

## **Article: Nursing Older People**

**Word count 3757 (including abstract and references in text)**

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### **Abstract**

This article describes the implementation of PARO, a therapeutic robotic seal to a mental health hospital setting for people with dementia. We observed therapeutic benefits including communication, interaction, emotional well-being and verbal fluency. However, we encountered a challenge from the Infection Prevention Control perspective. We present the findings on the monitoring, cleaning and testing of PARO under controlled conditions. PARO remained within the acceptable Infection Prevention Control standards. Our findings relate to a specific care setting but have wider implications. We conclude that PARO is an important therapeutic addition to dementia care. Infection Prevention Control perspectives hold the potential to inhibit its use based on hypothetical rather than known risk. By conducting the first Infection Prevention Control study with PARO in clinical practice we offer our cleaning testing protocols and results. These may reduce concerns, facilitate using PARO and invite wider discussion and research rather than blocking innovation.

**Key Words: PARO, Older People, Dementia, Infection Prevention Control**

### **Introduction**

PARO is a robotic seal, part of the wider group of robots in health care which are termed Socially Assistive Robots. Socially Assistive Robots are designed to promote wellbeing, mood, and communication by building and sustain engagement and interaction. They can also be used to

counter-act negative experiences such as loneliness, isolation and help people who need of comfort or affection.

PARO is Artificial Intelligence equipped with fur, light, sound, touch, temperature sensors. It is programmed to build and sustain interactions, by responding to people and 'learning' to repeat actions which prompt communication with it. Movement is limited to turning its head, wagging its flippers and tail. For many, PARO is appealing with reports of it having an uncanny realness or presence. Being a seal, it does not have the immediate associations with pets but has a more general appeal in terms of something which invites touch, interaction and engages people on an emotional and social level.

The nature of the device means that the fur is attached to the robot and is not designed to be removed regularly to be washed. To have a removable fur covering would detract from the engagement potential of PARO and lessen the life like presence. There have not been any documented difficulties with cleanliness reported in the literature in the 10 + years of use of PARO internationally.

## **Literature**

### **PARO and other Technologies.**

PARO is being researched in a number of settings such as nursing home, residential home and community settings with dementia and also in relation to depression in older people (Jøranson et al 2016; Piatt et al 2017). Research is emerging around specific benefits such as stress reduction, communication, interaction and improvements in emotional well-being (Marti et al 2006; Moyle et al 2013; Yu et al 2014; Kazue et al 2014; Aminuddin et al 2016). Studies are exploring PARO in comparisons with other approaches such as static artefacts, soft toys, real animals and other activities (Moyle et al 2016). PARO can be used with individuals or with groups (Robinson et al 2016) in nursing homes, hospital settings and in the community (Liang et al 2017). PARO is not without controversy and as with other Socially Assistive Robots, there are tensions around the ethics of robotics in health care with some concerned about dignity and falsehood, and others about robots replacing human interaction or are integrated into care for the future (Elder 2015 ; lenca et al 2016; Draper and Sorell 2017; McGlynn et al 2017 ). In relation to technology in health care, PARO enters clinical practice as novel medical device and as such sits alongside other devices such as Wii Balance Boards, devices whose primary use was non-clinical but have been used with effect with patients who have had stroke or knee replacements ( [Negus et al 2015](#); [Minyoung et al 2016](#)) Innovative technological devices are common in health care with the rapid expansion in the use of computerised equipment. Their design and use has been clearly defined as either non-direct patient contact (such as the use of iPads) or direct contact. For direct patient contact National Policies and local protocols are in place for cleaning and sterilisation. (Department of Health 2008, revised 2015). PARO presents a challenge to Infection Prevention Control as it combines robotic technology with soft 'fur' coverings and with no guidance on how to meet the rigorous Infection Prevention Control standards required of healthcare in the UK. Its

adoption as an aide has been organic in nature as practitioners recognise the potential for non-pharmaceutical management of distress in patients and clients.

### **Novel Devices and Infection Prevention Control Policy and Concerns.**

Healthcare, nursing, residential and social care settings are required to meet rigorous Infection Prevention Control standards under health and safety legislation (NICE 2011). This applies to all NHS bodies and Independent Healthcare and Adult Social Care in England (NICE 2012), and there is increased concern about antimicrobial resistance (Dancer 2014). Current guidance advises how the risk of infection in health and social care can be minimised for environments and equipment used. It is recognised how everyday objects can be contaminated with pathogenic micro-organisms; including door furniture ward fabrics and plastics (Messina 2011) Microbial contamination has also been identified on common electronic devices such as mobile phones and tablets (Rana et al 2013 ). However, the continued use of these everyday objects is accepted as they form part of the environmental fabric, or simply because they have been introduced by stealth and are now accepted as norm within the workplace. PARO was not a familiar device and presented Infection Prevention Control staff with something which from their perspective may pose a hazard.

Introducing novel devices such as PARO to hospital therefore raises concern about hygiene and cleaning. Scholten et al (2016) raised the issue of hygiene and robotics animal devices in a review of the literature with children in hospital. They conclude that it is important to gain knowledge about the safe hygienic use, particularly for robotics which cannot be cleaned in the traditional ways. This is necessary to avoid them being considered 'dangerous pals'. They offer opinion about the nature of fabrics, options for cleaning and testing of cleaning procedures. To date, this has not been done with PARO.

PARO is potentially controversial. On the one hand it may be an important therapeutic tool to help older people and people with dementia but on the other hand may be considered unsuitable to clinical settings by professional groups whose primary focus is minimizing infection prevention hazards rather than helping meet the physical, emotional and social needs older people and people with dementia. There is a real danger the Infection Prevention Control hesitancy may inhibit innovation. It poses a challenge in weighing up risk / benefit and required standards.

### **Using The Precautionary Principle**

In response to the potential Infection Prevention Control challenge posed by PARO, the Sussex PARO Project formed a new collaboration to explore the use of PARO in practice. We applied a framework offered by the Precautionary Principle (Raffensperger and Tickner 1999). The Precautionary Principle emerged in the 1980's and originates in environmental law and bioethics. It is usually applied to technologies or advancements that may be considered to pose severe risk and unknown / uncertain consequences or harm or threat. The emphasis is on the proponent to assume a burden of proof of safety (Walton 1988). At first glance, it may seem extreme to adopt a principle which is usually applied to international biohazards (climate change, Genetically

Modified crops, and chemical biohazards) to a therapeutic baby seal robotic device which has no known history of posing a risk. However, the principle offers a structure within which to show the conditions under which something is used and the nature of the actual (rather than assumed) risk.

We see that PARO offers an example where innovation may be stifled because of caution – ‘better safe than sorry’. Hathcock (2000) writes from the perspective of bioethics, risk management and is critical of hesitancy around introduction of innovative products.

‘Upon initial consideration, it might seem that the only alternative to precaution is recklessness but, in fact, excessive precaution leads to paralysis of actions resulting from unjustified fear. In many cases, the slight but non-zero risk associated with a product or process is far safer than the alternative of doing nothing’ (Hathcock 2000: p255)

We could argue that paradoxically, to inhibit PARO through excessive caution may mean that people with dementia and older people are denied access to something of clinical benefit. As well as using the Precautionary Principle as a guide, we are influenced by the Framework for Responsible Innovation (Stilgoe et al 2013). This invites thinking beyond risk and regulation by creating discussion about dilemmas and questions raised by innovation. By using the Framework for Responsible Innovation and the Precautionary Principle we move the knowledge about PARO and hygiene on from a position of uncertainty, hesitancy and unknown risk to a better understanding of cleanliness and contamination in a controlled setting.

### **The Sussex PARO study.**

We started a Practice Development Implementation of PARO in 2014 with a Participatory Action Research Study with NIHR and Ethics approval from Aug 2015-March 2016 and a further period of Practice Development and service evaluation which is ongoing. The clinical setting is a 10 bed stand-alone dementia unit in a UK National Health Service Dementia service catering for people with dementia who have severe behavioural and emotional distress arising from dementia. We have been exploring the process of implementing PARO to everyday practice and observing the therapeutic benefits. The study uses an inclusive methodology and involves people with dementia on the unit and their relatives, front line clinical staff of all disciplines, the Trust Lived Experience Advisory Forum, and nursing and psychology undergraduates attached to the ward. Our Infection Prevention Control study was nested within this wider practice development and action research process. In order to monitor the use, cleaning process and cleanliness testing of PARO under controlled conditions a brand new PARO was introduced to the unit in Jan 2017. This PARO does not leave the unit. The study of the cleaning and contamination levels monitored PARO being used in everyday clinical care with individuals and in group sessions from the beginning of Jan 2017 to end Sept 2017.

### **Methods:**

We used the following methods to gather information on the experiences of staff, relatives and people with dementia: interviews, field notes, dementia care mapping snapshots and observation.

For the Infection Prevention Control perspective the following procedures/protocols were followed in the clinical setting incorporating the Trusts, Hand Hygiene, and Standard Precautions Policies. We used standard equipment used in care settings - Clinell Green Wipes which are commonly used for surface cleaning of non-medical devices. For cleaning and the Adenosine Tri-Phosphate Luminometer which is used to measure levels of contamination. Adenosine Tri-Phosphate is derived from living organisms and the measurement of Adenosine Tri-Phosphate through detecting Relative Light Units (RLU) is an indication of cleanliness. It is recognised as a useful benchmark for cleanliness (Alfa et al 2015). For this study we used the benchmark of 50 Relative Light Units (RLU). Readings below 50 Relative Light Units (RLU) is the recommended level for social areas within the hospital settings (Mulvey et al 2011).

### **Stages in Cleaning and Testing**

- 1) The unit devised and implemented a cleaning and testing protocol (Appendix 1). A recording system which monitored the use and cleaning of PARO was also implemented. Nominated staff took responsibility for routine cleaning.
- 2) A new PARO was introduced at the beginning of Jan 2017 which was restricted to being used on the unit, and not being used in other areas.
- 3) PARO was used in everyday clinical practice in group sessions and with individuals. PARO was active in each week of the 9 month Infection Prevention Control study period.
- 4) To test levels of contamination, PARO was divided into zones (Figure 1). These were swabbed using the Adenosine Tri-Phosphate (ATP) Luminometer.
- 5) Testing PARO occurred at 4 weekly intervals and visits were not planned in advance with unit staff but were unannounced.

Insert Figure 1 here.

### **Results and Findings**

From the wider study and the Infection Prevention Control study, findings are presented in two areas:

- 1) The therapeutic benefits of PARO in a specialist dementia setting where people with dementia experience behavioural and emotional distress. Data spanning 2 years.

- 2) The effect of introducing a cleaning protocol and ongoing monitoring and testing of PARO in relation to NHS standards of infection for the NHS. Data spanning 9 months (Jan 2017 – Sept 2017).

### **1) PARO as a Therapeutic Tool for everyday care.**

We found many of the research findings replicated in every day practice. This is significant as many research settings are nursing or residential facilities rather than more acute settings catering people with higher levels of behavioural and emotional distress. PARO facilitated interactions between staff and people with dementia and relatives of people with dementia. People with dementia engaged with PARO in conversations and PARO's engagement with them prolonged and sustained interactions longer than might otherwise happen. We observed the calming influence lessening agitation and verbal distress in people and having a positive function in changing people's emotional from states of ill-being to well-being short spaces of time. The content of conversations was often emotive, with themes of loss, grief, children, caring and loving being present. More obvious themes of pets and reminiscence of pets occurred frequently. Given the client group more extreme levels of emotional and behavioural distress, staff have tried using PARO with people who experience touch in a way that is problematic but who require personal care. Here we find that PARO holds the potential to be an intervention which may counter some of the difficulties associated with people who find touch difficult. In addition, we found PARO to be a useful addition to work with people who were particularly withdrawn or unresponsive or who were unable to engage in many other usual activities. In the same way that clinical staff report people with dementia sometimes engaging more freely with pets or babies, we observed on man in particular, having a far wider range of vocabulary with PARO than when interacting with staff or other people with dementia. As was to be expected, some people were not drawn to PARO or felt that it was too much of a toy but at the same time remained curious about it.

Our study was designed to be observational and process oriented. Our research process illustrates that it is possible to introduce and implement PARO in a phased way to staff and then to clinical practice. It then forms part of the everyday range of non-pharmacological interventions. Our particular interest is in the reduction of some of the more distressing behavioural and emotional expressions that arise from dementia such as aggressive or fear responses, agitation and distress and negative emotional states which may persist. These warrant further investigation to explore how PARO may reduce agitation and the use of other measures such as medication and lessen the distress for people with dementia.

### **2) Infection Prevention Control Results.**

We offer these as preliminary clinical findings of Infection Prevention Control of a single PARO housed in a stand-alone 10 bedded unit. PARO was not moved off the unit. During the 9 month data collecting period PARO was used in daily practice in groups and with individuals. The ward staff followed the cleaning protocol (Appendix 1).

The findings indicate:

- Throughout the period Jan 2017– Sept 2017 all swab zones on PARO were within the benchmark of 50 Relative Light Units (RLU) threshold for cleanliness.
- Figure 3 shows each area of PARO which was tested after use and whether they were below 40 RLU (shown in blue) or between 40-50 RLU (orange)
- There were some occasions when the swab zones recorded levels of between 40-50 Relative Light Units (RLU) after use (orange) and nearer the higher level of contamination.

Insert Figure 2 here

- Most swab zones recorded a level of below 40 RLU (blue).
  - The head (H1) was under 40 RLU 73% of the time and only between 40-50 RLU 27 % of the time.
  - The underside of the front right flipper (FR3) was over under 40 RLU 50 % of the time and between 40-50 RLU 50% of the time.
  - The top of the rear right flipper (FR2) was below 40 RLU 78% of the time and between 40-50 RLU and 22% of the time.
- The variations in levels of Relative Light Units (RLU) reflect how PARO is handled and some areas are more likely to have higher touch and contamination. An example of this is the difference between the underside of the left rear flipper (FL4) and the top side of the front left flipper (FL1) This suggest that those areas in direct contact with the patient, or likely to be stroked or handled recorded higher levels of Adenosine Tri-Phosphate (ATP).
- The results indicate that using the recommended cleaning protocol using Clinell green wipes maintained PARO at below the 50 Relative Light Units RLU over the 9 month period.

### **Discussion and implications for practice.**

The therapeutic benefits of PARO would indicate further use and study in everyday clinical practice in this type of setting and in other dementia and older persons' settings. We have experienced PARO as a flexible device which can be used to support a range of physical, emotional, psychological and social needs in people with dementia. Our clinical setting shows that PARO has potential to be useful with people who experience high levels of behavioural and emotional distress. These include: agitation, distress, fear responses which may lead to aggressive behaviours. This may hold the potential for PARO to be an alternative to other measures such as medication to alleviate distress. PARO also proved beneficial to people who are withdrawn or less able to engage in other activities with staff and people who have difficulty or have lost much language and struggle to communicate verbally. This means that PARO may offer something for people who may be prone to being overlooked or left alone for long periods of time.

To implement PARO we advise some preliminary work with staff. This increases staff being engaged and having ownership of PARO as a therapeutic tool and seeing how it may be used to help improve the health and wellbeing of older people and people with dementia. This process of engagement and ownership will help avoid it being seen as something which only belongs to Occupational Therapy or is too novel to be used routinely in daily practice.

During the implementation of PARO it became evident that the Infection Prevention Control aspect held the potential for PARO to be blocked in some clinical settings. We have had communication with other Trusts in the UK and Canada where PARO has been inhibited by Infection Prevention Control. We are curious to know whether there are other places which have quietly avoided considering PARO because of an Infection Prevention Control concerns. We are troubled that PARO may have been inhibited in the absence of any data on the potential Infection Prevention Control risk simply that has a non-removable furry surface which cannot be put in a washing machine and cannot be cleaned in a traditional way. We pose that in the absence of any data, there is the danger of *paralysis in the absence of analysis*.

Our Infection Prevention Control findings indicate that PARO can be cleaned with Clinell green wipes using the protocol devised and cleanliness maintained below the threshold of 50 RLU. During this study the time allowed for cleaning was considered by the staff to be long and had the potential to limit the use of PARO by being considered too onerous. A second phase of the study has now started within a laboratory setting at the University of Brighton in the School of Pharmacy and Biological Sciences with a Microbiologist. This phase two study will measure the effectiveness of Clinell green wipes cleaning PARO fur samples that will be inoculated with a measured amount of common microbes identified in the health care environment. It is hoped that this study will validate the use of measuring ATP on soft fur coverings and establish the optimum cleaning time required to ensure PARO meets the threshold of 50RLU or less during its use therapeutically in clinical settings.

## **Conclusion**

We are committed to Responsible Innovation therefore we have continued to drive the use of PARO but with the addition of providing new information on the actual Infection Prevention Control risk. We offer a template for those considering PARO in other clinical settings or who are considering introducing other novel devices or artefacts to clinical practice which may cause paralysis or hesitancy from an Infection Prevention Control.

Our work offers insight into the use of PARO in everyday clinical practice and how we embraced the challenge. Infection Prevention Control concerns do need to be addressed for PARO to have widespread adoption in the UK. Our work is within a specialist secondary mental health unit for people with dementia with severe emotional and behavioural distress but the findings and the Infection Prevention Control findings apply to a wide range of care settings which would include



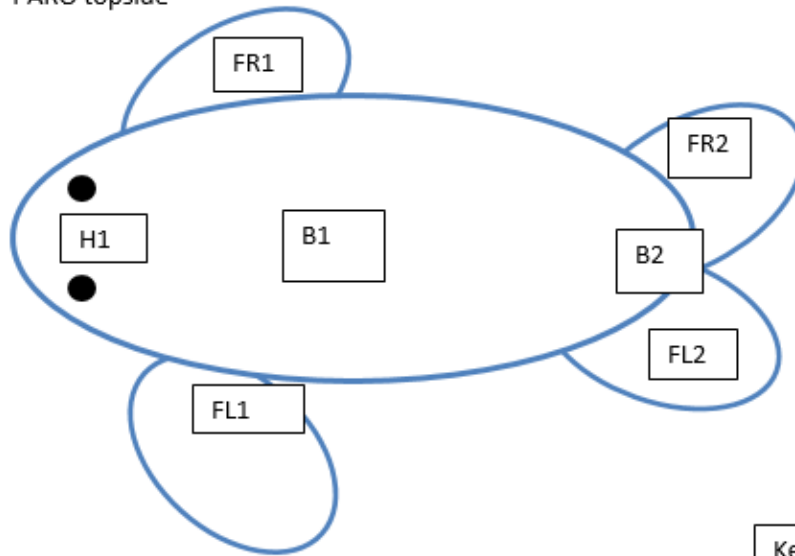
NHS acute hospital settings, nursing and care homes, community and private dwellings. We are aware of the potential for PARO to be of use to a wide range of services which offer support to older people and people with dementia.

We conclude that PARO is an important therapeutic addition to dementia and older persons care. Infection Prevention Control has the potential to inhibit this innovation. However, our study shows that over a 9 month period of using PARO in everyday clinical practice, using the protocols developed in collaboration with the uni, PARO remains within the Infection Prevention Control levels of contamination and can comply with local and national Infection Prevention Control requirements. It is disappointing if innovation is inhibited in the absence of any evidence of risk or exploration of how to overcome Infection Prevention Control issues. This applies to other less conventional objects used in practice or devices which are hard to clean. By conducting the first Infection Prevention Control study with PARO in clinical practice we offer our cleaning testing protocols and results which may reduce concerns and invite wider discussion rather than blocking innovation.

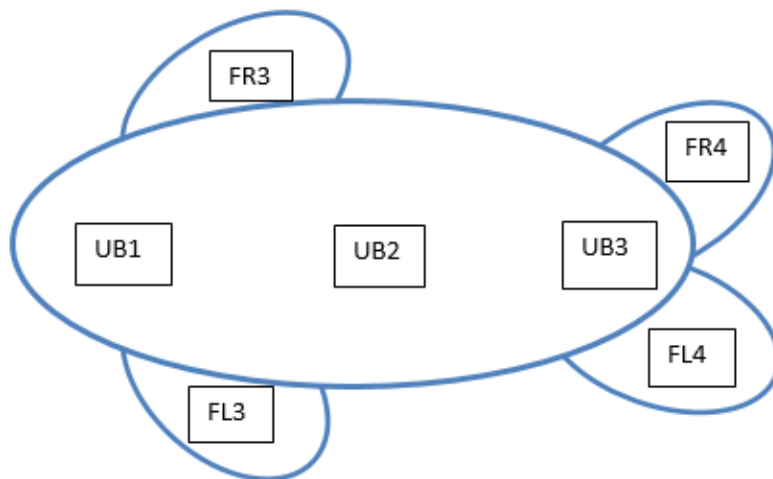
Acknowledgements. The staff, people with dementia and relatives who participated. Sussex Partnership NHS Foundation Trust Lived Experience Advisory Forum. Heads On Charity who funded the purchase of the second PARO and gifted it to the ward.

**Figure 1 PARO swab zones**

Zones PARO topside



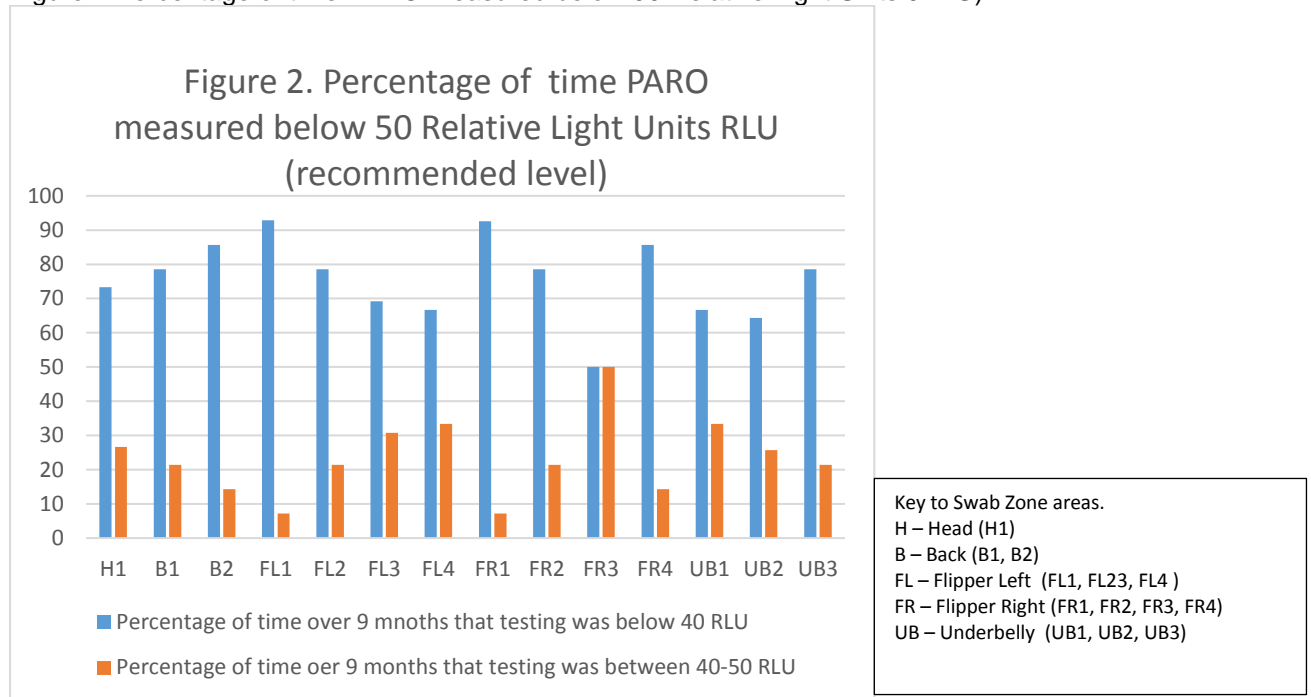
Zones PARO underside



Key

- H – Head
- B – Back
- FR – Flipper Right
- FL – Flipper
- UB - Underbelly

Figure 2 Percentage of time PARO measured below 50 Relative Light Units (RLU)



**Sussex PARO PROJECT: IPC and CLEANING PROTOCOL (VERSION June 2017)**

**The following protocol is to minimise contamination and cross contamination; monitor ipc measures; monitor levels of contamination. To be read in conjunction with risk and safety protocol and ipc testing protocol**

<p><b>GENERAL CONTAMINATION &amp; RISK REDUCTION MEASURES</b></p>	<ul style="list-style-type: none"> <li>• <b>COMPLIANCE WITH RISK AND SAFETY OVERVIEW PROTOCOL</b></li> <li>• <b>PARO IS NOT TO BE USED IF ANY PERSONS HAVE A PACEMAKER, INFECTION OR THERE IS A RISK OF CONTACT WITH BODY FLUIDS EXCLUDING SWEAT.</b></li> <li>• <b>IF THE CLIENT OR WORKER HAS EXPERIENCED INFECTION PARO REMAINS IN SEALED CONTAINER UNTIL CLEANING REQUIREMENTS HAVE BEEN MET AND INFECTION OR ILLNESS NO LONGER PRESENT</b></li> <li>• <b>AUDIT / REPORTING - FOLLOW ORGANISATION POLICY</b></li> </ul>
<p><b>PRIOR TO USING PARO WITH EACH INDIVIDUAL OR SETTING</b></p>	<ul style="list-style-type: none"> <li>• <b>INFECTION: CHECK INDIVIDUALS HAVE NO PHYSICAL SYMPTOMS OF INFECTION OR CHANGE IN PHYSICAL STATUS</b></li> <li>• <b>PARO : WIPE PARO WITH CLINELL WIPES (GREEN)</b></li> <li>• <b>HAND HYGIENE STAFF: CLINELL WIPES (GREEN)</b></li> <li>• <b>HAND HYGIENE WITH CLIENT: CLINELL WIPES (GREEN)</b></li> <li>• <b>COVERING CLIENTS CLOTHS : CLEAN PAPER ROLL TOWEL ON LAP OF CLIENT</b></li> <li>• <b>CLOTHING STAFF: PROTECTIVE CLOTHING FOR STAFF AS PER ORGANISATION POLICY</b></li> <li>• <b>ENVIRONMENT: CLEAN SURFACES (TABLES, TRAYS)</b></li> </ul>
<p><b>DURING USE OF PARO</b></p>	<ul style="list-style-type: none"> <li>• <b>MONITOR ENVIRONMENT FOR OTHER PEOPLE APPROACHING PARO WHO HAVE NOT CLEANED HANDS</b></li> <li>• <b>FACIAL CONTACT: AWARENESS OF MOUTH HYGIENE IF CLIENT IS KISSING OR HOLDING PARO TO FACE</b></li> <li>• <b>MAKE UP: CAUTION WHERE PEOPLE HAVE MAKE-UP OR LIPSICK</b></li> </ul>
<p><b>AFTER USE OF PARO</b></p>	<ul style="list-style-type: none"> <li>• <b>PARO: REMOVE ALL SIGNS OF VISIBLE DIRT. WIPE PARO WITH CLINELL WIPES (GREEN) FOR 2 MINUTES. ENSURE ALL ALL EXTERNAL SURFACES ARE CLEANED.</b></li> <li>• <b>WIPE CHARGER AND STORAGE BOX WITH CLINELL WIPES (GREEN) BEFORE PLACING PARO BACK IN BOX</b></li> </ul>
<p><b>ONGOING HYGIENE REGIME</b></p>	<ul style="list-style-type: none"> <li>• <b>CLEANING of PARO: MONTHLY: CHECK CONDITION OF FUR COVERING AND REMOVE ALL VISIBLE DIRT WITH SOFT BRUSH. VIGOUROUS CLEAN OF ALL SURFACES FOR 15 MINUTES USING CLINELL (GREEN) WIPES BY NOMINATED STAFF. ENSURE FUR IS MOVED IN ALL DIRECTIONS DURING CLEANING PROCESS</b></li> <li>• <b>CLEANING OF STORAGE &amp; CHARGING. REMOVAL OF VISIBLE DIRT ON EXTERNAL SURFACES, INSIDE AND OUTSIDE BOX &amp; CHARGER - WIPE WITH CLINELL (GREEN)</b></li> <li>• <b>AUDIT AND REPORTING: FOLLOW ORGANISATIONAL POLICY</b></li> </ul>
<p><b>MONITORING OF CONTAMINATION LEVELS</b></p>	<ul style="list-style-type: none"> <li>• <b>IPC TO CONDUCT QUARTERLY CONTAMINATION TESTING. – See IPC testing protocol</b></li> <li>• <b>FOR INFORMATION REGARDING IPC CONTACT: <a href="mailto:PARO@brighton.ac.uk">PARO@brighton.ac.uk</a></b></li> <li>• <b>CONTRIBUTE TO ONGOING DEVELOPMENT THROUGH OPTIONAL AUDIT REPORTING TO: <a href="mailto:PARO@brighton.ac.uk">PARO@brighton.ac.uk</a></b></li> </ul>

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