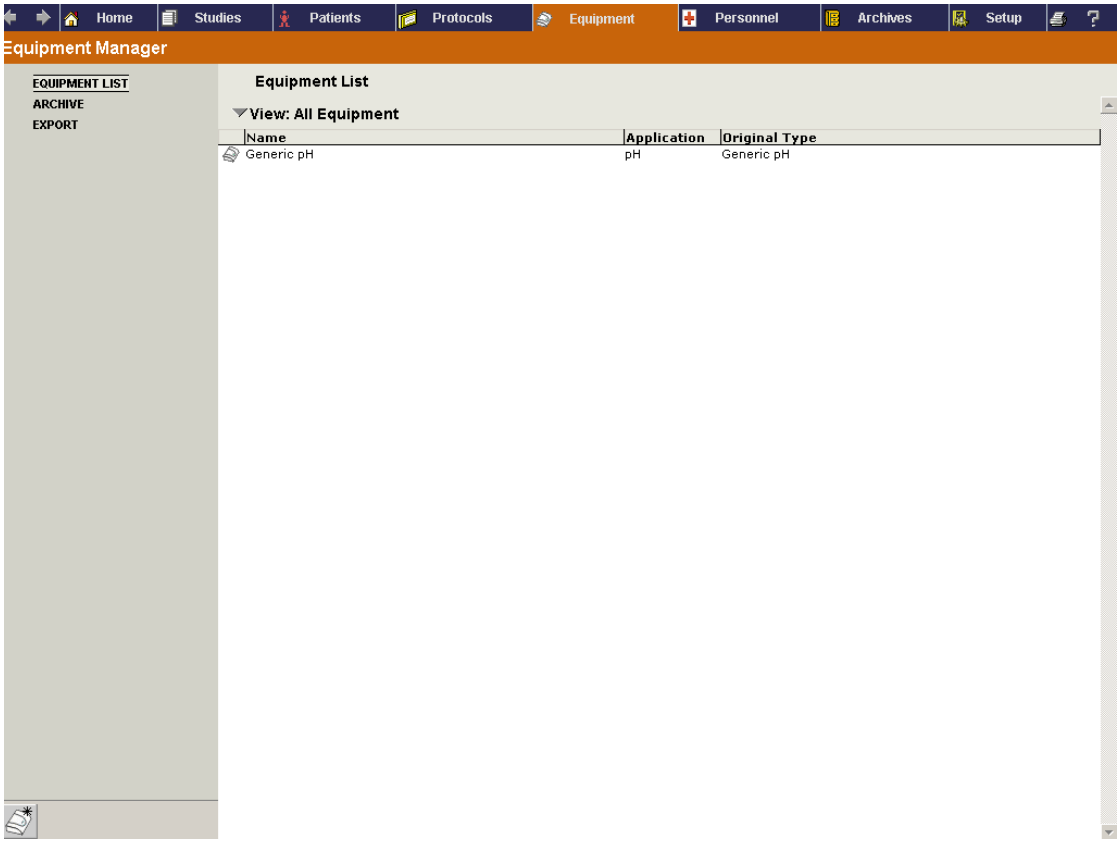
Equipment Manager

The Equipment Manager displays a list of all the Devices/Equipments registered in the system.

The View can be sorted out by:

- Name
- Application
- Original Type
- In Use

To access the ***Equipment Configuration*** for specific equipment, locate its entry and ***Click***.

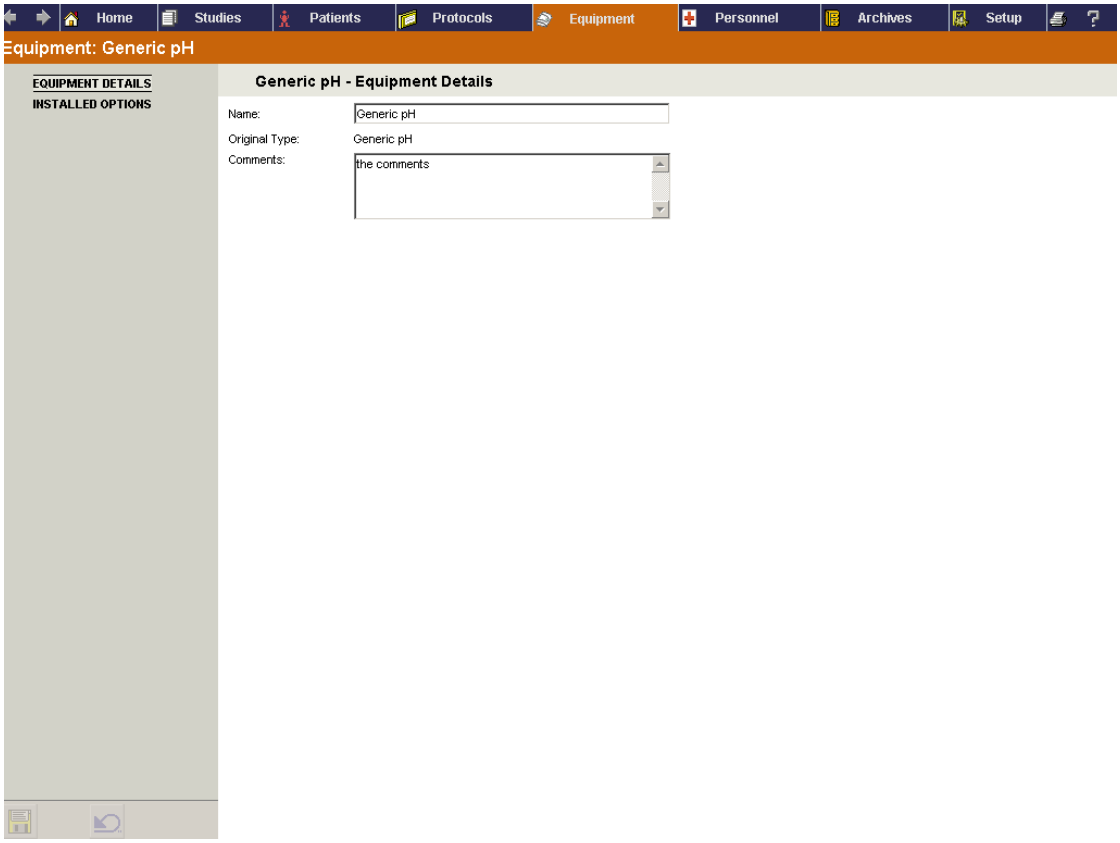


All Equipment

Equipment Details

In the Equipment Details view displayed, the name and the original type of the equipment (Generic pH) will be shown. Type-in boxes are available allowing you to enter the following information:

- Name
- Comments



Generic pH —Equipment Details

Tool Area

Create New Equipment

Save Changes

Undo Changes

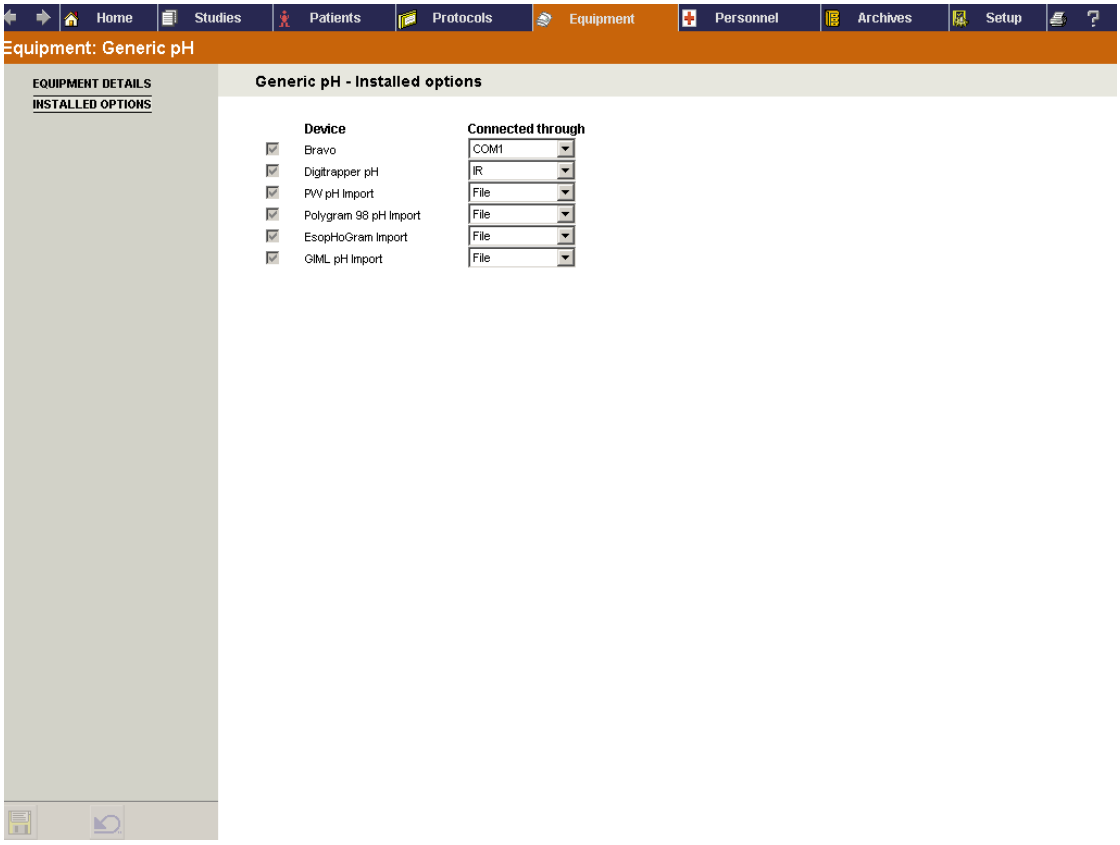
Delete Equipment

Installed Options

In Installed Options, only those devices that are installed appear on the ***Installed Options*** list.

The ***Generic pH*** Equipment can handle uploads from the following devices:

- Bravo pH Receiver
- Digitrapper pH
- Bilitec 2000
- PW pH Import
- Polygram 98 pH Import
- ASCII
- Digitrapper Mark III
- EsopHogram Import
- GIML Import



Generic pH –Installed Options

Tool Area

Save Changes

Undo Changes

pH Data Sources

The pH testing application accepts data from a number of sources:

- Upload from Bravo receiver
- Upload from Digitrapper pH
- Bilitec 2000
- Data import from Polygram for Windows
- Data import from Polygram 98
- Upload from Digitrapper Mk III
- Data import from EsopHoGram
- Data import in GIML format

The source is selected in the Equipment Configuration part of the protocol. The data is uploaded by pressing the red recording icon next to the device in capture. If the source is a physical device, the data will be uploaded from the device and if the source is a file a file browser will pop up so the user can select the file to import.

Upload from Bravo pH receiver

When using this data source a bravo infrared dongle is used to upload data from the Bravo receiver to POLYGRAM NET™.

Upload from Digitrapper pH

When using this data source an infrared dongle is used to upload data from the Digitrapper pH to POLYGRAM NET™.

Bilitec 2000

When using this data source a cable is connected between the Digitrapper Mk III and the computer on which POLYGRAM NET™ is running.

Data import from Polygram for Windows (PW)

When importing pH data from PW, a file browser opens when pressing the upload button in Capture. Using this file browser, locate the PW pH file (extension .inf) and select open.

Data import from Polygram 98

pH ASCII exports from Polygram 98 can be imported into POLYGRAM NET™. When importing pH data from Polygram 98, a file browser opens when pressing the upload button in Capture. Using this file browser, locate the Polygram 98 pH file (extension .asc) and select open.

Upload from Digitrapper Mk III

When using this data source a cable is connected between the Digitrapper Mk III and the computer on which POLYGRAM NET™ is running.

Data import from EsopHoGram

When importing pH data from EsopHoGram DOS, a file browser opens when pressing the upload button in Capture. Using this file browser, locate the EsopHoGram pH file (extension .txt) and select open.

Data import in GIML format

When importing pH data in GIML format, a file browser opens when pressing the upload button in Capture. Using this file browser, locate the GIML pH file (extension .xml) and select open.

Personnel

Personnel Manager

The Personnel Manager provides an overview of all the personnel known to the system—Physicians, Referring Physicians and Technicians.

To focus on a particular list of personnel, you can filter the View by clicking on the ***View*** header. From the box that appears, choose one of the options, and ***Click***.

- All Personnel
- Physicians
- Technicians
- Referring Physicians

The List can also be sorted out by:

- Name
- Surname
- Physician
- Referring Physician
- Technician
- Comment

Personnel can be deleted directly from the list by placing the cursor over the desired entry, right-click it, and then click the ***Delete Personnel*** box that appears.

To open the ***Personnel Details*** page, select the desired entry in the list and ***Click***.

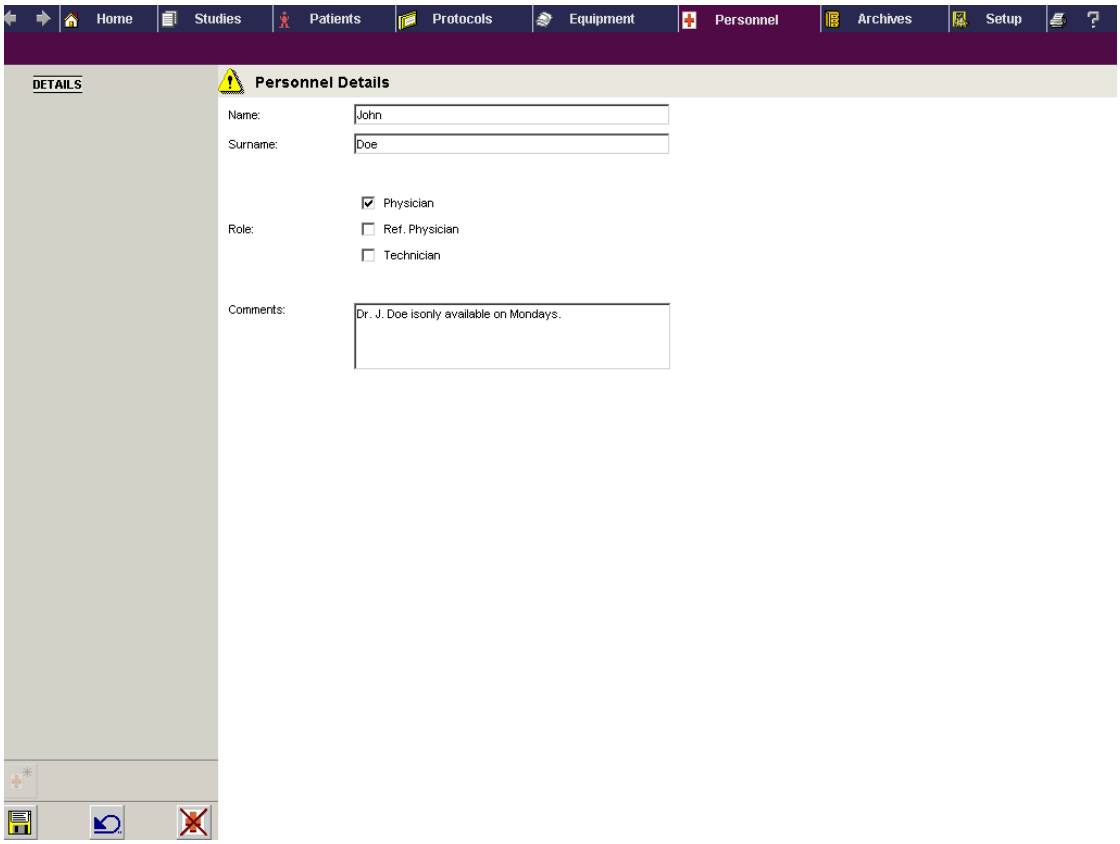
Creating New Personnel

To create New Personnel, click the ***New Personnel*** button in the Tool Area. The Personnel Details page will be displayed allowing you to enter the required information.

Personnel Details

Enter/select the following information:

- Name
- Surname
- Role:
  -Physician
  -Ref. Physician
  -Technician
- Comments



Personal Details

Tool Area

Create New Personnel

Delete Personnel

Undo Changes

Save Changes

NOTE Personnel Assigned to a study cannot be deleted.

Archives

Archive Manager

The Archive can be used as a regular backup, or to make a safety-copy. The following archives can be created:

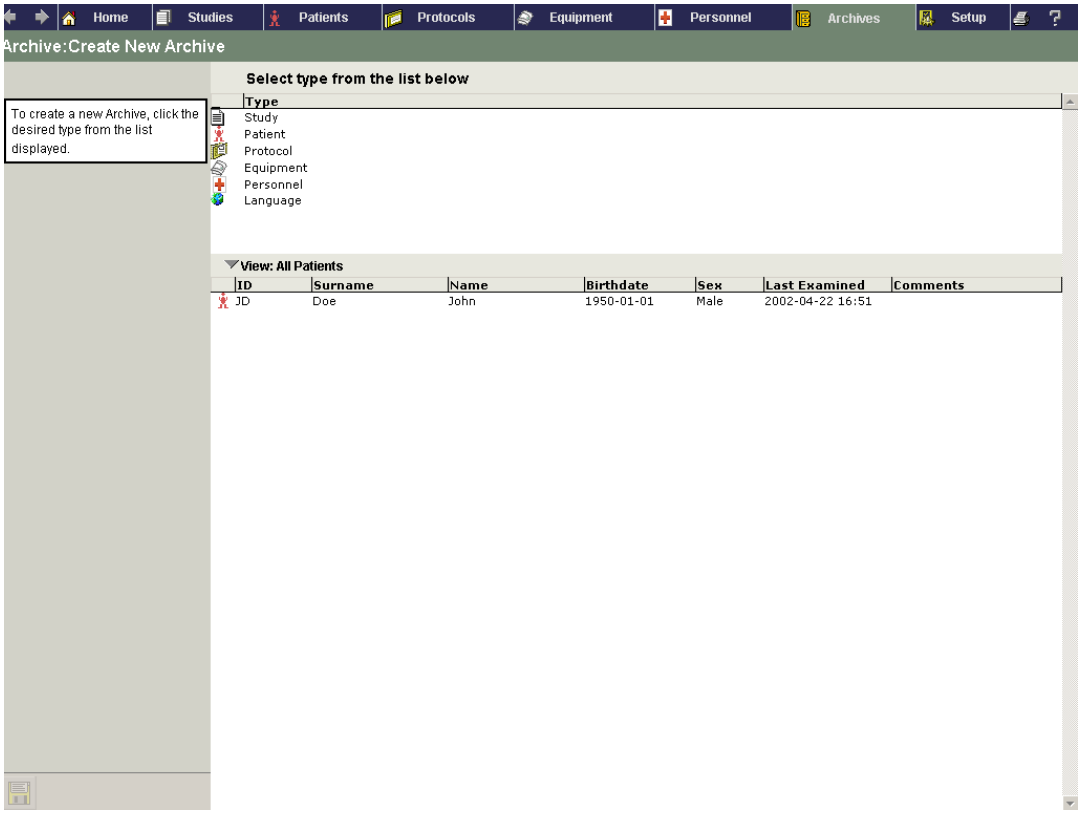
- Study
- Patient
- Protocol
- Equipment
- Personnel
- Languages

To review or retrieve an archive, locate its entry and ***Click***.

Create New Archive

To create a new Archive, click the ***Create New Archive*** button in the Tool Area. A list with all the types of archives will be displayed. Click on the type of archive you wish to create, and from the list below select the entries you wish to include. To save the New Archive, click the ***Save*** button in the Tool Area.

- When creating archives of Patients, Protocols, Equipments, or Personnel a copy will be created and saved in a file. The data will not be removed from POLYGRAM NET™.
- When creating archives of Studies they will be saved in a file and removed from the POLYGRAM NET™. Only ***Completed Studies*** can be archived.



Register New Archive

To register a new archive, click the ***Register New Archive*** button in the Tool Area. An Open Dialog box will be displayed allowing you to enter the name of the file.

Export

To export an archive, click the ***Export*** button in the Tool Area. From the list displayed, select the type of export you want, and click. A view will appear allowing you to select one or more entries. Click the ***Save*** button in the Tool Area to save the exported copy of the file/s. An Open Dialog box will be displayed where you can enter the name of the file. When exporting an archive —it is just a copy that is being exported; the data remain in the system.

Tool Area

Create New Archives

Register New Archives

Export Archives

Save Changes

Setup

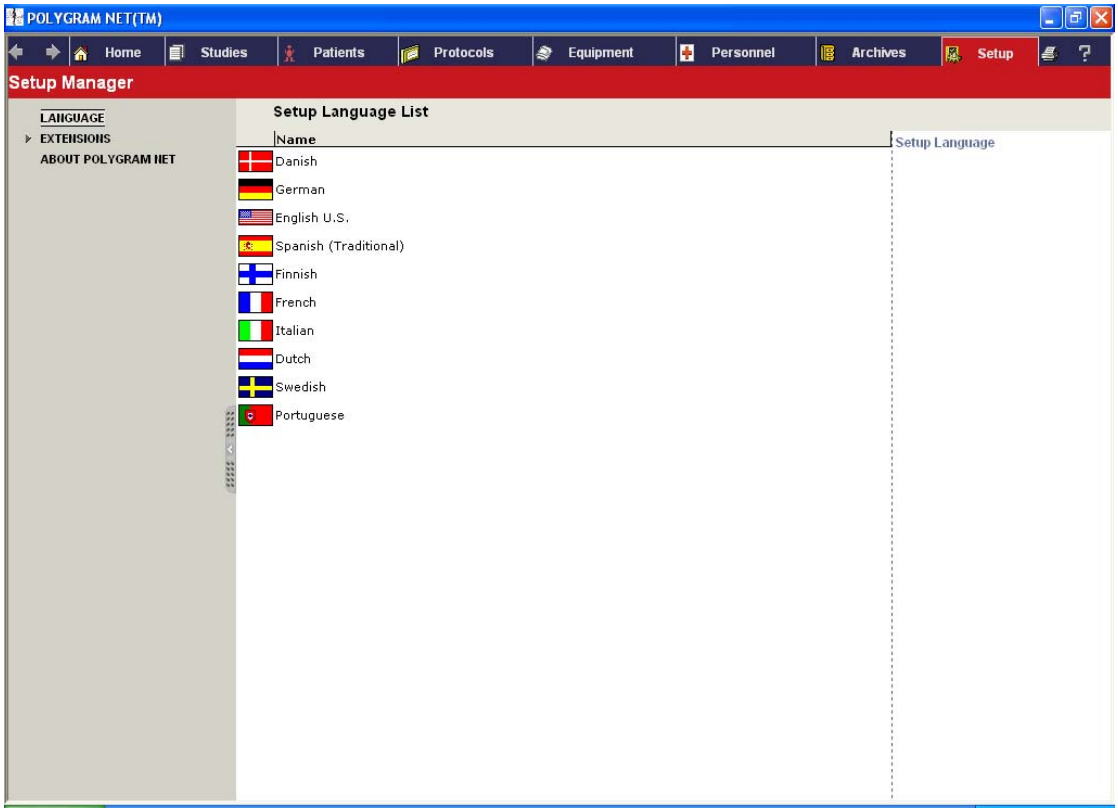
Setup Manager

From Setup Manager you have access to the ***Language*** and ***Extensions*** configuration pages.

Language

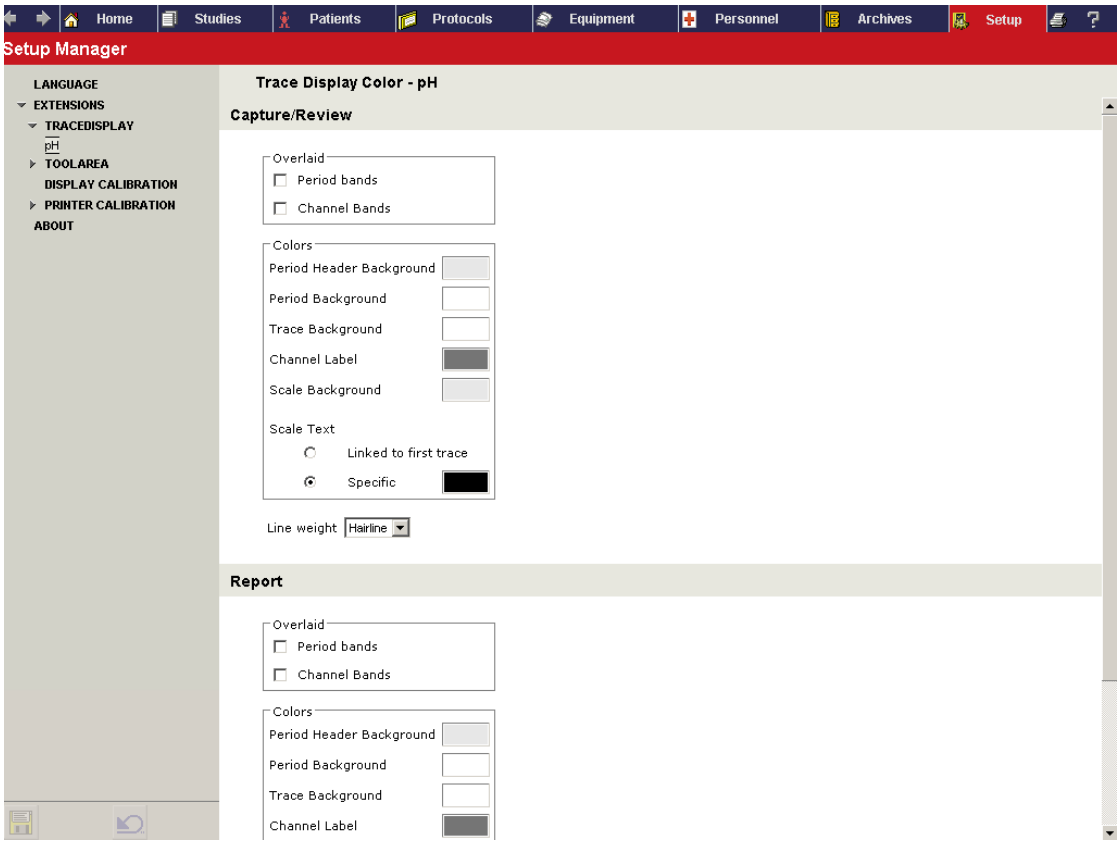
The Language Manager provides an overview of all the available languages supported by the system.

To modify the language being used by the system, click the ***Language*** of your choice (when available) from the displayed list. The language will then be changed, and you will be taken to the ***Home*** page.



Extensions

From Extensions, you will have access to the configuration of ***Trace Display***, ***Tool Area,*** and ***Display Calibration***.



Trace Display

In Trace Display, you can configure the display of the trace to suit your local needs. Capture, Review and Report settings can be controlled independently.

Overlaid

It is possible to overlay period bands and channel bands. If overlaid is selected for periods bands, all Symptoms/Events will be shown in one band. Otherwise they will be shown in one band per type of Symptom /Event. If Channel Bands is selected, all traces originating from the same sensor type will be shown in the same channel.

Colors

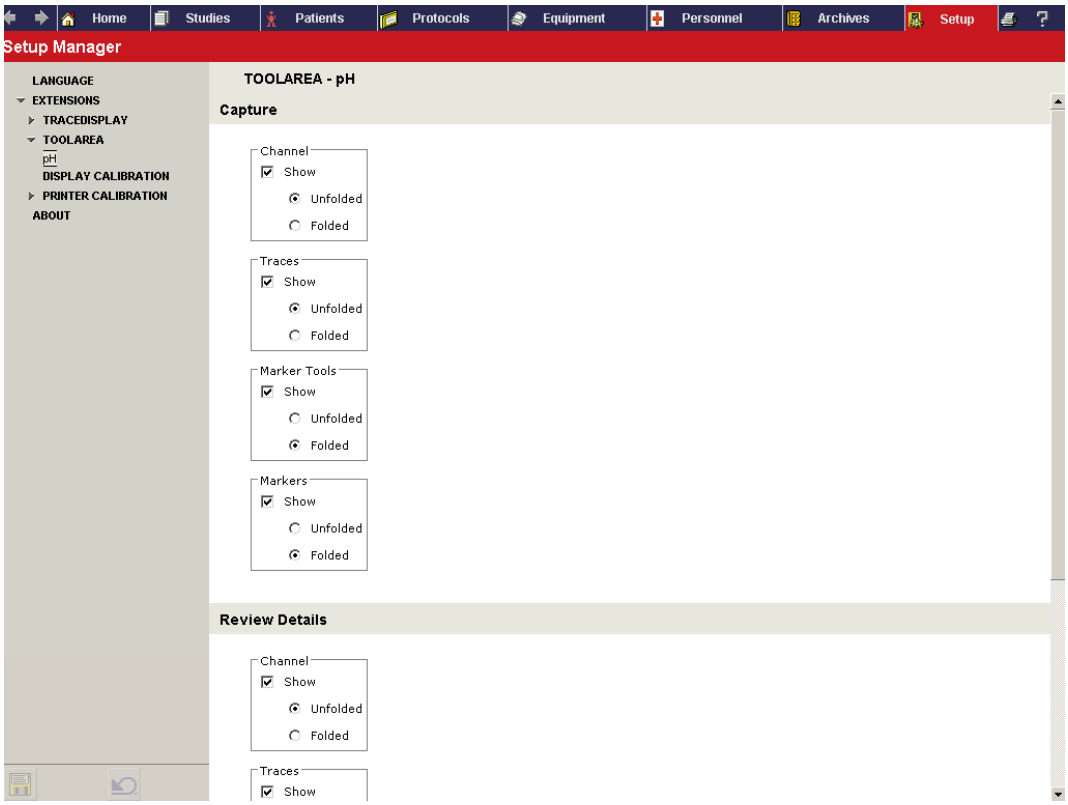
You can control the color used for the period header background, period background, trace background, channel label, and scale background. You can also assign a specific color to the scale text, or link it to the color of the trace.

Line Weight

You can control the thickness of the traces by setting the line weight. The available options are Hairline, Thin, Medium, Thick, and Heavy.

Tool Area

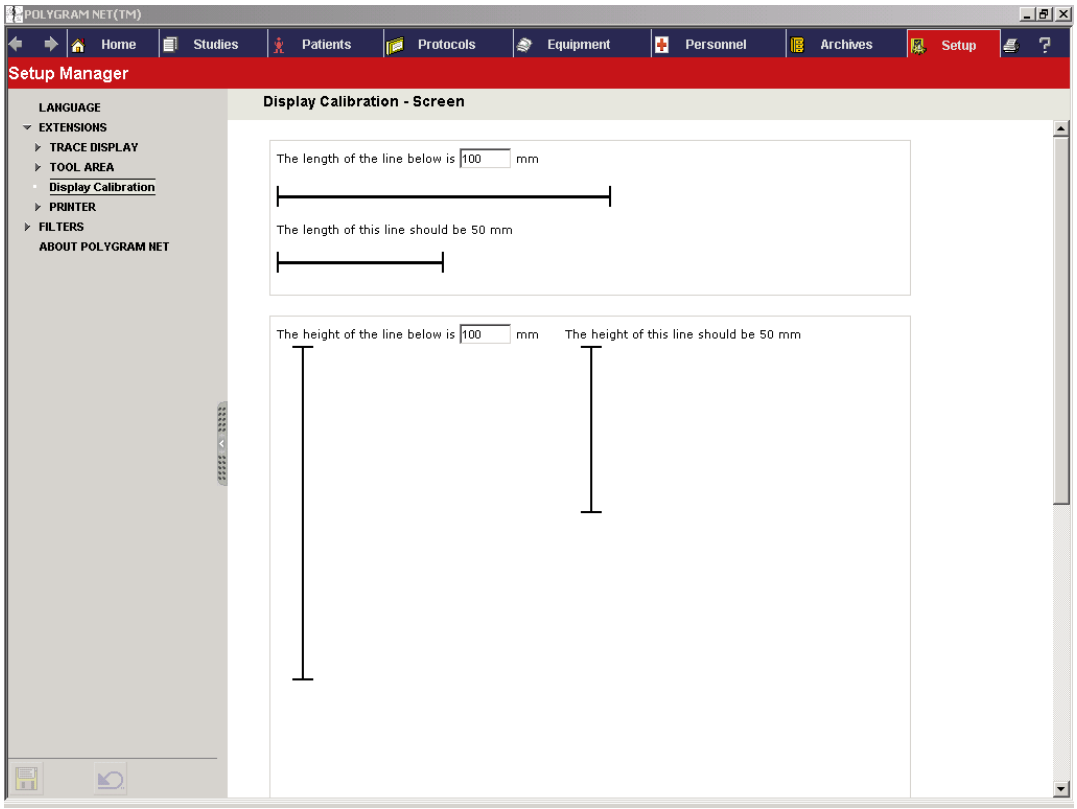
You can choose the tools you want to appear in the Tool Area of Capture and Review views by selecting their corresponding Show box in Extensions–Setup Manager. You can also choose whether the tools should appear folded or unfolded when entering a view.



Tool Area–pH

Display Calibration

If needed, the screen can be calibrated to reflect a real physical measurement. Using a "ruler" you must measure the first horizontal and vertical lines and update the length where needed. Check you adjustment by measuring the second line.



Display Calibration – Screen

Printer

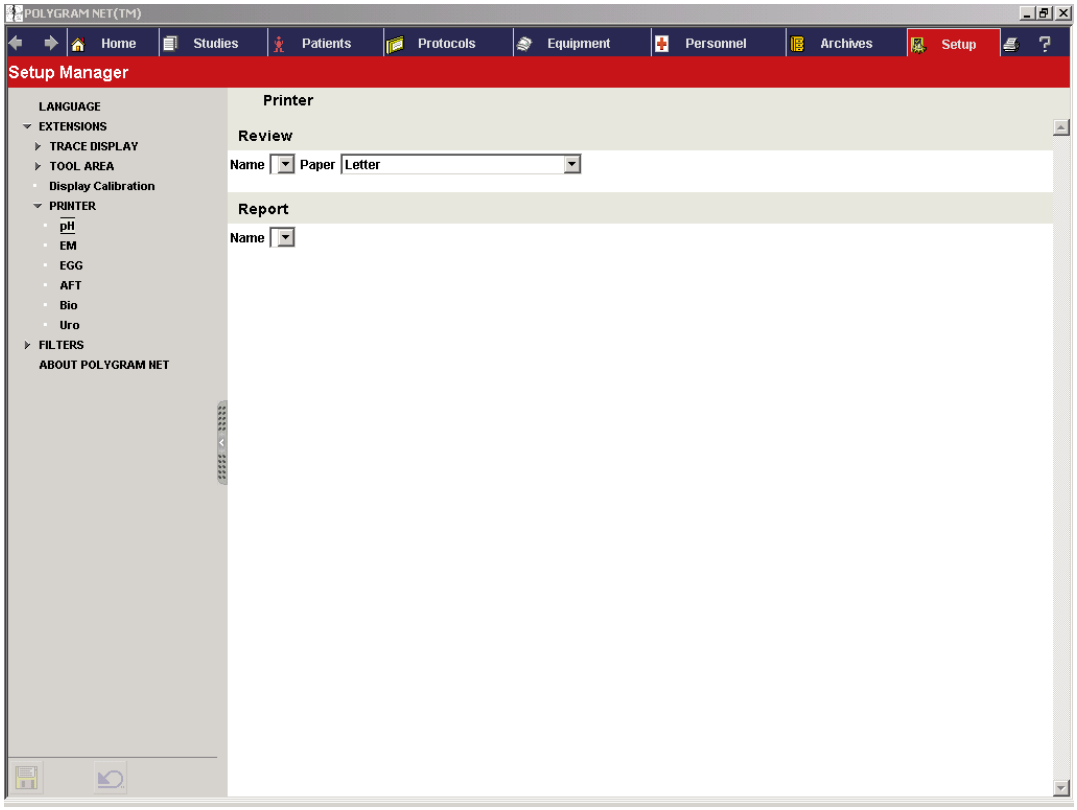
From the drop-down list boxes that appear in Printer–Setup Manager, the following configuration is available for printing:

From Review:

- Printer Name
- Paper Type

From Report:

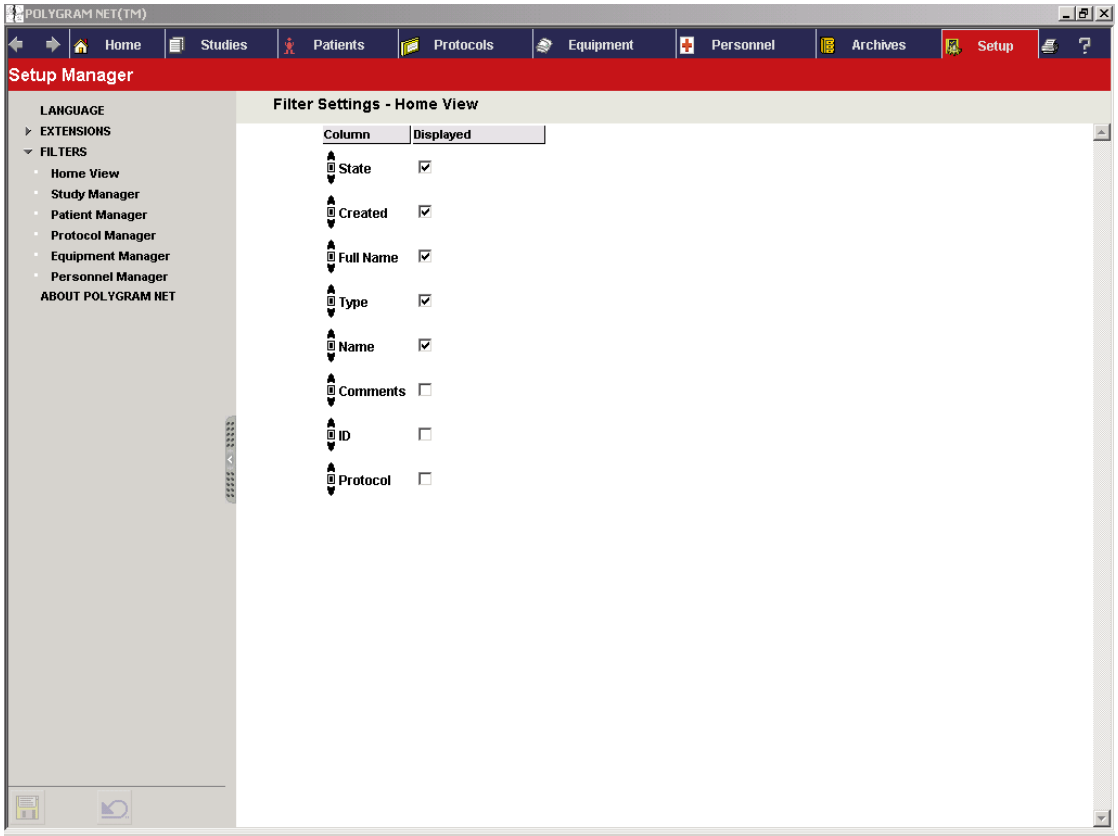
- Printer Name



Printer Configuration

Filters

You can enable or disable the lists that appear on all the Manager views by selecting or clearing the appropriate check box for a particular list in the Filters–Setup Manager.



Filter Settings–Setup Manager

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