

K952540

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Attachment D to Cover Letter
Acoustic Densitometry 510(k)

510(k) Summary of Safety and Effectiveness: 21CFR 807.92

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Date summary was prepared: May 16, 1995

2) **Trade Name:** Sonos Imaging System
Common Name: Ultrasound Imaging System
Classification Name: Echocardiograph 74DXK

3) Identification of Predicate Device

The predicate device for this submittal is made by Kontron Electronics and is called the Mipron Image Processing System. The 510(k) number for the Mipron system is K891689.

4) Description of the device and or modification being submitted for premarket approval.

This 510(k) submittal is for a SW modification to Hewlett-Packard ultrasound imaging systems that have been previously reviewed by the FDA and found to be substantially equivalent.

Functionality

This SW modification provides the capability to:

- 1) define a region of interest (ROI) in an image;
- 2) quantify the average brightness level in the ROI;
- 3) track the brightness level versus time for the ROI.

Scientific concepts

2D images are created using different shades of grey. These shades of grey are assigned acoustic unit levels. The highest number (64,128,256) is given to the bright end of the scale. The lowest number (0,1) would be given to the dark or black end of the scale. This SW feature looks at the grey levels stored in the digital scan converter for a predefined region of interest selected by the operator. The average intensity or brightness for that region is then computed for one point in time. Successive calculations can be performed over time for the same region of interest using a time interval selected by the operator. There is no unique algorithm associated with the computation of the average brightness level from the data stored in the digital scan converter.

Significant characteristics of the device

This SW modification has only one characteristic that can be considered significant. It provides the user with a quantifiable assessment of image brightness. Image brightness assessment on earlier HP ultrasound systems was purely qualitative.

The most significant aspect of this SW modification is the minimal impact it will have on system safety.

- 1) It does not affect acoustic output levels
- 2) It does not affect the dimensions of the product
- 3) It does not affect the patient contact materials of the product
- 4) The brightness level is not used to make a diagnosis
- 6) It does not affect the primary electrical specifications (current draw, ratings, leakage current etc) of the host system.

5) Statement of Intended Use

This SW modification does not affect the intended use statements of the previously reviewed HP imaging platforms. The users guide will be modified to indicate that the brightness measurement is available along with the other measurement primitives and mathematical quantities calculated from primitives such as: frequency, length, time, area, circumference, slope, velocity etc.

6) Predicate Device Comparison

Feature	Predicate Device	HP Acoustic Densitometry
Used w/ real time video ultrasound images	Yes	Yes
Used w/ ultrasound images played back from VCR	Yes	Yes
Ability to measure image brightness	Yes	Yes
Range of grey scale quantification (Grey Scale Acoustic Units: AU)	0-255	0-63
Ability to generate time vs intensity graphs (see Appendix E)	Yes	Yes
# of images stored for time vs intensity graph	25	60
Use of triggered images	Yes	Yes
Ability to post process image brightness	Yes	Yes
Ability to define a region of interest for brightness measurement	Yes	Yes