OB TraceVue System Guide

For unparalleled information access

PHILIPS

This document explains the benefits, features and functionality of Philips OB TraceVue.

Detailed technical specifications and ordering information are available in the Philips OB TraceVue Technical Data Sheet and Ordering Guide.

Content

At your side
every step of the way

OB TraceVue

- **Combines surveillance and alerting with comprehensive patient documentation and data storage in one system.**
- **Covers the entire continuum of obstetrical care across one or more pregnancies, from the first antepartum visit to delivery, postpartum, discharge, postpartum follow-up visits, and newborn nursery.**

Introducing Philips OB TraceVue

Philips provides an unparalleled combination of clinical measurement and information management experience to meet our customers' requirements. For more than 30 years, Philips fetal monitors have helped improve the quality of patient care by providing accurate fetal heart rate and uterine activity recordings.

With Philips OB TraceVue, we have combined our expertise in fetal monitoring with our experience in hospital information management to provide a new generation in obstetrical data management.

Philips knows the difference clinical expertise makes to patient care information systems. That is why we worked with the Department of Obstetrics and the Laboratory of Computer Science of the Massachusetts General Hospital (MGH)* and incorporated their knowledge, expertise and years of experience in the development of Philips OB TraceVue. This Philips system provides you with electronic medical records based in part on the MGH obstetrical medical record system that has been used for patient care by the MGH obstetrical staff for more than three years.

*A Harvard Medical School affiliated hospital.

Patient-oriented, information management for obstetrical care.

PC
Fetal Monitor
LAN
RS232
AP Antepartum
LD Labor & Delivery
PP Postpartum

OB TraceVue connects the entire department to the system for smooth information exchange and data access from any location, i.e. from the antepartum unit, the labor and delivery unit, the postpartum unit and the physician's office, etc.

How can it help you?

As part of the Philips Patient Care System, OB TraceVue offers you the highest quality data management capabilities. You get all the information and benefits you need for accurate and complete record keeping and data management in your OB department.

Photography taken at Municipal Hospital Pforzheim, Maternity Unit, Prof. Dr. D. Heinrich

OB TraceVue overview

Surveillance

You have access to patient records and surveillance from any PC location: the central station, bedsides, nurses' and physicians' lounges and offices. OB TraceVue keeps you updated on the progress of all patients, helping you achieve the highest efficiency and the best quality of care. You can maximize patient coverage with multiple displays on the overview screen, which allows you to monitor several beds at one time. You always know where you are needed most, so you can stay with a patient who needs personal attention. You are always aware of the progress of all the other patients thanks to system access from the bedside PC.

High quality, clear trace displays with integrated fetal and maternal parameters as well as annotated trace documentation allow continuous monitoring of the fetus and the mother. With the Philips Avalon Fm20 and FM30 fetal monitors, this includes triplet monitoring.

Alerting

Philips OB TraceVue system generates awareness of questionable tracings based on CTG trace analysis by issuing audible and visible alerts. The OB TraceVue system provides a diagnostic aid that may assist but does not replace the clinician's judgment.

Electronic patient record

Forms and flowsheet based patient charting for mother and newborn ensure prompt distribution of data, resulting in faster and unlimited access to complete patient records throughout your department. Patient data is stored for complete record keeping. To help you increase your quality of patient care, the system allows you to document and manage fetal, maternal, and newborn data required in your department and retrieve it when and where it's needed.

OB TraceVue's electronic charting capabilities allow seamless access to essential information supporting statistical evaluation and reporting for administration, research and quality assurance purposes. The availability of medical history at patient admission assists your patient care planning.

Data storage

You can store all patient data and traces on optical media for reliable records of all your data throughout the years. You have easy access to stored data and traces any time, as promptly as you need them, and the risk of losing patient information or FHR tracings is minimized.

Statistical reporting

OB TraceVue offers a set of predefined statistic reports for automatic report generation, improving and easing your routine reporting. In addition, ad-hoc queries offer prompt individual statistical evaluation, for example for research work.

The reports can be modified to your individual requirements or completely recreated to your own unique set, which corresponds to your routine charting and statistics requirements. A set of departmental logs allows the retrieval of detailed, individual patient information.

Interfacing to the Hospital ADT System

HL7 based interfacing to the Hospital ADT System dramatically improves the efficiency of data management in your hospital as it helps reduce errors in demographic data. Using this bi-directional link, you can easily retrieve patient data from the ADT system for admission to OB TraceVue and report transfers and discharges from OB TraceVue to the HIS.

Integration into the Hospital IT Infrastructure

OB TraceVue can be integrated into the hospital MS Domain infrastructure including user authentication via Microsoft Active Directory services.

Interfacing to Hospital-wide Third Party Charting solutions

OB TraceVue interfaces to hospital-wide third party charting solutions by exporting a configurable set of flowsheet data including vital signs, derived fetal heart rate parameters, alerts and notes. The export is based on HL7 outbound communication.

Software compliance

OB TraceVue can allow the parallel use of third party software on the OB TraceVue PC, reducing the amount of technology exposure in your department and saving important space. The OB TraceVue application can be minimized and resides as an icon on top of the third party application. The OB TraceVue application runs in the background, but the icon still reflects any alert situation and keeps you continuously informed of any suspicious changes in fetal heart rate and Toco patterns.

Intuitive user interface

With OB TraceVue you save important time and effort because it is extremely easy to use. With intuitive color icons, you can easily enter and access information using a mouse, keyboard, or touch.

Receiving traces from outside the hospital

To reduce the demands on hospital resources and the stress a hospital visit can have on the mother, increasingly patients are being monitored outside the hospital during the antepartum period. OB TraceVue combined with a Philips Avalon FM20, FM30, or FM-2 fetal monitor allows you to receive and review traces recorded outside the hospital.

Web access

By accessing an OB TraceVue client locally, or remotely from a PC with Microsoft® Internet Explorer and a secure LAN or modem connection from your office or home, you can be directly in touch with your patients' progress. You can manage your valuable time more efficiently and respond quickly and appropriately to patients' needs.

Modularity

OB TraceVue is a highly scalable system. It can be configured as simple non-stress test (NST) system, as a centralized departmental surveillance solution, or as a complete departmental point-of -care surveillance and charting solution that allows fetal, maternal, and newborn charting at every bedside.

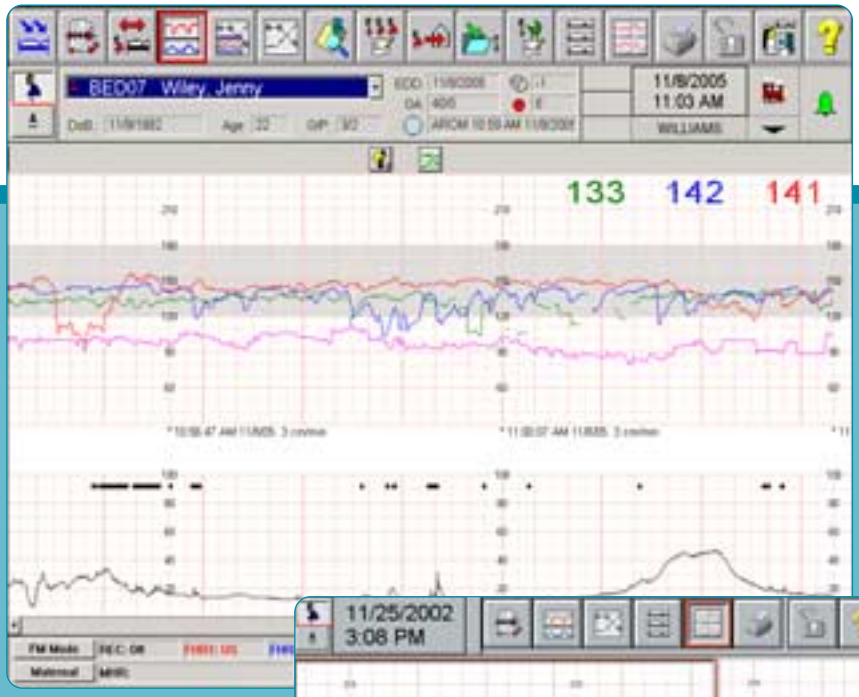
High-Availability

The OB TraceVue high-availability is based on a hot standby server that takes over data collection, surveillance, alerting and charting in the case the primary server becomes unavailable.

OB TraceVue applications

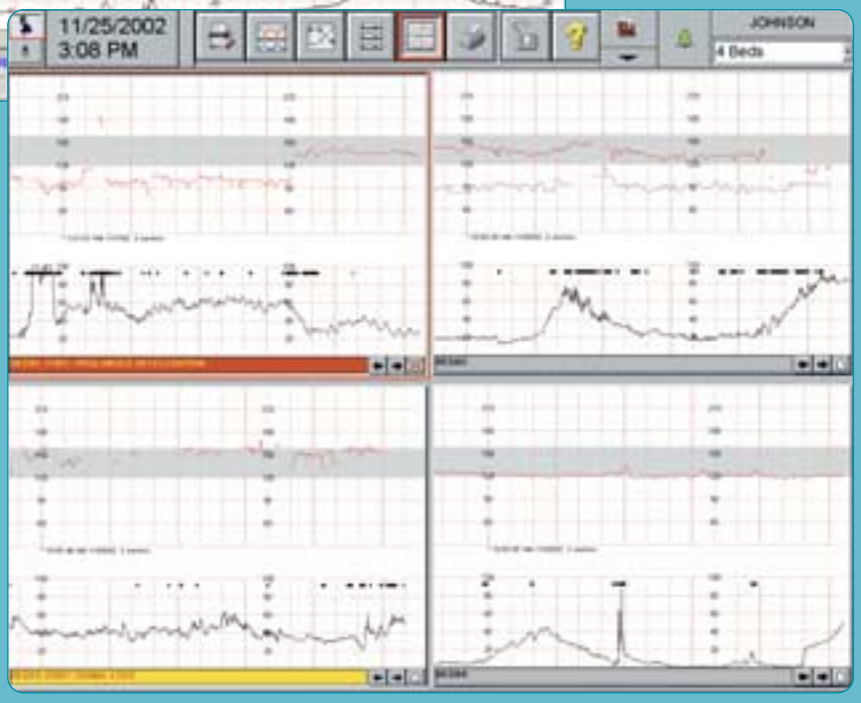
Surveillance

and alerting



1

Single trace screen presentation



The overview capability gives you at a glance status of either all or selected patients on the network.

The overview screen is configurable in 2, 4, 9, 12 and 16 bed presentation.

2

1 Single patient display
2 Multiple patient display

OB TraceVue provides a high quality, crisp color display of the information transmitted from the connected fetal or maternal monitors. These parameters include fetal and maternal heart rates, maternal vital sign parameters, fetal movement profile (Philips' FMP parameter) and nursing annotations. Various types of notes are provided to annotate traces (alerting notes, charting annotations, pre-defined or free text notes). Viewing previous sections of the trace is quick and easy with the scroll bar. With the Philips Avalon FM20 and FM30 fetal monitors, OB TraceVue can even help you monitor triplets.

You can access any single patient display from any location on the OB TraceVue network.

At peak times, in a busy antepartum clinic or labor and delivery unit, it is often impossible to watch all the patients at once and give the quality of care you would like. With OB TraceVue you can monitor the progress of all your patients, with up to 16 patients per overview display screen, throughout the department. You can also enter notes and acknowledge alerts, either directly from a bedside or centrally. This information is available on the OB TraceVue network wherever it is required.

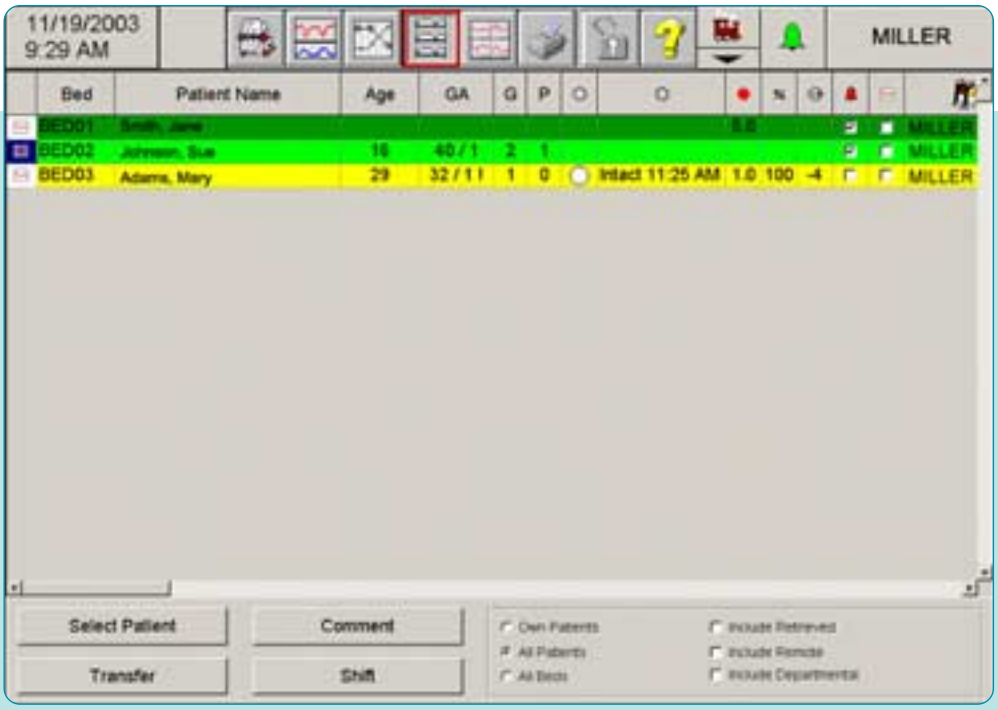
3 The electronic chalkboard

This continuously updated patient list displays the status of all the current patients. It supplements/ replaces the electronic chalkboard at the central nursing station and allows this information to be accessible throughout the OB department.

You can decide which patients you want to show in this list by selecting one of the following:

- Own Patients – for a list of only those patients for whom you are responsible.
- All Patients – for a list of all patients that have been admitted.
- All Beds – for a list of all patients, admitted or not.
- Include Retrieved – to include all patient records that have been retrieved from electronic optical disk storage.
- Include Remote – to include all patient records that have been received from a Philips Avalon FM20, Avalon FM30, or FM-2 by remote trace transmission.

You can also assign responsible caregivers either individually or in groups at the change of shift.



In the electronic chalkboard, you can add individual comments on each patient.

3

Surveillance
and alerting

Antepartum and intrapartum fetal trace alerting

The sooner you know about changes in fetal condition, the more time you have to make an informed decision and give optimum patient care. OB TraceVue's alerting feature creates awareness of questionable tracings and potential critical events, based on CTG trace analysis by issuing audible and visible alerts and placing yellow or red bells on the trace display.

Alerts can be acknowledged at any OB TraceVue PC.

The OB TraceVue system provides a diagnostic aid that assists, but does not replace, the clinician's judgment. Only the clinician has the knowledge of the patient and supporting information to appropriately interpret and respond to generated alerts. The recognition of high risk pregnancy factors such as pre- or post-maturity, poor fetal growth, reduced fetal movement, high blood pressure, multiple pregnancies, diabetes mellitus and others, is critical.

In the OB TraceVue system the combination of measurements, presentation of results and terminology corresponds to the definitions in the national Institute of Child Health and Human Development (NICHD) Guidelines. These guidelines were established by 18 leading American physicians.

There are two levels of alerts:

Basic alerting

With individual settings for each patient, the basic alerting feature will inform you when:

- Fetal tachycardia limit is exceeded for a specified duration
- Fetal bradycardia limit is exceeded for a specified duration
- Unclear signal, or loss of signal from transducers
- Coincidence detection (Cross Channel Verification) of two fetal heart rates, or fetal and maternal heart rates (with Philips Avalon FM20, Avalon FM30, and Series 50 fetal monitors only)
- Notification that trace paper on the fetal monitor has run out (with Philips Avalon FM20, Avalon FM30, and Series 50 fetal monitors only)

Example of Basic Alerting – Bradycardia. The gray area denotes the limit settings for tachycardia and bradycardia.

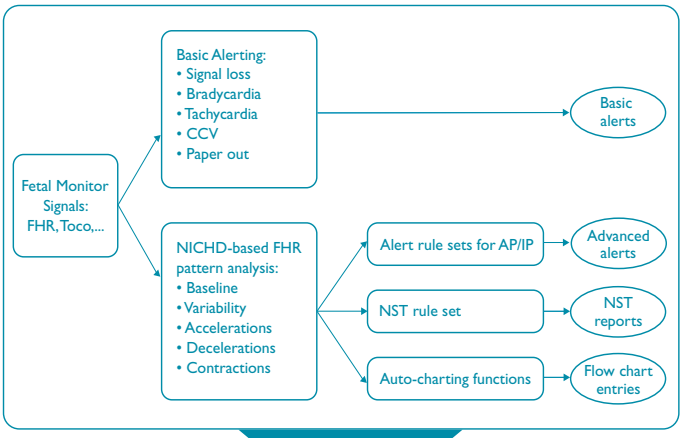
Advanced alerting

The advanced alerting feature analyzes trace patterns. The key elements of the advanced alerting feature are:

- FHR baseline
- Amplitude and frequency of long-term variability
- Number and type of decelerations, accelerations and contractions

There are two independent alerting rule sets for antepartum and intrapartum advanced alerting.

The base of the advanced alerting is the CTG pattern analysis.



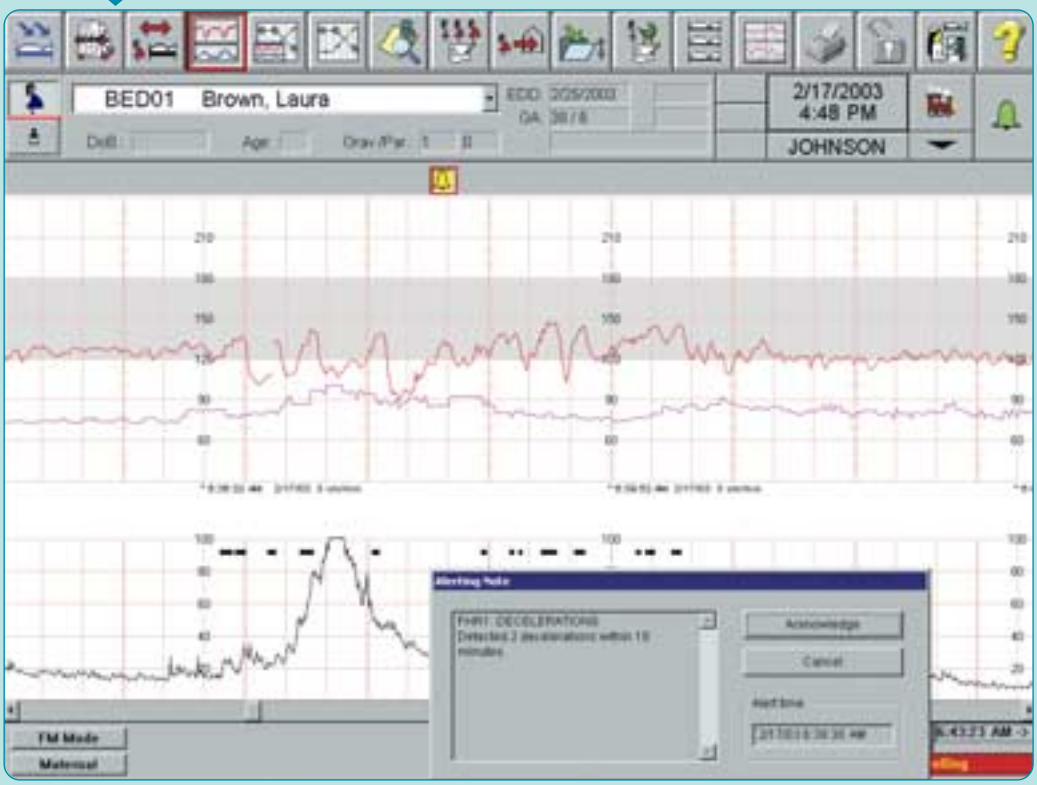
This NICHD based CTG pattern analysis is also used in the following application areas:

- Non-stress testing in conjunction with basic and advanced alerting
- Auto-charting (independent of selected alerting): the results of the pattern analysis regarding baseline, variability, acceleration, deceleration, and contraction are charted in the maternal flowsheet

Non-Stress test

The non-stress test is used for antepartum testing to assess fetal well-being. The test is started by turning on the fetal monitor and defining the reassurance criteria in OB TraceVue. An NST report is generated when the reassurance criteria are met the first time in the current monitoring phase. When performing NST with multiples, a separate NST report is generated for each fetus. For more details on NST report see chapter on patient documentation.

The NST test can be combined with basic or advanced alerting.



The screen shows an example of Basic and Advanced Alerting – variable decelerations. The gray area denotes the limit settings for tachycardia and bradycardia.

Patient documentation

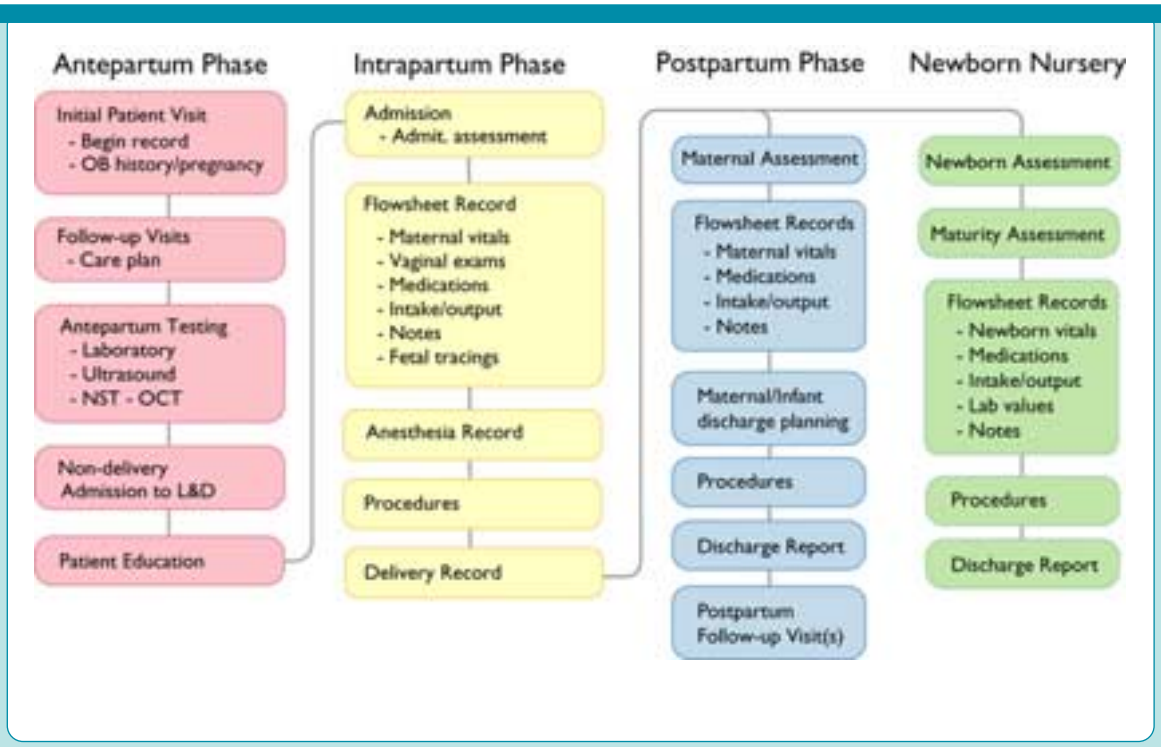
1 The patient flow

OB TraceVue's patient documentation and data management capabilities cover the full continuum of obstetrical care. This includes antepartum visits at hospital related outpatient clinics, labor delivery recovery and postpartum as well as newborn documentation and postpartum follow-up visits.

2 The patient model

The patient model allows you to record and document different encounters (visits) during a pregnancy as well as monitor and retrieve information from a patient's previous pregnancies.

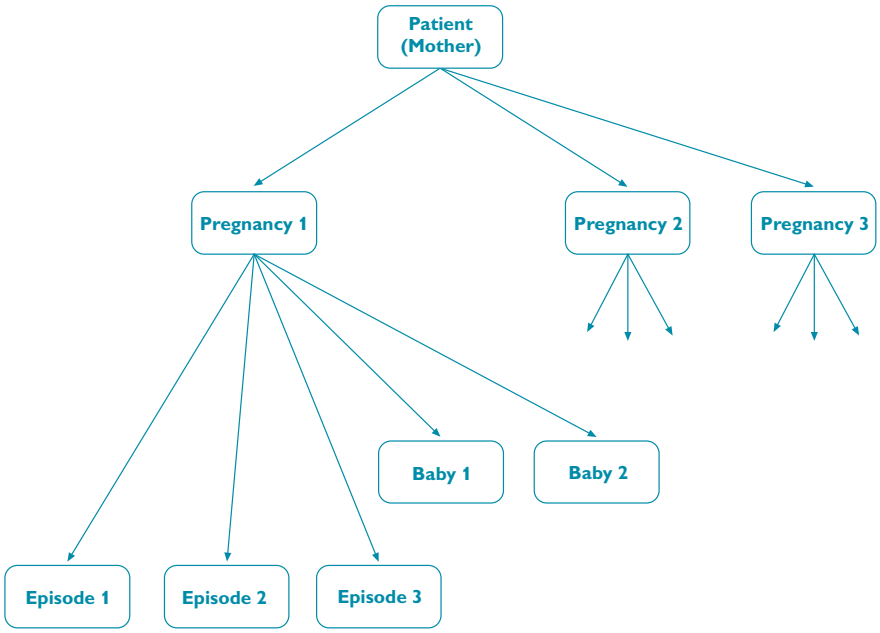
Once the fetus is delivered and the independent newborn record is created, OB TraceVue system maintains a link between mother and newborn.

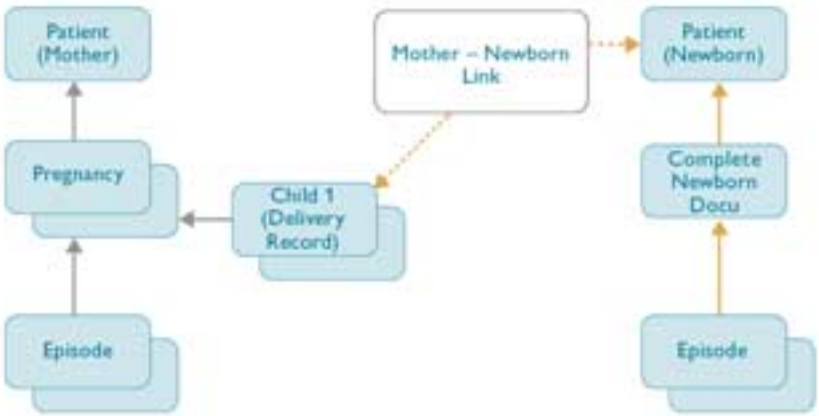


1 Patient Data Flow with OB TraceVue throughout the pregnancy

2a.

OB TraceVue patient related data model in a hierarchical structure





2b.

Mother – Newborn Link

Patient documentation

Forms based maternal and newborn charting

OB TraceVue provides you with a full set of data entry screens for forms based patient charting and viewing possibilities throughout the entire continuum of obstetrical care. OB TraceVue takes you through the progress of a patient over many years, including other pregnancies, which help you give informed, high-level care. The data entry screens are optimized for your PC monitor screen.

Forms-based patient information can be entered easily and quickly and accessed by clicking specific icons. Once within a patient form, you can select the specific data entry screen you need via Tabs. Extensive pull-down lists, which you can configure to suit your needs (e.g., for medication), help speed up your documentation process.

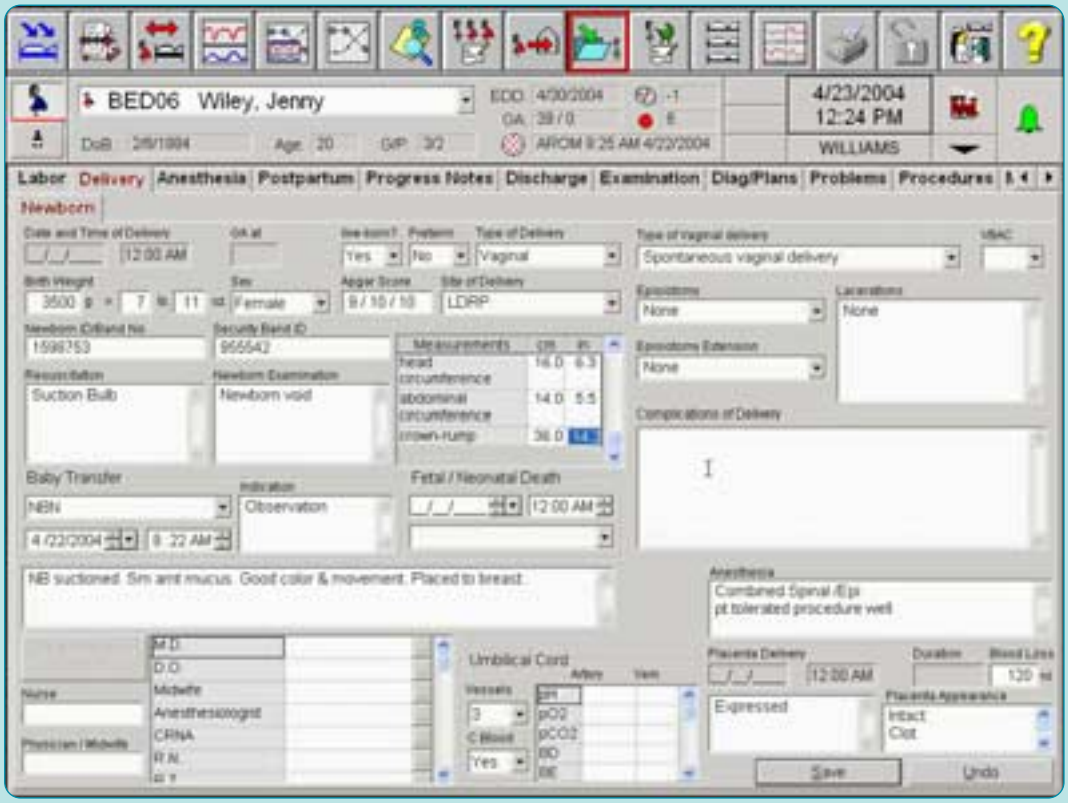
OB TraceVue offers a wide range of patient data entry screens for the different areas in your obstetrical department.

Antepartum record

- Demographics
- Care providers
- Obstetrical history
- Medical history
- Prenatal screening
- Current pregnancy information
- Prenatal visits
- Physical examinations
- Diagnosis/Plans
- Allergies
- Problem list
- Procedures
- Medications
- Lab
- Prenatal visits
- AP testing
- Teaching
- Record attachment

Obstetric admission record

- Demographics
- Providers
- Medical history
- Pregnancy
- Admissions
- Care provider progress notes
- Examinations
- Diagnosis/plans
- Allergies
- Problems
- Procedures
- Medications
- Lab
- Psychosocial evaluation
- Teaching
- Record attachment



Delivery form data entry screen for information on the delivery of the newborn

Labor, delivery, postpartum and discharge record

- Labor
- Delivery
- Anesthesia
- Postpartum
- Care provider progress notes
- Discharge
- Diagnosis/plans
- Problems
- Procedures
- Medications
- Lab
- Teaching
- Record attachment

Postpartum follow-up

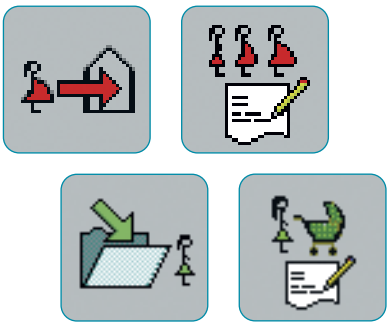
- Demographics
- Providers
- Care provider progress notes
- Postpartum follow-up visits
- Examination
- Diagnosis/plans
- Allergies
- Problems
- Procedures
- Medications
- Lab
- Record attachment

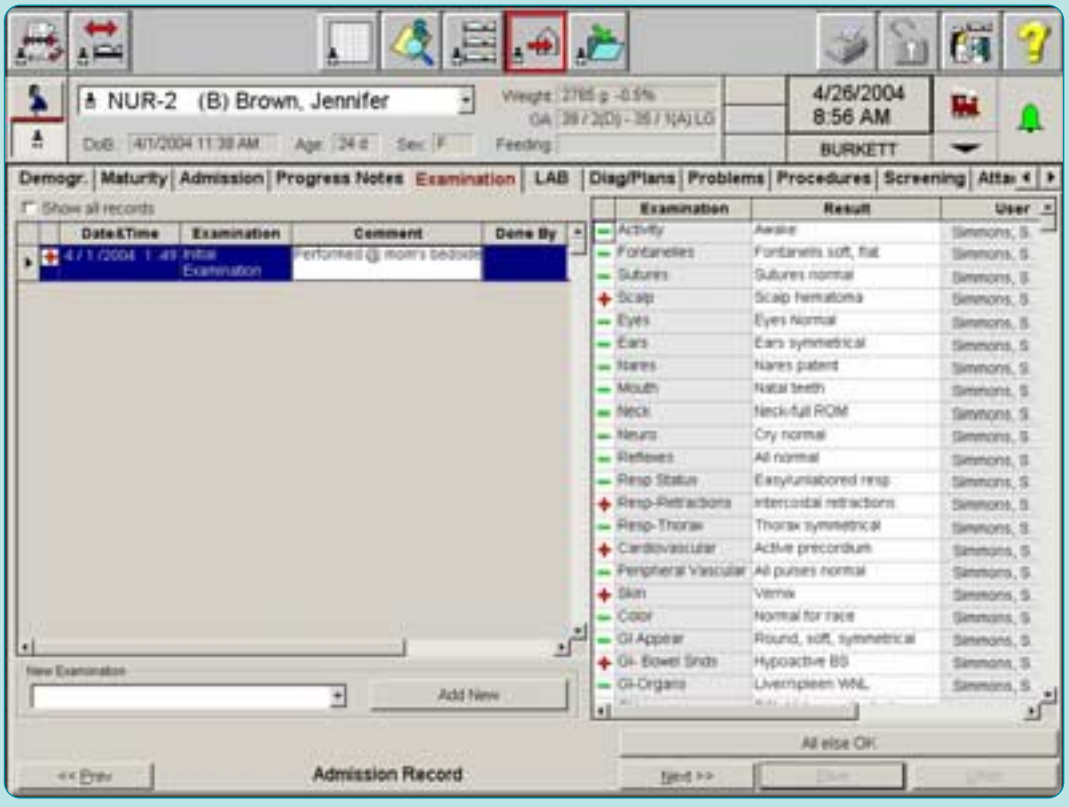
Newborn admission

- Maternal demographics
- Newborn demographics
- Newborn delivery (view only)
- Maturity assessment
- Admission
- Care provider progress notes
- Examinations
- Lab
- Diagnosis/plans
- Problems
- Procedures
- Genetic screening
- Record attachment
- Maternal teaching (view only)

Newborn discharge

- Discharge
- Examinations
- Lab
- Diagnosis/Plans
- Problems
- Procedures
- Genetic screening
- Record attachment
- Maternal teaching (view only)





Newborn examination

Patient documentation

Flowsheet based maternal and newborn patient charting

To complete your documentation procedures, you have a wide choice of flowsheets for efficient patient charting, featuring immediate and easy input and retrieval of all essential maternal, fetal, and newborn data you need to document or review. The data input on the flowsheets can be easily adapted to individual patient profiles. The default set includes:

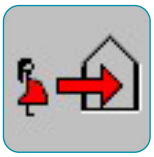
Maternal flowsheet

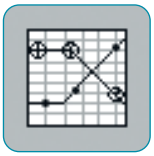
Antepartum / Intrapartum Flowsheet

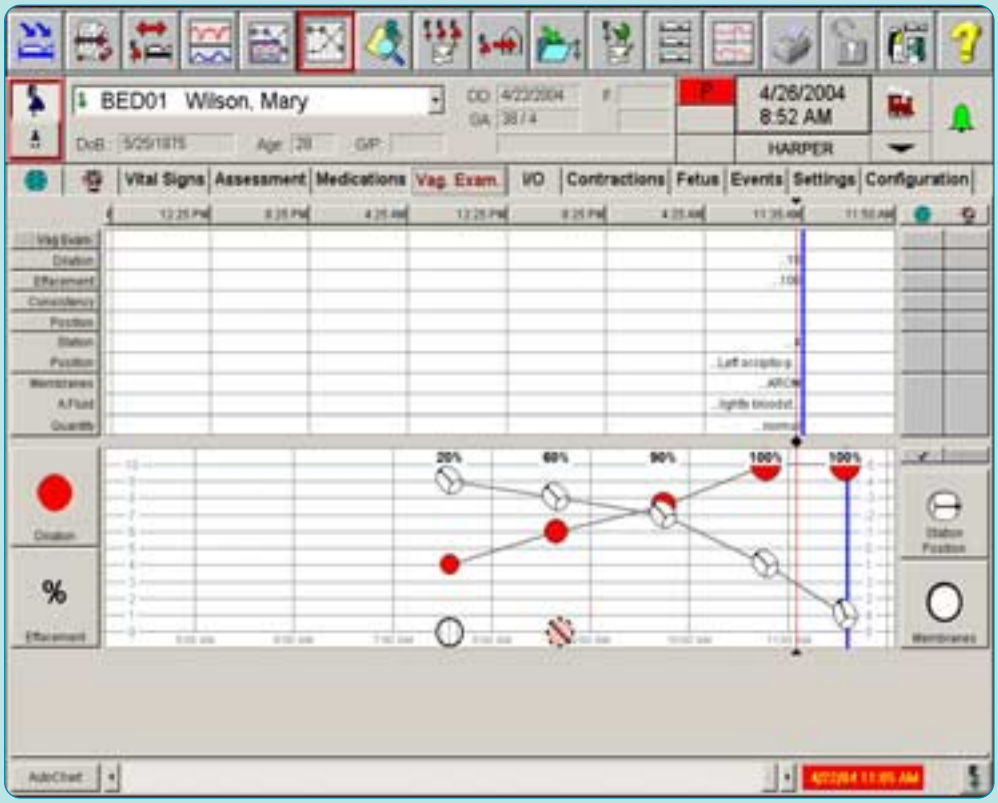
- Maternal vital signs
- Antepartum / intrapartum assessment
- Medication
- Vaginal examinations
- Intake and output
- Contraction documentation
- Fetal data
- Events

Postpartum Flowsheet

- Maternal vital signs
- Postpartum assessment
- Medication
- Intake and output
- Events





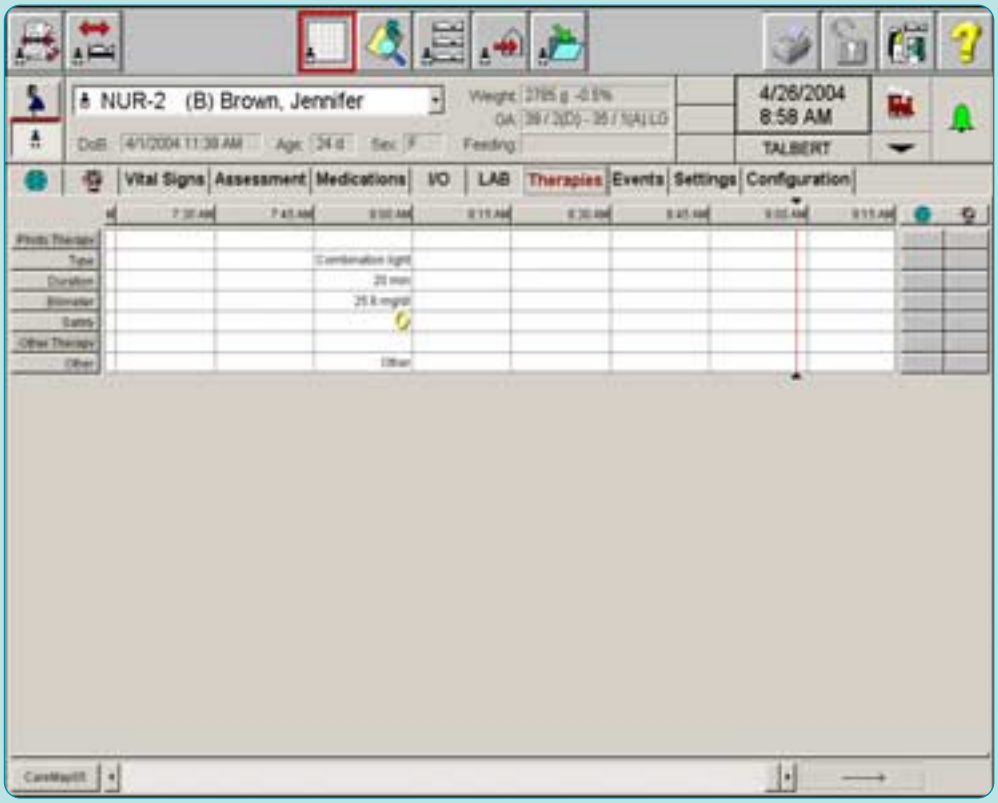


Maternal flowsheet vaginal examination screen

Newborn flowsheet

Newborn Flowsheet Charting

- Vital signs
- Assessment
- Medications
- Intake and output
- Lab
- Therapies
- Events



Newborn flowsheet intake/output screen

Patient documentation

Trace annotation

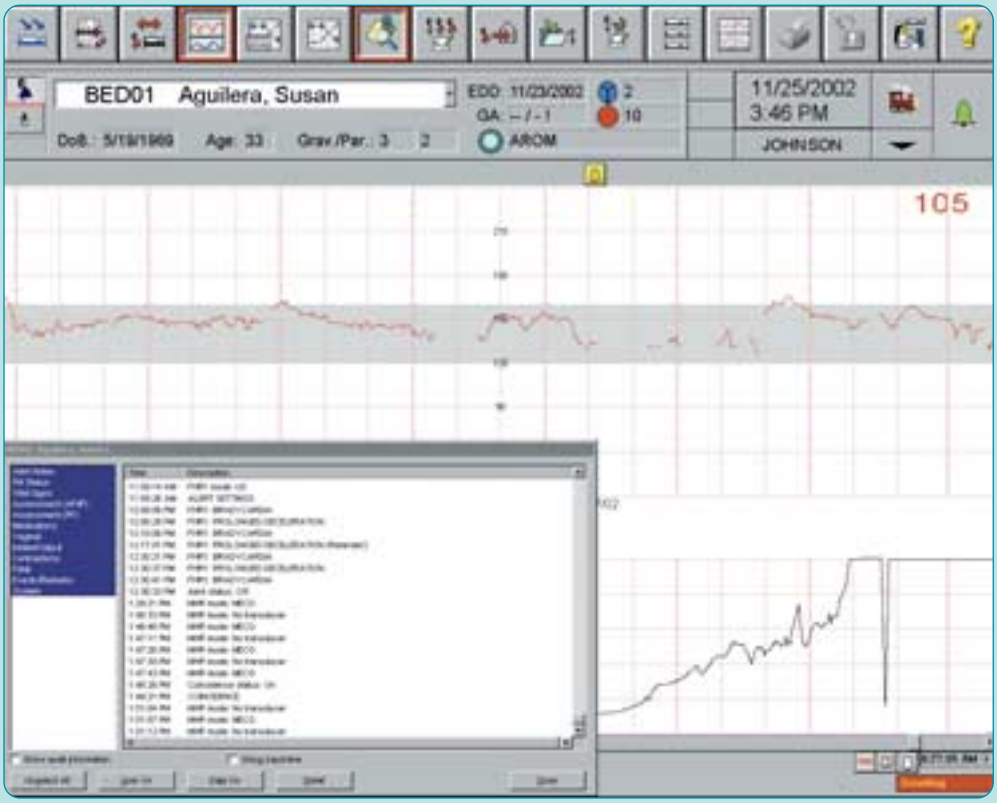
Notes normally written by hand on the fetal trace paper can be entered into Philips OB TraceVue.

Notes entered from Philips Series 50 fetal monitors by barcode reader will also be displayed in OB TraceVue as a free-text note.

Trace annotations are stored together with the traces on the optical disk for future retrieval.

Trace annotation is marked as an icon on the screen, but as text note on the printout.

Complete documentation for every phase



Example of trace annotation entered on the fetal trace, the icon in the top section of the screen marks the position of the annotation in relation to the trace.

Non stress test support

OB TraceVue provides Non Stress Test (NST) support for antepartum testing. The patient is monitored for a user-definable time period (typically 20 to 30 minutes) to test whether certain reassurance criteria are met:

- Acceptable number of accelerations and decelerations obtained within a specified time frame
- The FHR is within pre-defined acceptable limits
- The long-term variability is between 5 and 25 bpm

An NST report is generated when the reassurance criteria are met the first time in the current monitoring phase and a green bell appears on the trace. When performing NST with multiples a separate NST report is generated for each fetus. OB TraceVue supports triplet monitoring.

This test does not take into account any form of external fetal stimulation and uterine contractions.

```
NST Report for FHR1:                                    12.10.2002
_____________________________________________________________________________

Saint James Hospital
Georgetown

_____________________________________

Doe Jane

Age:         21
Gravida:      1
Para:         0
Gestational Age: week 34, day 5
_____________________________________

Monitoring Period

Time:               11:44 - 12:06
FHR1:               US
FHR2:               No transducer
TOCO:               external
Duration:           22 minutes
_____________________________________

NST Criteria*: met
_____________________________________

Trace Interpretation Summary (average over 10 minutes)

FHR Baseline:     120 bpm   (Range: 118 bpm - 129 bpm)
Variability:       14 bpm
Short Term Var.: 0.9 bpm   (3.8 msec)

Accelerations:      2
 at:  11:59  12:02

Decelerations:      0

Contractions:       3
 at:  11:57  12:00  12:04

_____________________________________

(*)     Interpretation Criteria:

User defined criteria for reassuring CTG tracing:
- valid recording within 9 of 10 minutes
- baseline heart rate between 120 and 160 bpm
- at least 2 accelerations in 10 minutes
- not more than 1 deceleration(s)

Additional criteria:
- moderate baseline variabiliy (5 - 25 bpm)
- no severe or prlonged decelerations
```

Printout of a NST report

Reporting

Printouts

OB TraceVue allows you to print annotated traces and all other patient documentation in high resolution and in color for superior quality of reporting. You can print out the whole trace or a section (e.g. shift report).

You can select from the following list of printouts:

- Traces in high resolution and color
- Flowcharts in high resolution and color
- Notes list, a complete detailed list including all free text or predefined notes
- Forms
- NST Report
- Audit trail
- Current screen content

To make printing out forms easy for you, OB TraceVue provides a default forms printout package, which you can adapt. You can also modify the content and layout of the printouts to your specific needs. Flexible forms printout is based on Microsoft® Word. All the layout possibilities of Microsoft® Word are available when you design your forms printouts. You can embed graphical elements, such as your hospital logo.

This user configurable reporting is done using a copy of the OB TraceVue database on a separate server (external database server). Separating into two servers is necessary to guarantee the smooth operation of the surveillance and alerting portion of OB TraceVue. This prevents possible hazard conditions caused by external user programmed database accesses (a user can test his/her reports without affecting the surveillance and alerting functionality of the system).

Examples of report printouts

Statistical reporting

Patient documentation is subject to local medical and legal requirements. The same applies to administration and QA statistical documentation. OB TraceVue helps you comply with such local requirements.

OB TraceVue offers you a set of predefined statistics allowing automated report generation. Furthermore, you can conduct ad-hoc queries from the database supporting prompt statistical evaluation and reporting for your administrative, research and quality assurance purposes. Statistical reporting is based on Microsoft® Excel. You get reports in a tabular layout, or you can put them into graphs.

OB TraceVue offers a broad range of predefined reports so that you can choose those that best fit your needs, such as:

- Weekly, monthly, quarterly and yearly statistics
- Logs (admission log, delivery log, discharge log, newborn log, etc.)

You can also set up individual reports with OB TraceVue. If required, please contact your local Philips support organization.

Available maternal logs:

- Patient creation log between dates, sorted by last name
- Admission log between dates
- Labor and delivery log between dates
- Undelivered log between dates
- Live birth log living between dates
- Fetal death log between dates
- Stillborn log between dates
- Perinatal death log between dates
- Open pregnancies log
- Pregnancy log for cases open for more than 12 months
- Discharge log between dates
- Transfer log between dates by transport type (in and out)
- Schedule patient log
- Patient zip code log
- Provider list

Available newborn logs:

- Newborn creation log
- Nursery admission log
- Nursery discharge log

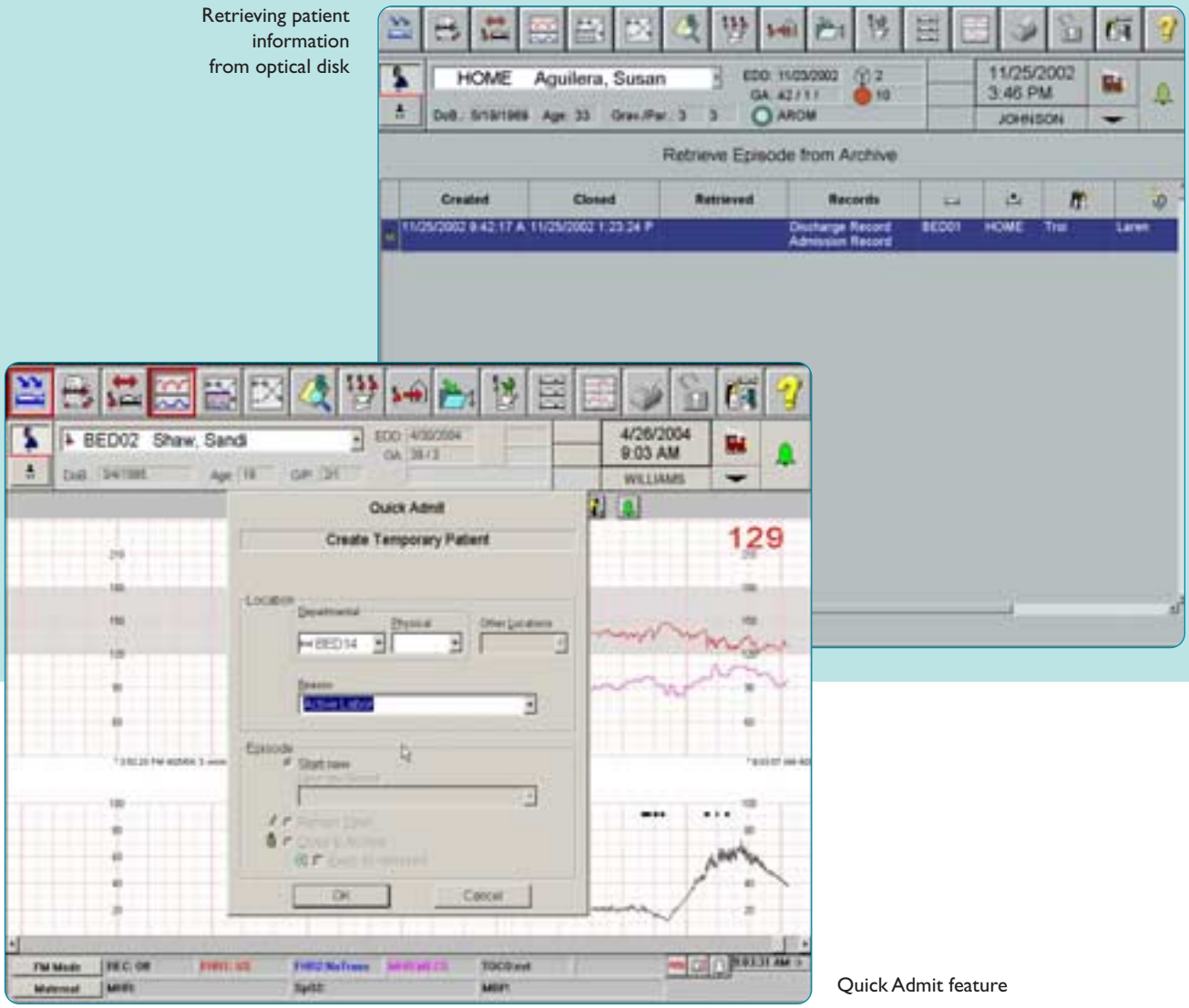
Data storage

Optimum data and trace storage and retrieval

The current medical liability environment requires detailed and accurate documentation.

Consequently, most hospitals must maintain extensive labor and delivery documentation for many years. OB TraceVue addresses this requirement directly with its optional data storage capability. Optical disk media can store the information for more than 30 years (according to accelerated life-time test from the media manufacturer). All stored data for mother and newborn can be easily reviewed and printed in original quality. Long-term storage for more than 20 years requires the customer to implement a technology rollover strategy that is compatible with the latest storage hardware technology.

Retrieving patient information from optical disk



Quick Admit feature

Fetal heart rate, maternal heart rate, FMP, $FSpO_2$* and uterine activity signals are sampled four times per second and stored with the same trace fidelity on the optical disk.

OB TraceVue's software also ensures the integrity of the patient data.

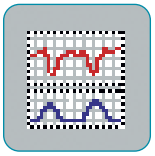
Quick admit

When you don't have enough time to go through the routine procedure of setting up a new maternal record patient, the "Quick Admit" feature solves this problem for you.

"Quick Admit" initiates data storage and reserves a new patient record for completion at a later time. This allows monitoring and storage to begin immediately.

Retrieval of stored data

All retrieved maternal and newborn records can be handled in the same way as active patient data, except you cannot edit or add anything to the stored data. You can easily scroll through retrieved traces on the screen and review/printout patient documentation.



* Fetal SpO_2 not available in the United States and Japan.

System Architecture

OB TraceVue is based on a PC client/server architecture. Client PCs are run on Microsoft Windows XP professional; the servers use Microsoft Windows 2003 Server.

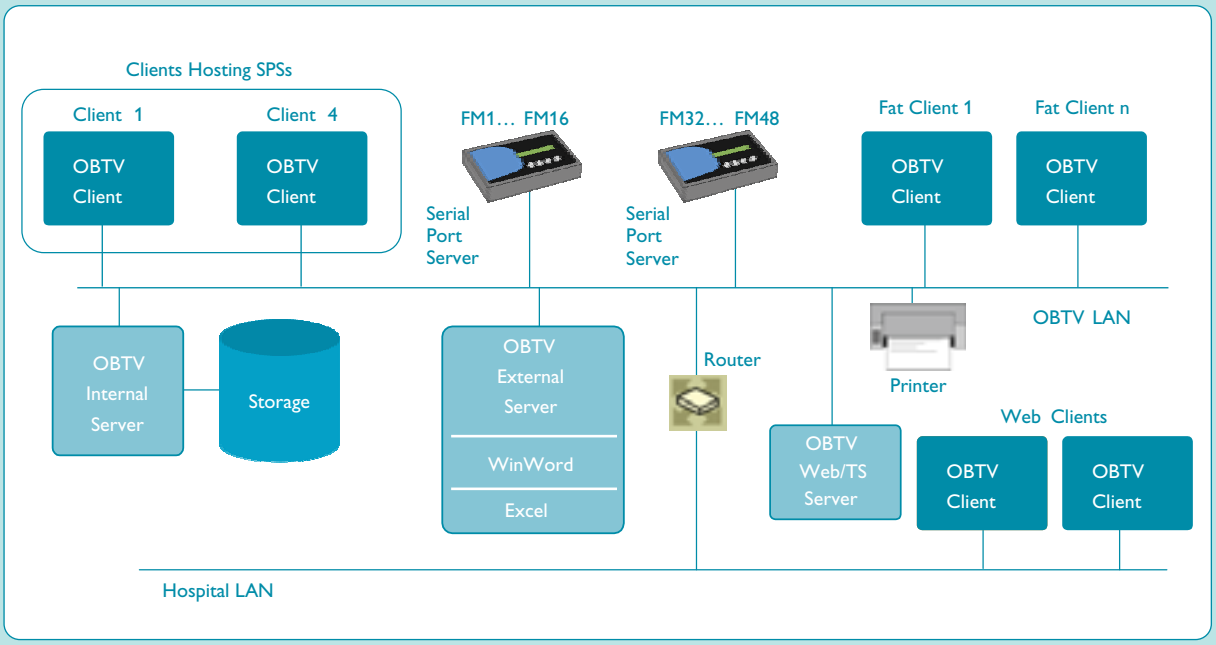
The internal server is responsible for surveillance, alerting, charting and archiving. In order to guarantee reliable operation, the internal server cannot be accessed by customers. A high-availability option is available for the internal server as shown in the picture above. Typically, the storage device is located at the internal server. In the case of the high-availability option, the storage device is moved to the external server.

Charted data is replicated, in near real-time, to the external server where data can be queried by customers. Reports and statistics are run from the external database. Queried data can be exported to a data repository as part of a Philips professional service engagement.

The WEB/TS server hosts the web enabled OB TraceVue WEB/TS clients.

OB TraceVue clients can be either full clients or thin clients (WEB/TS clients). OB TraceVue clients can be deployed anywhere in the hospital network infrastructure if the network fulfills the required specifications.

All PCs can be integrated into the hospital Microsoft Domain infrastructure including user authentication via Microsoft Active Directory services.



OB TraceVue architecture

System Interfacing and Integration into the Hospital IT Infrastructure

Interfacing to the Hospital ADT System

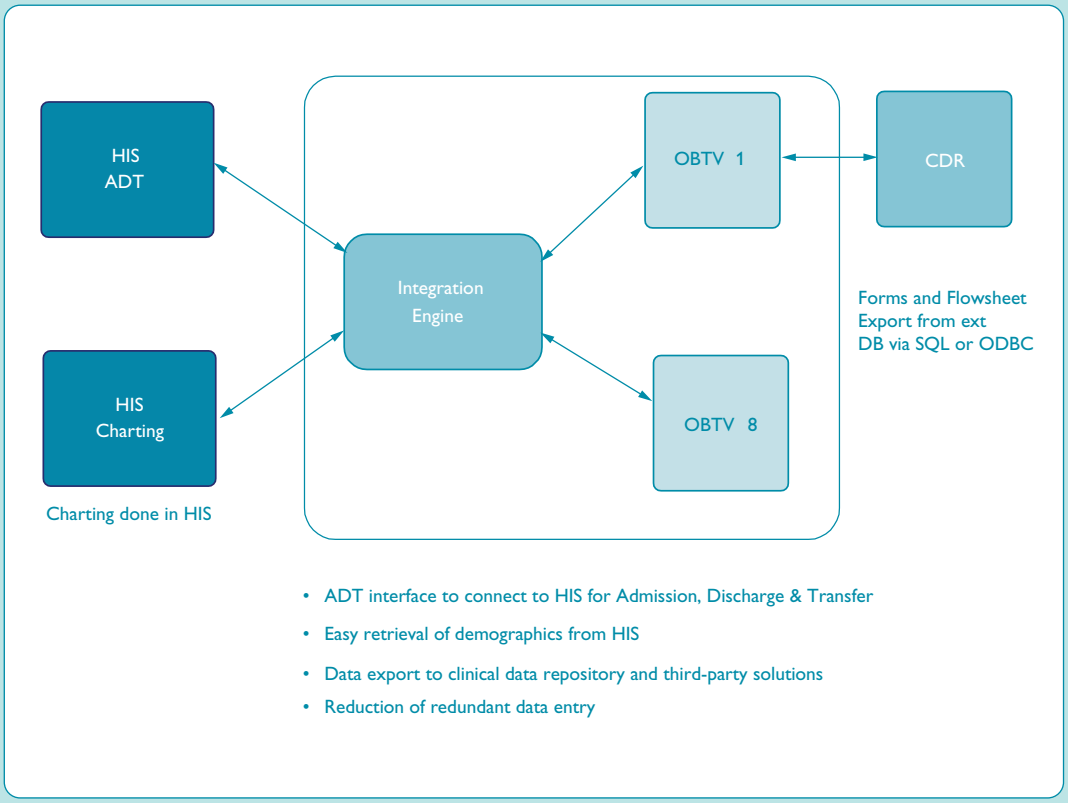
Philips OB TraceVue uses an ADT (Admission, Discharge and Transfer) interface to connect to your Hospital Information System (HIS). The ADT interface is on a non data acquisition client PC. The ADT interface is based on the Health Level 7 (HL7) specification.

The bi-directional link allows the transmission of demographic patient data from the HIS to OB TraceVue for admission, and the reporting of transfers and discharges from OB TraceVue to the HIS.

The ADT interface allows you to pre-admit obstetric patients quickly by using the demographics transmitted from the HIS to OB TraceVue, avoiding redundant data entry. You can then do the final admission to your department with all relevant patient information at a later point in time.

HL7 based interfacing to the Hospital ADT System dramatically improves efficiency of data management in your hospital as it helps reduce errors in demographic data.

The ADT interface includes mother and newborn.



OB TraceVue system interfacing

Interfacing to Hospital-wide Third Party Charting solutions

OB TraceVue interfaces to hospital-wide third party charting solutions by exporting a configurable set of flowsheet data including vital signs, derived fetal heart rate parameters, alerts, and notes. The export is based on HL7 outbound communication.

Data export into Clinical Data repositories (CDR)

Data export from OB TraceVue to a Clinical Data Repository (CDR) can be implemented by querying the external database of OB TraceVue. The External database is SQL- and ODBC compliant for easy access by third party software.

Integration into the Hospital IT Infrastructure

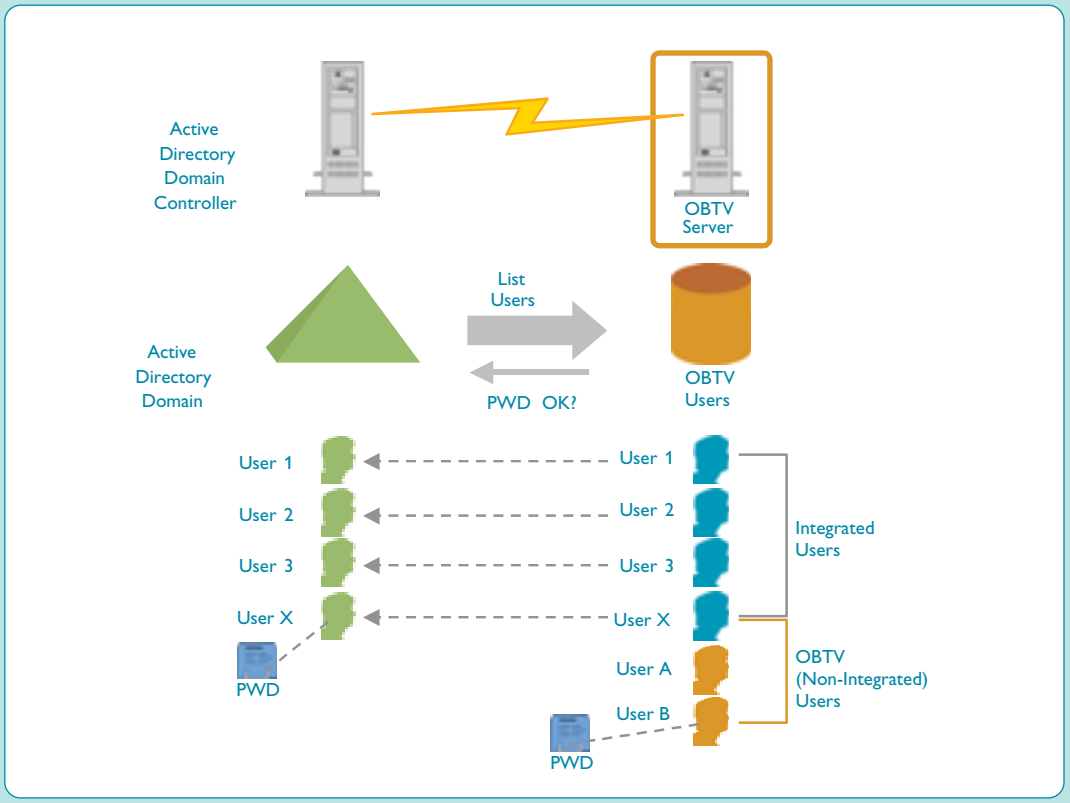
OB TraceVue can be fully integrated into the hospital Microsoft Domain and Organizational Unit (OU) infrastructure including user authentication via Microsoft Active Directory service.

The OB TraceVue users on an OB TraceVue application level will use Active Directory for user authentication. OB TraceVue user roles and responsibilities for the OB TraceVue application are kept in OB TraceVue.

The OB TraceVue application distinguishes two user types:

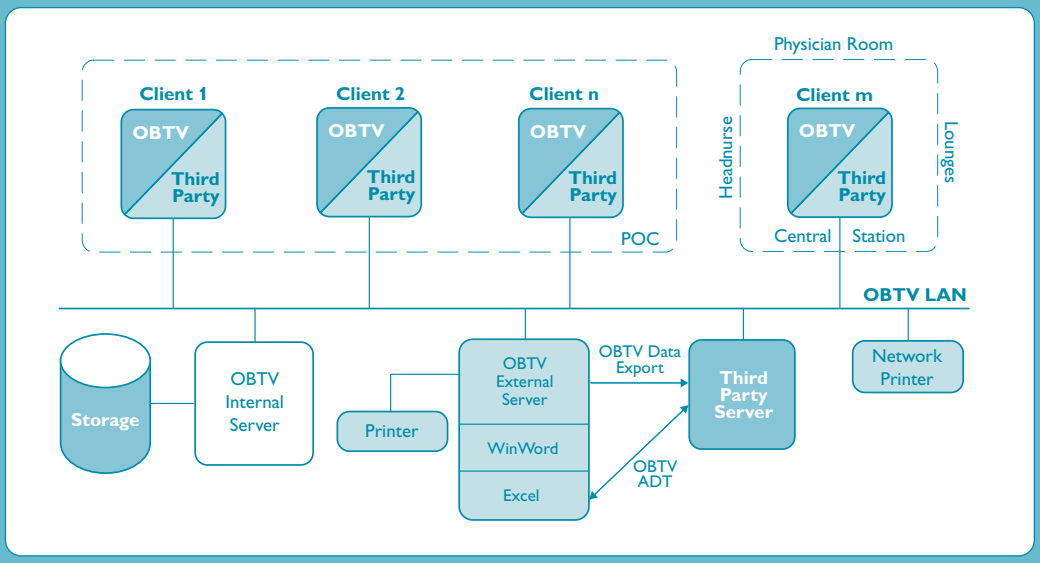
- Active Directory integrated
- Local OB TraceVue

OB TraceVue users who are not Active Directory integrated for the application can still be Active Directory integrated from an operating system and network perspective.

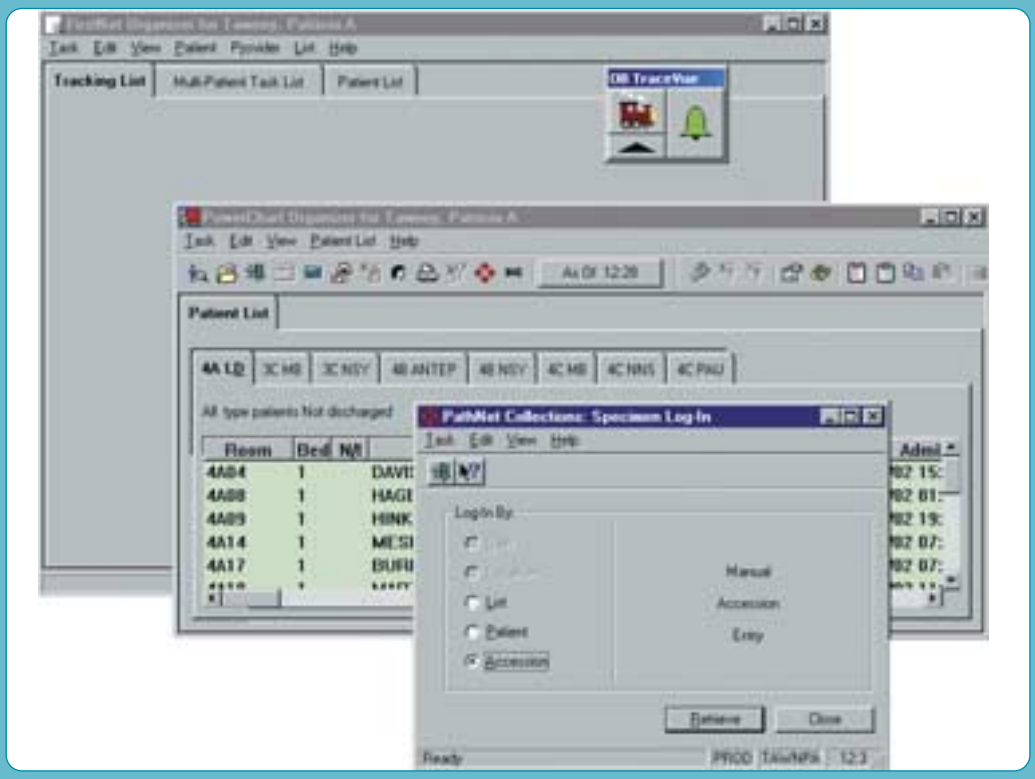


Active directory support in OB TraceVue (user authentication

Compatibility with other software products



OB TraceVue clients hosting third-party client software.



An example of a third-party software application running on an OB TraceVue client (OB TraceVue iconized).

In your day-to-day work in the obstetrics department, you need to meet your specific local medical/legal documentation requirements. Often local third party solutions may be better suited to address specific requirements.

The OB TraceVue application can allow parallel use of third party software (for example, Microsoft® Word) on your OB TraceVue client PC*. Using this facility you can reduce the amount of equipment needed in your department and save valuable space. Each application runs in a separate window, keeping its own unique user interface. The OB TraceVue application can be iconized and sits on top of the third party application. The icon still reflects any alert situation (flashing and sounding bell) and keeps you continuously informed on your patients' and on your system's condition, even when you are busy.

The installation requires special testing to ensure failure-free performance and smoothness of operation.

OB TraceVue and the third party software can exchange patient data via the OB TraceVue ADT link and the OB TraceVue export database server.

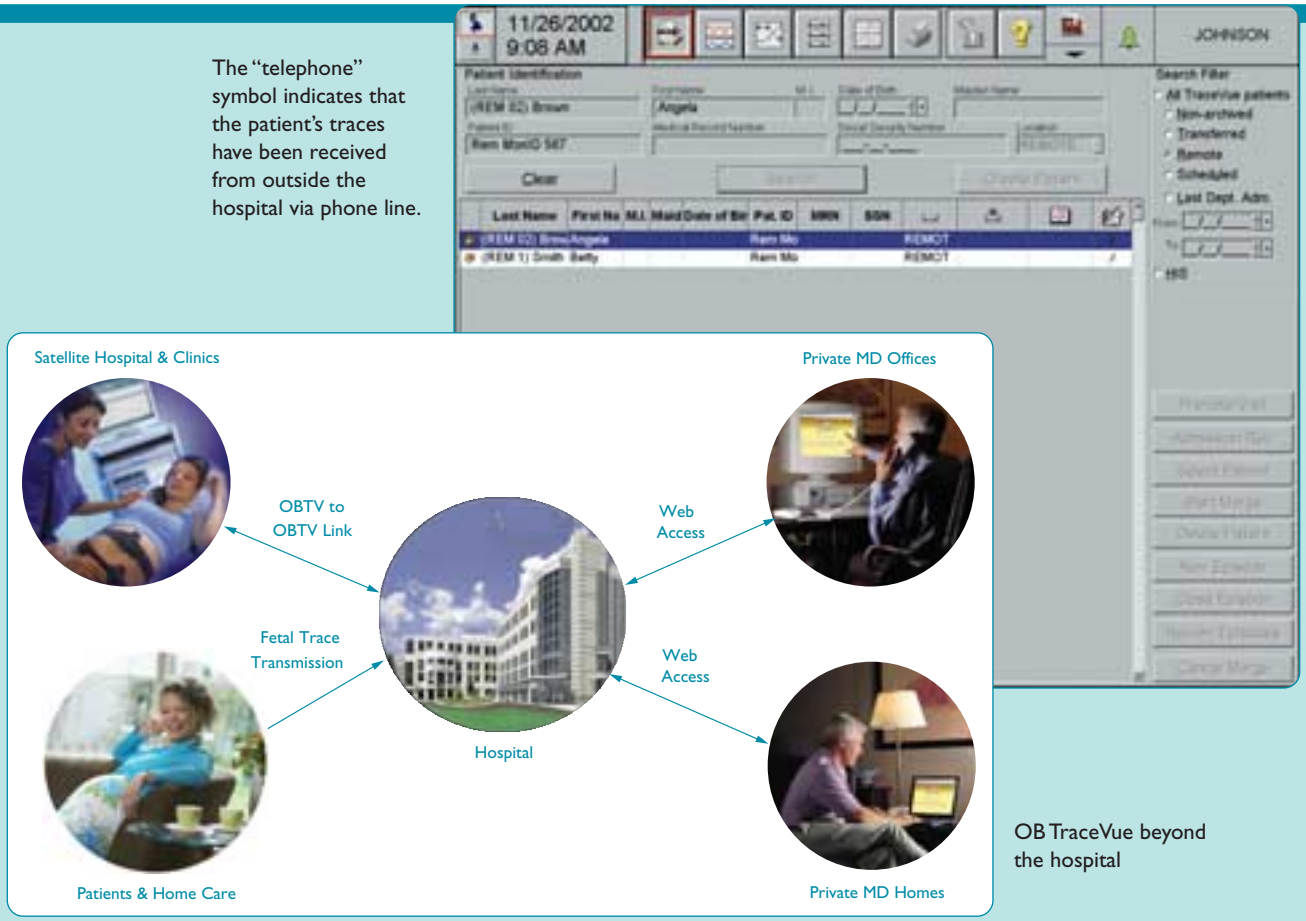
Patient data export from OB TraceVue to the third party solution can be implemented via the external database export facility as project business. For details, please consult your local Philips representative.

There are various ways you can set up your third party solutions with OB TraceVue. The third party software can be standalone or client/server based departmental. Such installations can be set up with the third party server residing within the OB TraceVue network or outside it, but as part of the hospital network.

*All third party software must be tested for compatibility. For details please contact your local Philips representative. The liability for the combined solution lies with the system integrator who integrates the third party software at the OB TraceVue client PC. This includes testing and documentation.

Communication

The "telephone" symbol indicates that the patient's traces have been received from outside the hospital via phone line.



OB TraceVue beyond the hospital

OB TraceVue is not restricted to the OB hospital department. It can communicate with other hospital OB TraceVue systems, the private physician office/home and fetal monitors connected via modems (remote patients).

Remote trace transmission (Remote patient)

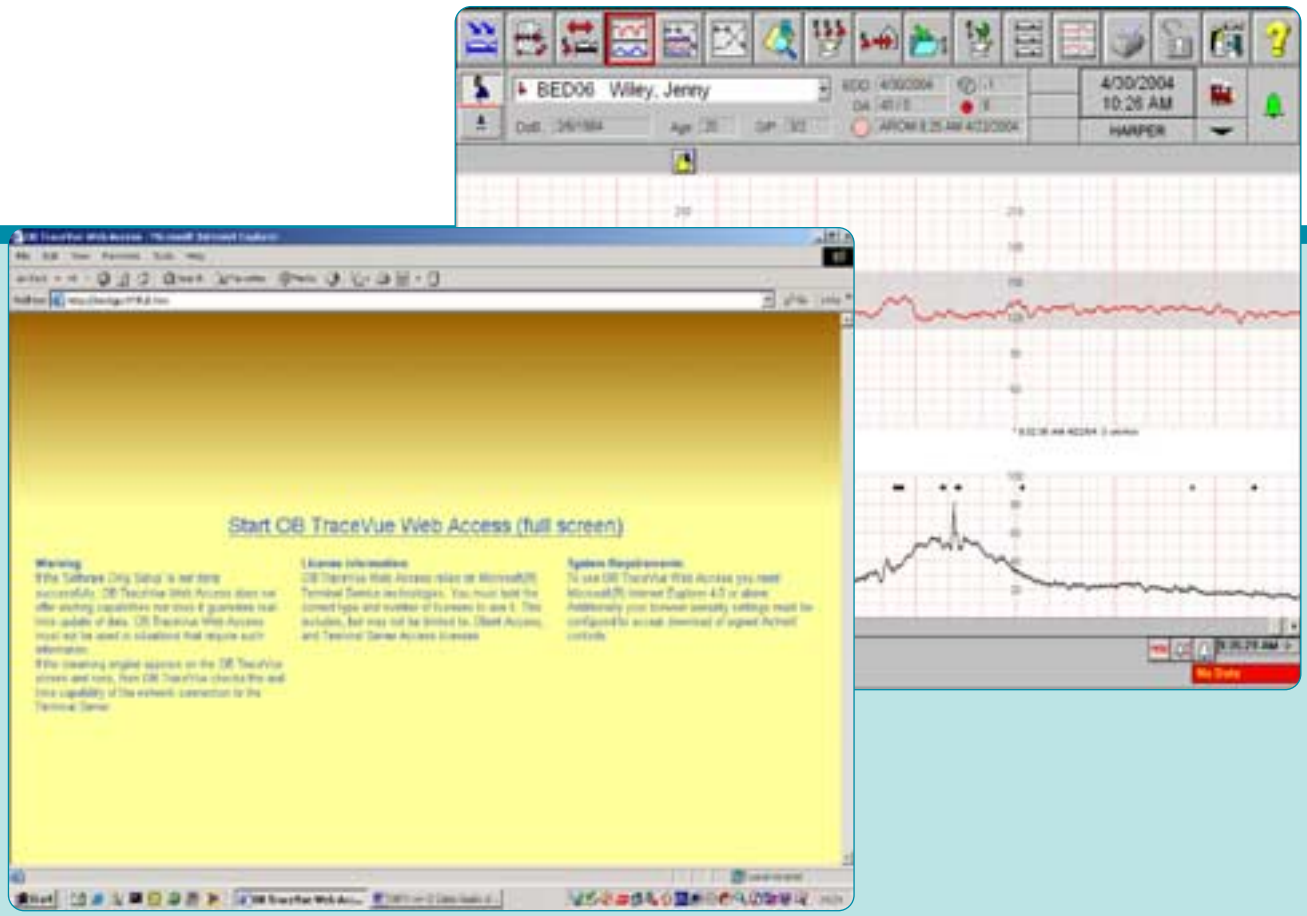
Increasingly, patients are being monitored outside the hospital to reduce the demands on hospital resources and to reduce fetal and maternal stress. OB TraceVue in combination with a Philips Avalon FM20, Avalon FM30, or FM-2 fetal monitor and a modem enables community healthcare providers and small antepartum clinics to transmit fetal traces over public telephone lines to obtain remote consultation. The transmission of these traces is protocol secured.

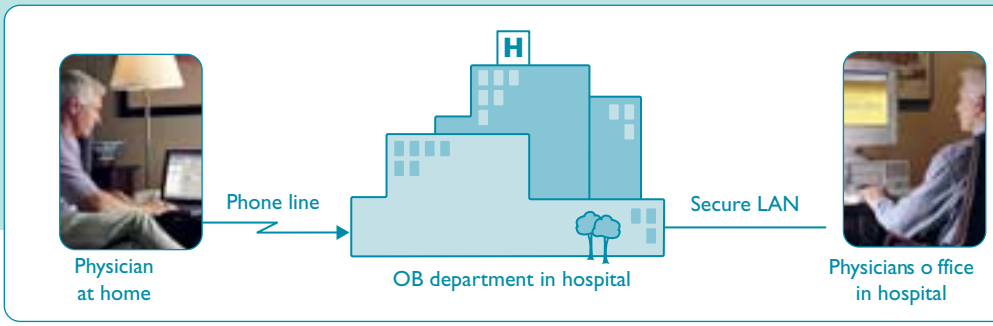
With the exception of alerting, these traces are handled the same way as locally received traces.

For review purposes the received traces can be scrolled on the screen. They can also be printed completely, or partially to show a certain time period. All trace presentation is in high quality. These traces can be stored on the optical disk with the necessary patient identification for later retrieval.

Trace transmission is initiated after monitoring to minimize telephone costs. Therefore, there are no alerting capabilities for remotely transmitted traces.

* Please check availability with your local Philips representative





Web access

Web access can be either used locally within the department or remotely from physician's office or home PC with Microsoft® Internet Explorer and a secure LAN or modem connection. It supports full read/write access to OB TraceVue patient documentation including reviewing patient traces and making notes. Web access to OB TraceVue is implemented via Microsoft® Internet Information services (IIS) and terminal services. Web access delivers the efficiency, convenience and reassurance of OB TraceVue to locations away from the OB department. The clinician, while remote, can be directly in touch with the patient's progress and does not need to wait for a faxed trace from the care team before deciding on a plan of action. Clinicians can manage their valuable time more efficiently and respond quickly and appropriately to patients' needs.

OB TraceVue-to-OB TraceVue communication

OB TraceVue allows you to transfer patient records from one system to another, just like moving a patient from one bed to another bed.

Typically a large birthing center has a system for inpatient care and one for outpatients in a separate outpatient clinic. Patient records will be moved to the inpatient system for delivery and will be moved back to the out patient system for the next delivery.

OB TraceVue-to-OB TraceVue patient record transfer can become also important when the patient has all her records in hospital A but delivers in hospital B due to unexpected reasons.

Patient Data Confidentiality and Security

What is covered by data confidentiality and security?

- Authentification of users
- Access control
- Audit trail
- Physical security and disaster recovery
- Protection of remote access points
- Data authentification
- Protection of external electronic communication
- Software discipline
- Education and training
- VIP patient treatment

Audit Trail

The audit trail records all user access and updates to the OB TraceVue System including:

- All user logons and logoffs including failed logons
- Audit trail of patient data being viewed by users (module level only)
- Audit trail of users viewing patients (module level only)
- Device status of monitors (logged in the patient notes system)
- All patient administration - admission, discharge and transfer - (logged in the patient notes system)
- All entered patient notes (flowsheet data). All changes are time stamped and user trailed. Deleted notes are still available in the audit trail.
- All modified patient data in audit trail (new value, deleted items, date, time and user). Patient data modifications done via Web clients are tagged separately in the audit trail. Web clients can be assigned remote status.
- Episode retrievals from the archive (date, time, episode, user)
- Clinical configuration changes of the system

Documentation

OB TraceVue is intuitive and easy to use, but to help you get the most from the system we also provide written and online documentation. Some materials are task-oriented, some are for reference and others are for quick, immediate use to solve problems or queries. Here is a list of the materials available and for which audience they are designed:

For clinical users

Online Help
Quick Reference Guide
Alerting Application Note

For system managers

System Administration and Configuration Guide
Online Help
Export Database Dictionary

For service/biomedical personnel

System Administration and Configuration Guide
Online Help
Installation and Service Manual
Integration Guide

For the implementation team

System Administration and Configuration Guide
Installation and Service Manual
Integration Guide
Ordering Guide
Site Preparation Manual

For clinical trainers

System Administration and Configuration Guide
Online Help
Quick Reference Guide
Export Database Dictionary
Training Kit
Alerting Application Note

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The application software (M1381D) of the OB TraceVue system complies with the requirements of the Council Directive 93/42/EEC of 14 June 1993 (Medical Device Directive).

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