



ACKNOWLEDGEMENT - CT Exprès™ hand switch

April 11, 2014

Dear customer,

This letter is to make you aware of an issue with the CT Exprès™ contrast media injection system that when used with the hand switch feature may be potentially hazardous to patients. No patient have been harmed with the CT Exprès™ system.

Although rare, the hand switch used with a specific sequence of procedure steps has been observed to intermittently cause the injector to erroneously stay in injection test mode which may alter safety features.

Consequently, the injection may result in an over delivery of contrast media equivalent to the programmed post flush volume .

The root cause is software-hardware based. A new software version is being created to resolve the problem.

While the hand switch is not used profusely by end users and they are not required to do so, Bracco Injeneering has voluntarily decided to withdraw this optional hand switch feature from the market to secure the safety of patients until the new software is available. Your assistance and cooperation in this effort is needed.

You are kindly requested to read and acknowledge this letter. Please do so by completing the "Acknowledgment" form (attached to this letter) for each CT Exprès™ and hand switches in your possession and ship the hand switch(es) to your Bracco Injeneering local representative.

The software update is scheduled to be released June 2014. Installation of the software update for your CT Exprès™ injector will be done during the preventive maintenance and the hand switch will be returned to you at that time (as recorded in "Acknowledgement" forms).

Please accept a sincere apology for any inconvenience that this action might cause and do not hesitate to contact your Bracco Injeneering local representative for further questions or comments.

We thank you for choosing CT Exprès™ and we confirm our commitment in providing you with safe quality products.

Acknowledgment - CT Exprès™ hand switch

Hospital/City/Department: _____

CT Exprès injector unit SN: _____

CT Exprès control panels SN: _____

I declare:

- to have read the letter: "Acknowledgement - CT Exprès™ hand switch"
- to possess the hand switch to not possess the hand switch
for the use of the above mentioned CT Exprès™ injector
- (if in possess of the hand switch), to immediately stop its use and return the
hand switch to my Bracco Injeneering local representative.

Name: _____

Function: _____

Departement: _____

Date: _____ Signature: _____