	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Sir Andrew Morris, Chief Executive, Frimley Park Hospital** **2. [redacted], Medical Director, Frimley Park Hospital**
1	**CORONER** **I am Karen HENDERSON, assistant coroner for the coroner area of Surrey**
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013
3	**INVESTIGATION and INQUEST** On 18th August 2015 I commenced an investigation into the death of Peter John Keep, 82 years of age. The investigation concluded at the end of the inquest on 8th June 2016. The medical cause of death given was: 1a. Pulmonary Oedema 1b. Perforation of the right ventricle 1c. Insertion of pacemaker for heart block 2. My conclusion was: Died from a recognised complication of a necessary procedure
4	**CIRCUMSTANCES OF THE DEATH** Mr Keep was a generally fit and well 82 year old man who was admitted into Frimley Park Hospital on 1st August 2015 following a fall at home. During his admission he was incidentally found to have Mobitz type 2 heart block and was recommended to have a pacemaker insertion. He consented and this was undertaken on the 4th August 2015. Prior to the procedure he was very anxious and I heard evidence he had a needle phobia. He was given 2.5mg 'diazemuls' (diazepam) intravenously and as he was still anxious was given a further 2.5 mg 'diazemuls' some ten minutes or so later. He was then given 2.5 mg diamorphine intravenously. During the initial part of the procedure I heard evidence that he was relatively settled. However, the pacemaker insertion was proving difficult and required multiple attempts without success. Mr Keep became uncomfortable and began waving his arms around during the time the pacemaker wires were being inserted. I heard evidence that the movement more likely than not would have increased the risk of ventricular perforation. He was given a further dose of 2.5 mg diazemuls. Shortly thereafter he 'lost' his airway and required a nasopharyngeal airway and high flow oxygen mask for an unspecified period of time. No consideration was given to abandoning the procedure or to ask for assistance. The pacemaker insertion continued and shortly thereafter Mr Keep had a precipitous fall in his blood pressure. He was found to have developed cardiac tamponade as a consequence of a perforation of the right ventricle from the attempted insertion of a pacemaker wire. This was treated with a pericardial drain which drained 500mls of blood. Mr Keep's blood pressure improved and a decision was made to continue with the pacemaker insertion with another cardiologist. Shortly after completion, Mr Keep suffered a pulseless electrical activity cardiac arrest and despite full resuscitation died later that night on the Intensive Care Unit in Frimley Park Hospital.

5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise for concern. In my opinion there is a risk that future death will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The MATTERS OF CONCERN are as follows: 1. Inappropriate use of sedation and a lack of a sedation policy for cardiac electrophysiological procedures. 2. An absence or a lack of knowledge of a Trust policy for safe sedation outside the operating theatre environment, which could therefore not be considered or implemented. 3. An incoherent approach to sedation for procedures in the catheter Lab. with different clinicians using different drugs inconsistently e.g. use of an anxiolytic for discomfort. 4. No regular training for safe and appropriate use of anxiolytics and analgesics e.g. understanding their action and possible adverse effects or consideration of appropriate age related dosing. 5. Lack of an action plan for patients who do not tolerate the procedure. 6. Lack of an action plan as to who to call for assistance in circumstances when a patient's airway is lost or there is difficulty in placing a pacemaker wire. 7. Lack of understanding as to what observations are taken and are required during the procedure e.g. belief that the pulse oximeter measures respiratory rate
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you and your organisation: Frimley Park Hospital NHS Trust has the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of its date. I, the coroner, may extend this period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons: [redacted] (wife), [redacted] (son), [redacted] (son), [redacted] who may find it useful or of interest. I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	**DATE: 14th October 2016** **SIGNED: Dr Karen Henderson**