**Establishment Letterhead**

**URGENT - Field Safety Notice**

To all users of the <medical device name>

**Re: <medical device name> with <short description of the malfunction>**

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the *<part of the medical device that causes the malfunction>* of the *<medical device name with**specific details to enable the affected medical device to be easily identified e.g. type of medical device, model name and number, batch/lot or serial numbers of affected medical devices and part or order number>.*

**When does this malfunction occur and what are the potential risks ?**

<*A factual statement explaining the reasons for the Field Safety Notice including description of the medical device deficiency or malfunction, clarification of the potential*

*hazard associated with the continued use of the medical device and the associated risk to the patient, user or other person and any possible risks to patients associated with previous use of affected medical devices>*

**What steps can the user take to avoid the potential risk of this issue?**

*<Include as appropriate:*

o *Identifying and quarantining the medical device,*

o *method of recovery, disposal or modification of medical device,*

o *recommended review of patients previous results or patient follow up, if applicable,*

o *timelines>*

***<Only if applicable>* How will the issue finally be resolved?**

Xxxxx Sdn.Bhd. is preparing a modification of *<medical device name>* that will resolve this potential malfunction. The field modification will be available from <date>.

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System’s instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours

*<signature of Manager / Regulatory Affairs >*

*<name>*

*<date>*

Contact person of this notification

………………………………………

Department ……………….…….………….

Telephone ………………………………….

Fax …………………………………..……...

E-mail ………………………………………

**Acknowledgement of receipt**

I hereby confirm as the owner / responsible operator of the *<medical device name>* with the Serial number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(optional) that I received the following document:

**Field Safety Notice**

<medical device name> with <short description of the malfunction>

Place : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Company stamp :