### Technology:
Four-dimensional (4D) ultrasound

### Manufacturer:
The only manufacturer at the present time is GE Medical Systems which markets the Voluson 730 4D Ultrasound System.

### Purpose:
4D ultrasound is used for imaging various parts of the body such as the breast, prostate and abdomen, and in particular for pediatric imaging, obstetrics and gynecology, needle placement in biopsy and in cardiology for the diagnosis of heart disease (echocardiography). Most of the recent media attention on 4D ultrasound has focused on its use in prenatal diagnosis, and this application is the sole application considered in this bulletin.

### Current Regulatory Status:
The Voluson 730 Ultrasound System received a 510(k) premarket approval from the US Food and Drug Administration in November 2000. The System received licensing from Health Canada in March 2002 (Kathleen Savage, Health Canada, Ottawa: personal communication, 2002 Dec 17). At present there are 13 of these units in Canada, including three units at the Hamilton Health Sciences Centre (two units in the *in vitro* fertilization clinic and one unit at McMaster University's Department of Obstetrics and Gynecology), a unit on trial at the Winnipeg General Hospital, and several in private clinics in Alberta, Ontario and Quebec. GE Medical Systems Canada expects to have another eight units installed in Canadian centres by the end of 2002 (Larry Gayowsky, GE Medical Systems Canada, Mississauga, ON: personal communication, 2002 Dec 13).

### Description:
The fourth dimension in 4D ultrasound (also called "dynamic 3D" or "real-time 3D") refers to the ability to see high quality, three-dimensional images in motion. In 2D ultrasound the image is made up of a series of thin slices and only one slice can be seen at a time. With 3D ultrasound a volume of echoes is taken which can be stored digitally and processed to produce life-like images of a fetus. With 4D, these images can be seen to move in real-time similar to a video.

The technology is not new, but it has not been in widespread clinical use until recently, mainly due to improvements in computers and the capabilities for digital processing, storage and display of images. The technology allows the viewer to see the stored images in various ways, for example, surface rendering provides an image similar to that seen in a photograph or video, whereas the transparent maximum mode provides high quality rendering of the skeleton of the fetus. Another option for viewing images is as orthogonal planes, which allows the assessment of cross-sectional anatomy. In addition, 3D and 4D ultrasound offer an improved way to measure volume, particularly the volume of irregular or complex shapes. This may improve the evaluation of tumour growth or regression in response to treatment.

### Cost:
The cost of the GE Voluson 730 ranges from C$200,000-250,000, depending on the different components purchased. The Voluson 730 includes the capabilities for high-resolution 2D ultrasound, 3D (volumetric) ultrasound, and real-time 4D ultrasound.
The key issues around this technology are whether or not 4D ultrasound increases diagnostic accuracy due to the better clarity of the images, and if so, whether patient management is improved as a result. At present, there are no published, comparative studies of 4D ultrasound that show its effect on patient management.

In one of the few published studies to date, Kurjak et al. compared the use of 2D to 4D ultrasound in the detection of fetal movement in 98 pregnant women between six to twelve weeks gestation. The main finding of their study was that 4D ultrasound allowed fetal movements to be visualized one week earlier than with 2D scanning.3

An editorial on 3D ultrasound makes a number of points that are also relevant to the assessment of 4D ultrasound.4 First, there are no published, randomized controlled trials comparing 2D and 3D ultrasound in prenatal diagnosis. Many existing studies use "a biased study sample" of women suspected of having an obstetric or gynecologic abnormality previously identified by a 2D scan. The editorial does not provide actual data from the findings of these studies, but states that, despite their shortcomings, they indicate "small but substantive gains" in diagnostic accuracy.

A recent review cites several prospective studies that found an overall improvement in diagnostic accuracy in the detection of cleft lip using 3D ultrasound, in comparison to 2D. For example, one study of 71 fetuses found that although 2D and 3D scans both detected all cases of cleft lip, the 3D ultrasound diagnosed normal lip formation in 92% of fetuses, in comparison to 76% for 2D.5 The technology also offers some advantage to the physician and parents in communicating information about fetal facial abnormalities and any planned treatment.6

Earlier generations of ultrasound technologies, particularly 2D, are widely used for diagnostic imaging, and 2D, in particular, provides the foundation for prenatal diagnosis and is likely to continue to do so for some time.7 It is likely that 4D ultrasound is more of an incremental development, rather than a revolutionary change, in ultrasound imaging technology. The technology is currently an add-on to 2D ultrasound, rather than a replacement for it. As with many medical technologies, much depends on the skill of the operator, and there is a long learning curve in the use of 3D and 4D ultrasound. At present there is little in the published literature to indicate how much of an improvement in diagnostic accuracy it offers or the extent of its impact on patient management. A recent review concludes:
The clinical usefulness and the potential applications of real-time 3D or 4D ultrasound have not yet been fully established, therefore no published material is available at this time. Several applications may, however, become important. Fetal behavior can be studied by observing the various body movements. Previously, the study of behavior-focused fetal physiology was the purview of electronic methods, such as heart rate recordings, tocodynametric registrations of movements, and real-time 2D ultrasound. These will almost certainly be studied anew and will prove to be more accurately defined using the real-time 3D ultrasound method. Near real-time 3D or 4D ultrasound will undoubtedly enable an even closer look at various fetal anomalies in which motion plays a significant part. In addition, as the acquisition of the scan or images becomes faster, it is only a matter of time before true real-time 3D evaluation of the fetal heart motion and anatomy will become a reality.

There is a potential for 4D ultrasound to be used inappropriately. Commercials in the US for the 4D ultrasound unit, aimed at consumers rather than physicians and health care organizations, have focused on facial pictures of the fetus in the late stages of pregnancy, rather than in the first trimester, where prenatal diagnosis for fetal abnormalities usually occurs. According to a newspaper report, anti-abortion groups believe that the clearer pictures of the fetus offered by the technology help to promote its existence as a human. One US pro-life group has reportedly purchased a 4D ultrasound unit and is offering scans to women in their first trimester of pregnancy who might be considering abortion.

Some private US clinics are promoting 4D ultrasound scans to pregnant women on a "self-referral basis for the purpose of enhancing parental bonding." Enhancement of parental bonding is often mentioned as a benefit of 4D ultrasound, but, other than anecdotal reports, the only published studies of this aspect of prenatal ultrasound have used 2D and 3D units and these found only short-term benefit. A review of the psychological aspects of ultrasound examinations in pregnancy concluded that "there are no proven long-term effects of ultrasound visualization on bonding with the fetus or on pregnant women's health-related maternal behaviour…"

The medical director of a perinatal ultrasound clinic in one US hospital explains that "good medical sonographers can determine 'very little' additional information about the health of the fetus from a 3D or 4D ultrasound compared with a traditional two-dimensional image."

References:

Emerging Technology List

FOUR-DIMENSIONAL ULTRASOUND FOR PRENATAL DIAGNOSIS


CCOHTA would like to thank Dr. Patrick Mohide, Professor and Chair of the Department of Obstetrics and Gynecology at McMaster University, for his thoughtful comments on the draft of this summary.

This summary was prepared by Leigh-Ann Topfer, MLS and David Hailey, PhD; CCOHTA.

This series highlights medical technologies that are not yet in widespread use in Canada and that may have a significant impact on health care. The contents are based on information from early experience with the technology; however, further evidence may become available in the future. These summaries are not intended to replace professional medical advice. They are compiled as an information service for those involved in planning and providing health care in Canada.

These summaries have not been externally peer reviewed.

ISSN 1499-108X (online only)

The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) is a non-profit organization funded by the federal, provincial and territorial governments. (www.ccohta.ca)