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**"Leading the Way with Ultrasound for 25 years!"**

## Recommendations for Purchasing New and Used Ultrasound Systems for Pregnancy Centers

### Ultrasound Equipment

The technology, resolution and pricing of ultrasound systems has made many changes in the last 10 years with a range of options. There are 7"– 19" CRT or LCD monitors; B&W printers, mobile, hand carry and battery operated systems; carts; data management programs; network connections; warranties and other options. Brand new high quality diagnostic B&W ultrasound systems suitable for the pregnancy center's need of high resolution imaging to confirm fetal development and verifying viability cost approximately \$12K - \$21K. Systems with color and pulse wave Doppler normally cost an additional 10K – 15K. and not recommended for limited ultrasound. Due to the additional heat and energy that may cause harmful effects to the embryo, the pregnancy centers are advised not to use color or Doppler in the 1<sup>st</sup> trimester. If you choose to add Doppler without color the price is between 18K – 21K. Your medical director may choose allow the use Doppler after 10 weeks if abortion minded.

### AIUM Official Statement on use of Doppler:

*Fetal Safety Diagnostic ultrasound studies of the fetus are generally considered safe during pregnancy.<sup>45</sup> This diagnostic procedure should be performed only when there is a valid medical indication, and the lowest possible ultrasonic exposure setting should be used to gain the necessary diagnostic information under the ALARA (as low as reasonably achievable) principle.<sup>46–48</sup> A thermal index for soft tissue (Tis) should be used at earlier than 10 weeks' gestation, and a thermal index for bone (Tib) should be used at 10 weeks' gestation or later when bone ossification is evident. In keeping with the ALARA principle, M-mode imaging should be used instead of spectral Doppler imaging to document embryonic/fetal heart rate. The promotion, selling, or leasing of ultrasound equipment for making "keepsake fetal videos" is considered by the US Food and Drug Administration to be an unapproved use of a medical device.<sup>49</sup> Use of a diagnostic ultrasound system for these purposes, without a physician's order.*

## **Care Net Medical Advisory Board Statement Doppler us IN Medical PRC Feb. 2012\***

*“Medical PRCs are charged with adhering to the same standard of care as the rest of the medical community. Since the M-mode allows for adequate documentation of the fetal heartbeat with less potential for harm, Care Net recommends that centers refrain from using Doppler, in any form, during the first trimester, but especially before the 10<sup>th</sup> week from the last menstrual period. “*

### **Trans-vaginal Ultrasound in 1<sup>st</sup> Trimester:**

Due to the high rate of miscarriages in the 1<sup>st</sup> trimester the medical indication for Centers to provide ultrasound is to determine the viability of the pregnancy. This is obtained by examining the size, shape growth and location of the gestational sac and embryo. Using only TAS for evaluation of viability is not conclusive or recommended. [According to Aneet Kaur and Amanit Kaur:](#)

*From last two decades, ultrasound has become an essential diagnostic modality in the field of obstetrics for evaluation of pregnancy and fetal well-being. However, the standard transabdominal scanning using lower frequencies with relatively poorer axial resolution is unsuitable for imaging first trimester conceptus. The introduction of higher frequency transvaginal probe that can be placed close to the pelvic organs and has better resolution has opened entirely new possibilities to study in detail the early gestation.*

*To conclude TVS reliable identified normal and abnormal pregnancies and various developmental markers at an earlier stage than with TAS.*

### **Guidelines for Vendors to Participate in Grant Program:**

Vendors should agree to charge 20% - 30% over wholesale price on equipment.- This will eliminate the Centers paying different prices for the same, additional software that is not needed or software that is missing but will be added for an additional fee. If you participate in a grant program you refrain from exclusive relationships.

### **Minimum System Recommended**

- Diagnostic Imaging Ultrasound System – 5 years old or less from a major manufacturer
- Full obstetrical calculations package with report page
- M-Mode
- Scroll or Image Positioning
- i-Zoom –(Intelligent Zoom)
- i-Touch, i-Scan (Automatic Image Optimization)
- Harmonics or (THI)
- Dynamic Focus
- 9” , 12” or 15” monitor
- Auto Digital Reporting
- Digital Storage
- Broadband 2.5 – 5MHz Abdominal Convex Transducer with harmonics options.

- 5.0 – 8.0 MHz Transvaginal Transducer
- Two-year parts and labor warranty

## Minimum Peripherals Recommended

A black and white page printer is similar to a Polaroid camera in that you push a button and get a printout of what you see on the screen in a matter of seconds. Page Printers are physically small and are approximately 7” W x 5” H x 13” L They feed directly off the back of the ultrasound system and can capture any image that is displayed on the screen. The paper is inexpensive to give pictures to the patients.

## Recommended Features on the Ultrasound System

- **OB Calculations Package** – Almost all newer systems have what is called an OB Calculations Package. This package is a software program built into the ultrasound system, accessible from the system keypad. The package varies greatly from system to system, but below are certain minimums you want to look for:
  - **Pre-installed Gestational Age Tables** - include capabilities to handle BPD (Biparietal Diameter), FL (Femur Length), HC (Head Circumference), CRL (Crown-Rump Length), and AC (Abdominal Circumference), and GSD (Gestational Sac Diameter). The sonographer will acquire certain images, take measurements, and from the parameters, the system will calculate the estimated age and display it on the monitor.
  - **Report Page** – This feature inputs the calculated fetal age, patient identification, and other information onto a single screen that may be printed with the page printer. Some report screens are more inclusive than others, but the minimum report page should provide the patient identification information, LMP (Last Menstrual Period date), EDD (Estimated Due Date), GA (Gestational Age), and any of the BPD, FL, HC, CRL, or AC measurements taken. The fetal heartbeat should also be included on the report page.

Enhanced systems will provide an additional screen for growth curves and may also be printed for the patient’s record. The chart is not a critical feature but is very helpful for quickly and easily determining if the baby is within the normal growth pattern for his/her gestational age. Normally PRC’s do not utilize this function unless they are performing pre and post natal care with their patients.

- **Auto Reporting:** A few systems will allow for integrating your normally written ultrasound report into the machine software. While utilizing an inkjet printer a formal 8.5 x 11 report page with the images included may be given or sent digitally to the physician for their signature. Corrections on the report and/or images may be made even after the report is generated by assessing the software function. The information on the report is a customized formatted programming in the machine software usually done by the application specialist.
- **Digital Storage:** Digital storage allows digital transfer of images to a flash drive, DVD or Dicom for physician to report.

- **Ellipse or Trace Method for Measuring Circumference** – Both Head Circumference (HC) and Abdominal Circumference (AC) are parameters used to determine the gestational age and to evaluate fetal growth. Most PRC's do not use the AC function unless they are performing prenatal care.
- **Scroll** – This feature on the system provides the ability to move the image up or down on the screen. This feature allows the sonographer to obtain a clear image because he/she is able to enlarge or magnify the area of interest and then scroll or position the image to the center of the screen. This feature is very important for viewing cardiac motion and normal fetal anatomy in the first trimester when the baby is small.
- **Dynamic and Auto Focus** - Dynamic Focus controls the outgoing and incoming sound beam's focal point that allows the sonographer to control the focus to the area of interest. This feature provides for much better image resolution. Most, if not all, newer systems have this feature. On some systems, an Auto Focus enhances the Dynamic Focus which in turn enhances the Focal Zone offering the best resolution.
- **i-Touch or Auto Image Optimization** - This is a single button that provides image optimization after the transducer is placed on the area of interest. This option is excellent for PRC's and new sonographers to optimize their image. Small adjustments in the gain may still be needed.
- **Harmonics or THI** - This function will clear out artifacts in sonolucent structures and enhance the clarity of the images. Most newer systems will have this function for the Trans abdominal probe but it is suggested that this function be available for the Trans-Vaginal probe also.
- **i-Zoom or Intelligent Zoom**- Will enable enlargement of the image by placing and sizing a box around the area of interest. This is important for the 1<sup>st</sup> trimester imaging when the baby is small and difficult to see. If enlarged to much resolution will be lost. However, newer technology now allows i-Zoom with any loss of resolution in the enlarged image.
- **Post Cini Capture and Review** - This function allows you to save up to 12 seconds of the previous images in motion. This is an excellent option for PRC's who want to show special activity of the baby and save onto a clip. It will also allow for post measurements or additional images that were needed for the report.
- **Adjustable Sector Angles** - The narrow angle is best for early heart rates because of the faster frame rate. Newer systems now have wider angles up to 140 for viewing larger babies and structures.

## Used (or Pre-owned) Versus New: A Look at the Options

### *Used or Pre-owned Systems*

These systems offer lower prices but have certain risks. Most come with little or no warranty or service coverage. A system circuit board costs \$1000 - \$5,000 to be repaired, depending on the system and type of board. A new probe can cost more than \$5,000 if it needs replacing. Parts and/or knowledgeable technicians may not be available to repair 6 to 7- year-old systems.



So why would anyone want to buy a pre-owned system?

Some of the newer (5 years old or less) pre- owned systems that were used in demonstrations, or only for a few years at a clinic or hospital, still have many years of use left in them. The technology is new enough to cover both abdominal and transvaginal scanning capabilities, with almost all systems providing a complete OB Calculations package. Some of the dealers provide service and/or warranty coverage with the system, easing the worries of obtaining parts and service. Best of all, the price is usually thousands less than for a new system.

One of the major drawbacks, however, is availability. Most good, pre- owned ultrasound systems do not remain available on the open market for more than a few days. A center must have funds available to take advantage of a good bargain on short notice. New high resolution B&W systems are now affordable in the \$12,000 – \$15,000 range which will include a 1 – 2 year warranty so there is no need to taking the risk of purchasing a used system...

A note on “refurbished” machines. The term “refurbished” does not necessarily, and rarely does, mean the machine has been completely redone. Most often, if a part needs to be replaced it is by another used part in many cases and the electronics check is performed. If all parts are functioning correctly, the unit is cleaned up, possibly repainted, and it is now refurbished.

### *New Systems*

New systems offer state-of-the-art technology with full one year warranties for all service and parts. Some machines have two-year warranties plus discounts for multiple year service contracts. Service contracts average \$2000 - \$5000 per year depending on equipment included. Know what you are getting for your money and evaluate your total “cost of ownership” Don’t be surprised after the purchase on what the cost will be to main your equipment and make sure that the company has a reputation for high quality systems and service. Some companies have national Service with Engineers servicing equipment while others utilize the sales representative who is not an engineer.

Sonographers will prefer the latest imaging technology to obtain the best images and to be able to visualize early cardiac motion and other details. The patient will be encouraged by the

professional, high resolution images of her baby.

### ***Portable, Small, Lower Weight Systems Now Available***

The new portable systems today provide images that are very close or the same in quality and resolution to the larger general radiology systems weighing hundreds of pounds and used for complete diagnostic service. Excellent imaging technology and affordable pricing in a system that you can hand-carry to various centers increases its value significantly. Various self adjusting carts are available and should hold your system, portable printer and probes. The screen on the portable system is usually very small. Connecting a larger screen (TV or computer monitor) to the system allows mom and family to see the baby while the sonographer views the smaller monitor.

### ***3D and 4D Systems***

This type of imaging will cost between 35K- 70K and is not recommended for the limited ultrasound used within the PRC's. It is mainly used in late 2<sup>nd</sup> and 3<sup>rd</sup> trimester for the total survey scan or when an abnormality is suspected. Some companies also use it for non-diagnostic photo imaging which is not supported by the AIUM or FDA. Using 2D imaging in 1<sup>st</sup> and early trimester allow for better viewing of the baby. Some systems have color mapping that simply changes the gray scale to different colors giving 4D effect without the extra exposure of color imaging.

## **Ultrasound Supplies Needed**

### ***Miscellaneous Supplies***

#### ***Exam Table***

A pre-owned exam table may be donated from a local hospital or physician. It should be equipped with stirrups for vaginal scans. The head portion of the table should be able to be raised. All exam tables are very heavy.

#### ***Transmission Gel***

This medium allows the sound waves to travel from the transducer to and through the skin. There must be sufficient gel on the skin to facilitate the travel of the sound waves and provide a good image to the system. It is available in a variety of viscosities and does not stain clothing. Sterile gel should be used for the trans-vaginal scans. Gel warmers are available for heating the gel prior to application.

#### ***Disposable Drape Sheets***

These disposable paper sheets allow for discreet and professional exams by keeping the patient as covered as possible before, during, and after the exam. They are available from many sources and may be purchased in bulk quantities.

#### ***Latex and Non-Latex Disposable Exam Gloves (Non-Sterile)***

To ensure cleanliness and safety for both the patient and the sonographer, you should have an

ample supply of disposable gloves. Note that they come in different sizes - usually a box of Medium and box of Large will suffice.

### ***Probe Covers for Vaginal Probes***

Various probe covers are available, latex and latex free, and must be used when performing a vaginal scan. Some sleeve” type covers may have a seam on the end which may cause artifacts while scanning. Use proper technique when applying, removing and disposing of covers. Follow any OSHA guidelines mandated by your State.

### ***Probe Cleaning***

Abdominal probes may be cleaned with T-spray, Sani Wipes HB or other manufacturer recommended agents. No alcohol based solvents should be used.

Vaginal probes must be soaked in a solution recommended by the manufacturer. Special soakers for the vaginal probes can be purchased through various supplies. If any incorrect solution is used, it may damage the probe parts and void the probe warranty. The AIUM (American Institute of Ultrasound in Medicine) recommends a high level disinfectant for soaking vaginal the probes.

Cidex or Cidex Plus is a high level disinfectant but should be used in a ventilated area with very specific precautions. A new Hydrogen Peroxide solution is now available that enables an 8 minute soak and without the fumes associated with glutaraldehyde or products.

### ***Disinfectant or Germicide***

You will need to disinfect the transducer(s) and all other equipment or instruments that come in contact with the patient after each exam. There are several types of disinfectant sprays and liquids available on the market. Follow the recommendation of your sonographer and manufacturer’s specifications and instructions for each instrument or piece of equipment.

### ***Transvaginal Probe Covers***

If you have a trans-vaginal transducer, you will need to have a supply of probe covers, including a supply of non-latex ones. These can be purchased from a major medical supplier in bulk quantities to decrease costs.

### ***Printer Paper***

Paper for the black and white page printers used with ultrasound systems come in rolls. You will need to purchase this paper specifically for the type of printer.

## ***Optional Equipment***

### ***Separate Viewing Monitor***

This is an option if the system does not have a large enough monitor, or if the monitor in the system cannot be readily viewed by the patient. An additional monitor would usually be connected to the back of the ultrasound system, or mounted on the wall, and would be directly connected by a coaxial cable to the video signal (image) of the ultrasound system.

### ***Gel Warmer***

Gel warmers provide additional comfort for your patient. They are basically sophisticated baby bottle warmers designed to fit .25 ml bottles.