Revision date: 26/11/2021
Revision number:00/ Nov 2021

Ultrasound Paper

Instructions For Use

Device Classification:

This product shall be classified into class 1 according to Medical Device Directive 93/42/EEC and 2007/47/EC Rule 1.

Device Description:

Ultrasound paper can show a general pictorial representation of the device, e.g Photograph. It can give high resolution and good durability image.

Applications:

Ultrasound machines

Intended Used:

Ultrasound is a medical diagnostic technique in which very high frequency soundis directed into the desired body part. The tissue interfaces reflect the sound, anda computer produces a photograph or a moving image on a television processes the resulting pattern of sound reflection. Ultrasound can be used to examine many parts of the body, but best-known application is the examination of the fetusduring pregnancy. The image can be printed on synthetic paper for use in diagnosis.

Instructions of Use:

The fixing of the paper recording, paper photographic into printing devices is differed from different printing devices. User shall refer to instruction on label for recommended model.

For thermal reaction to take place, the heat sensitive side should in touch with printing head.

Indications:

Results printed on the medical chart can be used for detecting normal/ abnormal heartbeat of patients.

Contraindications:

Thermal medical recording chart shall not be use if it has change to black, because this shows thermal reaction already taken place.

Warnings:

Thermal medical recording chart did not contain any hazardous substances and dangerous mechanical move parts, there is no any warning needed when using the products.

Precautions:

These are no any significant potential undesirable and serious outcomes (death, injury or serious adverse events) to the patient/user, or side effects from the use of this product thermal paper, under normal conditions, no any precautions is needed.

Potential Adverse Effects:

These are no any significant potential undesirable and serious outcomes (death, injury or serious adverse events) to the patient/user, or side effects from the use of this product thermal paper, under normal conditions.

Legal manufacturer:

Global SCP Medical Systems Pte. Ltd., Singapore