Document Control

<table>
<tr><td colspan="5">Title
Ionising Radiation (Medical Exposures) Regulations Procedures & Protocols
For Use of the Fluoroscan InSight FD Mini C-Arm in Orthopaedic Extremity Surgery</td></tr>
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<tr><td colspan="2">Directorate
Surgery</td><td colspan="2">Department
Orthopaedics</td><td>Team/Specialty
Orthopaedics</td></tr>
<tr><td>Version</td><td>Date Issued</td><td>Status</td><td colspan="2">Comment / Changes / Approval</td></tr>
<tr><td>0.1</td><td>Mar 2020</td><td>Draft</td><td colspan="2">Initial version for consultation</td></tr>
<tr><td>0.2</td><td>Apr 2020</td><td>Draft</td><td colspan="2">Amendments made following initial consultation</td></tr>
<tr><td>1.0</td><td>Apr 2020</td><td>Final</td><td colspan="2">Approved by Orthopaedic Governance Group & Radiology Management Group</td></tr>
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<tr><td colspan="3">Document Class
Standard Operating Procedure</td><td colspan="2">Target Audience
Orthopaedics, Theatre Staff, Radiographers</td></tr>
<tr><td colspan="3">Distribution List
Orthopaedic Surgeons, Radiology & Theatres</td><td colspan="2">Distribution Method
Trust's internal website</td></tr>
<tr><td colspan="3">Superseded Documents
New Document</td><td colspan="2"></td></tr>
<tr><td colspan="2">Issue Date
April 2020</td><td colspan="2">Review Date
April 2023</td><td>Review Cycle
Three years</td></tr>
<tr><td colspan="3">Consulted with the following stakeholders: (list all)
• All users of this document
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• Radiology Clinical Lead
• Radiology Governance Lead
• Radiation Protection Advisor (RPA)
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Education/ training will be provided by:
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</table>

Approval and Review Process • Trauma & Orthopaedic Governance Group • Radiology Management Group	
Local Archive Reference G:\Orthopaedics Public Drive **Local Path** Orthopaedics\Jagodzinski\Mini C-arm **Filename** \Ionising Radiation (Medical Exposures) Regulations Procedures & Protocols For Use of the Fluoroscan InSight FD Mini C-Arm in Orthopaedic Extremity Surgery	
Policy categories for Trust's internal website (Bob) • Diagnostic Imaging Trust's internal website	**Tags for Trust's internal website (Bob)** Practitioner, Operator, IR(ME)R, Medical Physics

CONTENTS

1. Background

A mini c-arm unit is used to provide imaging during operating procedures and assessments, and is operated predominantly by Orthopaedic and Plastic Surgeons for imaging extremities, however may also be operated by Radiographers as defined in these procedures.
Although the mini c-arm system produces a much smaller dose than conventional image intensifiers it is still governed by the requirements of the Ionising Radiation Regulations 2017 (IRR17) and the Ionising Radiation (Medical Exposures) Regulations 2017 (IR(ME)R 17)

2. Purpose

The Standard Operating Procedure (SOP) has been written to:

- Establish a series of procedures under which a Medical Practitioner can act as referrer and operator.
- Allow other Healthcare Professionals to act as an Operator for the use of the mini C-arm.
- Monitor and manage the inappropriate, unauthorised or unsafe use of the mini C-arm in line with the Trust's Disciplinary Policy

3. Scope

This Standard Operating Procedure (SOP) relates to the following staff groups who may be involved in the use of the mini c-arm in Theatres and other rooms as designated in the Local Rules and who have been trained and authorised to do so:

- Orthopaedic Surgeons
- Radiographers
- Medical Physics
- Engineers
- Nurses

4. Location

This Standard Operating Procedure applies to the mini C-arm (Fluoroscan InSight FD) used in Theatres and Other Rooms as designated in the Local Rules at the North Devon District Hospital, Barnstaple.

Staff undertaking this procedure must be able to demonstrate continued competence as per the organisations policy on assessing and maintaining competence.

5. Equipment

Fluoroscan InSight FD Mini C-arm.

6. Procedure

6.1. General Health and Safety Requirements

All staff working with Ionising Radiations must do so in accordance with the requirements of the Ionising Radiations Regulation 2017 (IRR17) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R).

All staff must read and adhere to the appropriate Local Rules.

These procedures are for compliance with IR(ME)R and must be followed by those with responsibilities under the regulations.

6.2. Designated Areas of Use for the Mini C-arm

The Fluoroscan InSight FD Mini c-arm belongs to theatres, and will be used in Day Surgery Theatres 5 & 6 as well as other rooms in Fracture Clinic and Outpatients as designated in the Local Rules.

The mini c-arm is only to be used for procedures detailed in this document, carried out in designated operating theatres and rooms.

Any planned use of the mini c-arm outside of these areas must be authorised by the Radiation Protection Adviser or nominated deputy.

6.3. Identification of Duty Holders

Referrer – Registered Medical Practitioner.

Practitioner - listed surgical clinical procedures in this document are justified by the Clinical Lead for Radiology acting as Practitioner. Any other procedures must be individually justified by a Consultant Radiologist.

Operator – the Operator carries out practical aspects of the exposure including authorising the individual exposure under the protocols as detailed in appendix 2, imaging and any manipulation of the equipment controls and display. Operators may also undertake QA measurements.

All Operators must be suitably trained and authorised to act in this capacity in accordance with these procedures.

6.4. Use of the Mini C-arm

The mini C-arm may only be used by those trained and authorised to do so, and only in accordance with the procedures contained within this document.

No person may manipulate / use the mini c-arm in any way unless deemed a suitably trained Operator in accordance with these procedures.

A risk assessment must be carried out before any new or changed activity involving the use of the mini c-arm.

The mini c-arm used within this Trust can only be operated by password, supplied by the System Administrator.

Suitably trained Radiographers may also act as Operators.

Suitably trained engineers, radiographers, medical physics staff and other staff on a named basis are authorised to use the equipment for maintenance and QA purposes.

6.5. Training Requirements

Medical Practitioners and other Healthcare Professionals may only act as Operators for use of the Mini C-arm if they have undergone suitable training; in most instances this will include the following points:

1) Hold a certificate of attendance at a dedicated mini C-arm training course or demonstrate the completion of an appropriate on-line training course (e.g. e-IRMER on the e-learning for health website).

2) Documented practical training in the use of the equipment (Appendix 2)

3) Carried out practical clinical training under the supervision of designated training supervisor (Appendix 3). The designated training supervisor will determine when the individual has carried out sufficient cases to demonstrate competence and understanding of optimisation of image quality.

This log will consist of a list of names of authorised mini C-arm operators, along with their training records and course certificates.

The *responsible person* will keep a copy of the log that will be producible on request.

Those surgeons who have not fulfilled the above criteria, and require imaging to facilitate their procedure, must ensure a trained and authorised Operator is available for the case, or refer to the covering radiographer who will operate the mini c-arm if available.

6.6. Referral

The referrer is the surgeon who books the patient for the procedure or examination that requires imaging. Referral is either by a letter in the clinical or the waiting list booking form. In urgent trauma cases, the operator may receive a verbal referral, prior to the letter reaching the records.

Once the referral has been made the patient's details and examination will be entered onto CRIS to create an episode; this may be done as an appointment for a future date or prior to the examination itself to provide a worklist for the mini c-arm.

6.7. Justification & Authorisation

The following procedures are justified:

1) Reduction of fractures, dislocations and subluxations*
2) External, internal or percutaneous fixation of fractures or joint disruptions*
3) Location of bone fragments or foreign bodies*
4) Positioning of K-wires, screws and implants*
5) Confirmation of the effect of surgery on bones, joints or soft tissues*
6) Positioning of needles for joint aspiration or injection*
7) Dynamic examinations under anaesthesia for diagnostic purposes*

* adult and paediatric hand, wrist, forearm, elbow, foot and ankle. Paediatric knee

All other procedures must be individually justified by a Practitioner (Consultant Radiologist)

The Operator will authorise the exposure in accordance with the written criteria contained in this protocol. Completion of all patient fields, users' details and procedure performed are inputted into the mini c-arm. If the referral does not meet the agreed criteria, a Practitioner must individually justify the exposure.

6.8. Patient Referral and Verification

Verification of patient ID is carried out as a part of standard theatre procedures and includes positive checks of the name, DOB and hospital or NHS number; this must also be performed if the procedure is carried out in a designated room other than theatres. Whilst the process of identifying the patient may be carried out by another member of the theatre team, the Operator is still responsible for ensuring it has been carried out correctly and in accordance with this protocol.

6.9. Recording of the Procedure and Clinical Evaluation

Following the procedure, it is the operating surgeon's responsibility to make a clinical evaluation of the exposure in the patient's medical records by:

1) Noting the outcome, in the operation note the screening time and dose area product are also recorded and stored on the x-ray unit, and should be recorded on CRIS for audit purposes.
2) Images and DAP report must be sent to PACS for archive; this may be done via Wifi or cable hook up in any of the PACS points (DSU, Main Theatres or Radiology).
3) A print of the relevant images may also be attached to the patient's notes if required

6.10. Optimisation

The operator has control over each exposure and must make all efforts to reduce the dose to the patient as far as reasonably practicable including:

- Keeping screening time to a minimum.
- Positioning the part to be examined properly.
- Collimating the beam as much as possible to only view the required anatomy.
- Ensuring the X-ray tube is as far away from the patient as is possible - and a minimum X-ray distance of 30cm
- In difficult cases if the reassessment screening time (the maximum screening time recommended for that procedure and listed in Appendix 2) has been reached, an assessment of the procedure should be undertaken and one of the following options selected:
  1) If progress is being made, to continue the case, after deciding a cut-off screening time

2) To seek assistance or advice (this is mandatory if a junior surgeon exceeds the maximum recommended screening time)
3) To complete the procedure with no further screening.
4) To abandon the procedure if it seems unlikely the desired outcome will be achieved.

6.11. Irradiation of Women of Child-bearing age (12- 55 years)

For use of the mini c -arm for procedures in this document, the risk to the foetus from any exposure to ionising radiation is very small and much less than 1mSv.

All exposures under this protocol do not involve direct irradiation of the abdomen of women of child bearing age (12 – 55 years).

There is, therefore, no requirement for the Operator to establish likelihood of pregnancy with regard to the medical exposure.

However, if the patient is known to be pregnant, then measures should be considered to minimise the dose to the foetus.

6.12. Medico-Legal Exposures and Research Exposures

No medico-legal procedure may take place without prior consultation of a consultant radiologist who must act as Practitioner for the exposure. Any research involving the use of medical exposures must have prior authorisation in accordance with Trust policy.

6.13. Procedures for Quality Assurance of Standard Operating Procedures

The *responsible person* is designated as the System Administrator for this purpose.

Procedures will be reviewed at least every 2 years and any copies updated.

All work under the procedures is subject to assurance compliance monitoring by the Radiation Safety Group.

6.14. Procedure for Quality Assurance of Mini C-arms

The *responsible person* is responsible for the Quality Assurance programme for the mini c-arm equipment. The system administrator will coordinate the quality assurance and maintenance, such that:

1) The equipment will be subject to appropriate maintenance in accordance with the manufacturer's specifications.
2) Routine quality assurance will be carried out in accordance with recognised standards.
3) The equipment will be made available for maintenance and Quality Assurance as required.
4) An appropriate handover arrangement will operate.

6.15. Procedure for Patients Receiving Unintended or Greater Than Intended Doses.

If an incident occurs where the dose to the patient is significantly more than intended, this should immediately be reported to the RPS and RPA. A Trust incident report must also be completed.

The RPS and RPA will investigate the incident and determine if the incident is reportable to the appropriate authority.

For all other incidents involving the use of the mini C-arm the Trust incident procedure should be followed. In addition, the RPS and RPA should be notified. The responsible person and the referring clinician will decide if it is appropriate to inform the patient. An entry to this effect will be placed in the patient's notes.

To minimise the risk of such incidents all exposures using the mini C-arm must be carried out in accordance with this protocol and all staff must have received adequate training.

If an Operator feels he or she has not had sufficient training or lacks sufficient experience to carry out a procedure they must seek assistance and inform the *responsible person* who will ensure that they receive further training before being allowed to act as an Operator again.

6.16. Procedure for Comforters and carers.

The Fluoroscan will be used in an operating theatre and it would not be usual practice for a comforter or carer to be present during the procedure. However, on occasion, this may be necessary either in the theatre or in another room as designated in the local rules.

In the rare occurrence of a comforter or carer is present they will receive a dose much less than 1mSv per year and will be issued with protective a lead apron in line with the staff that are present.

The NDHT radiology comforter and carers form must also be completed and signed, then scanned onto the patients CRIS examination episode; all carers and comforters forms should be forwarded to the radiology governance lead for audit purposes.

7. References

- Ionising (Medical Exposures) Regulations 2017. Statutory Instruments 2017 No 1322 http://www.legislation.gov.uk/uksi/2017/1322/pdfs/uksi_20171322_en.pdf
- Ionising Radiation Regulations 2017. Statutory Instruments 2017 No. 1075 http://www.legislation.gov.uk/uksi/2017/1075/pdfs/uksi_20171075_en.pdf

8. Associated Documentation

Northern Devon Healthcare NHS Trust Policies for:

- Northern Devon Healthcare NHS Trust Radiation Policy: http://ndht.ndevon.swest.nhs.uk/wp-content/uploads/2015/07/Medical-Radiation-Policy-Nov18.pdf

- Radiology IR(ME)R procedures: https://www.northdevonhealth.nhs.uk/2017/09/radiology-irmer-procedures/

- NDHT incident reporting policy and procedures: http://ndht.ndevon.swest.nhs.uk/indicent-reporting/incident-policy-and-procedures/

- NDHT disciplinary procedure: http://ndht.ndevon.swest.nhs.uk/wp-content/uploads/2019/10/Disciplinary-Policy-v3-0.pdf

- Radiology Carers and Comforters forms: \\NDS.INTERNAL\PUBLIC\radiology\FORMS\General Information for Carers and Comforters Supporting Patients Consent Forms.doc

Appendix 1

Examination Protocols for the of the use of the Mini C-arm

Prior to exposure, the operator must ensure that the patient's details and those of the planned procedure are correctly entered into the mini C arm, and that the dose meter is set to zero

Protocol A Reduction of fractures, dislocations and subluxations	
Justification for use of ionising radiation	Intra-operative radiological examination of the configuration of the fracture and the quality and stability of fracture or joint reduction achieved
Points at which radiation employed	Prior to fracture manipulation At intervals during manipulation After manipulation Following application of an external splint
Purpose of Screening	To determine the effectiveness of the manipulation To determine stability of joint or fracture reduction. To obviate the need for post-operative radiographs To reduce the need for repeat anaesthesia and manipulation
Optimum screening time	< 60 seconds
Reassessment screening time	4 minutes
Assessment of outcome	Surgeon's operation note Print of images and DAP reports should be sent to PACS and secured to operation note

Protocol B External, internal or percutaneous fixation of fractures or joint disruptions	
Justification for use of ionising radiation	Intra-operative radiological examination of the anatomical reduction of the fracture or joint and the integrity of the fixation
Points at which radiation employed	Following fracture manipulation Prior to insertion of implants Following insertion of implants
Purpose of Screening	To confirm the reduction of the fracture or joint To confirm the position or integrity of implants To obviate the need for a post-operative radiograph To reduce the need for revision surgery
Optimum screening time	< 60 seconds
Reassessment screening time	4 minutes
Assessment of outcome	Surgeons operation note Print of images and Dap report should be sent to PACS and secured to operation note

Protocol C Localisation of bone fragments and foreign bodies	
Justification for use of ionising radiation	Intra-operative radiological examination to locate foreign body or bone fragment
Points at which radiation employed	Prior to surgical exploration At intervals during the surgery Following surgical intervention to the bone fragment or foreign body
Purpose of Screening	To optimize efficient localization and / or removal of a fragment, thereby reducing operative time, minimising soft tissue dissection and increasing the chances of a successful outcome

Optimum screening time	< 60 seconds
Reassessment screening time	4 minutes

Protocol D Positioning of K-wires, screws and other implants	
Justification for use of ionising radiation	Intra-operative radiological examination of the position and integrity of the fixation device or implant
Points at which radiation employed	Prior to hardware insertion Following hardware insertion
Purpose of Screening	To confirm the correct position and effect of the wire, screw or implant To obviate the need for a post operative radiograph To reduce the need for revision surgery
Optimum screening time	< 60 seconds
Reassessment screening time	4 minutes
Assessment of outcome	Surgeons operation note Print of images and DAP report should be sent to PACS and secured to operation note

Assessment of outcome	Surgeons operation note Print of images and DAP report should be sent to PACS and secured to operation note

Protocol E Various, e.g. Ligament reconstruction, joint debridement	
Justification for use of ionising radiation	Intra-operative radiological confirmation of the effect of surgery on bones, joints or soft tissues
Points at which radiation employed	Following the surgical intervention
Purpose of Screening	To confirm the desired surgical effect has been achieved (e.g. that a joint has been adequately debrided of osteophytes, that a ligament reconstruction has satisfactorily reduced a joint, etc) To obviate the need for post-operative

	radiographs To reduce the need for revision surgery
Optimum screening time	< 60 seconds
Reassessment screening time	4 minutes
Assessment of outcome	Surgeons operation note Print of images and DAP report should be sent to PACS and secured to operation note

Protocol F Joint aspiration or injection	
Justification for use of ionising radiation	Intra-operative radiological confirmation that the needle is positioned in the joint space
Points at which radiation employed	Before inserting the needle into the joint After inserting the needle into the joint
Purpose of Screening	To avoid unintentional extra-articular injections
Optimum screening time	< 30 seconds
Reassessment screening time	2 minutes
Assessment of outcome	Surgeons operation note Print of images and DAP report should be sent to PACS and secured to operation note

Protocol G Dynamic fluoroscopic screening under anaesthesia for diagnostic purposes	
Type of Surgical procedure	
Justification for use of ionising radiation	To acquire information from dynamic screening not available on static films. To allow screening of a joint, without the limiting effect of pain
Points at which radiation employed	During manipulation and movement of the joint
Purpose of Screening	To acquire information to assist diagnosis, and help plan treatment
Optimum screening time	< 120 seconds
Reassessment screening time	4 minutes
Assessment of outcome	Surgeons operation note Print of images and DAP report should be sent to PACS and secured to operation note

Appendix 2
Training Log of Operators using the Fluoroscan InSight FD Mini C-arm System during extremity surgery

Name of Operator			
	Date	Authorising Signature	Staff Signature
Attendance at an approved theoretical course on the use of Mini C-arm II			
Copy of Pass Certificate nominated deputy			
Receipt of local rules from the RPS			
Practical training (equipment) – completion of competencies			
Practical Training (Clinical case)			
User is satisfied they have received sufficient training and feel competent in the safe use of the mini C-arm			
Authorisation by the *Responsible Person*.			

Appendix 3 Designated Training Supervisors

Mr Nik Jagodzinski

Appendix 4 Definitions in the context of these procedures

Referrer
"means a registered medical practitioner, who is entitled in accordance with Trust Procedures to refer individuals for medical exposure to a practitioner"

Practitioner
"means a registered medical practitioner, who is entitled in accordance with Trust procedures to take responsibility for an individual medical exposure"

Operator
"means any person, who is entitled, in accordance with Trust procedures, to carry out practical aspects of a medical exposure"

Justification
Consideration of the net benefit of a medical exposure taking into account;

a) The specific objectives of the exposure and the characteristics of the Individual
b)The total diagnostic or therapeutic benefits of the exposure
c) The individual detriment the exposure may cause
d) The efficacy, benefit and risk of alternative techniques having the same objective but involving no or less exposure to ionising radiation

Authorisation
The documented indication that justification has taken place. Indicated by the signature of the Practitioner or Operator (if authorisation under agreed justification criteria)

Medico-Legal Procedure
"Medico-legal procedure" means a procedure performed for insurance or legal purposes without a medical indication;

Responsible person
Defined in this protocol as the person with specific duties in relation to the management of Radiation Protection in the context of the use of the mini c-arms

Radiation Protection Supervisor
Person appointed under IRR17 with specific responsibilities to supervise the work within the Controlled Area and ensure that it is carried out in accordance with the Local Rules

Radiation Protection Adviser
Appointed by the Trust under IRR17 to give independent expert advice on matters concerning ionising radiations

Controlled Area
Designated area where there is a higher risk of exposure. Subject to access control through Local Rules and Systems of Work

Local Rules
Required where a Controlled Area exist. Set out rules for the safe working within the Controlled Area