

## Supplement Appendix 1

### NG Tube Safety Innovation Process

Timeframe	Development process	Human factors <sup>1-3</sup> and medical device design <sup>4-6</sup> principles incorporated
Feb 2012	<b>Concept genesis.</b> Medical student (TB) attends misplaced NG tube RCA workshop, resulting in TB generating an innovation for promoting pH as the first line method	RCA NG tubes scenario using: <ul style="list-style-type: none"> <li>• Timeline</li> <li>• Swiss Cheese Model (active and latent failures)<sup>1</sup></li> <li>• Contributory factors (Organisational accident model; Fishbone diagram)<sup>2</sup></li> </ul>
Apr 2012	<b>Initial collaboration.</b> Curriculum leads facilitate contact between TB, AC and NG Steering Group	<ul style="list-style-type: none"> <li>• Seek user input</li> <li>• Involve users early and often</li> </ul>
Apr 2012	<b>NG Steering Group meeting.</b> Discussed key features of the pack in relation to context of use.	
Apr 2012	<b>NG Tube Pack proposal development.</b> A proposal for potential manufacturing partners was developed by TB, AC and NT	<ul style="list-style-type: none"> <li>• Follow industry conventions and consensus standards (e.g.,<sup>4</sup>)</li> </ul>
Jun 2012	<b>Initial contact with industry.</b> Met with procurement manager who put us in touch with Enteral UK	
Jun 2012	<b>Initial NG Tube Pack proposal submission.</b> Proposed contents included: <ul style="list-style-type: none"> <li>• NG tube: This should not have the label attached which states the tube should be flushed after insertion – a contributing factor to NG accidents.</li> <li>• Purple Syringe for aspiration; Nasal Plaster to hold tube in place; Gloves; pH paper with increments of 0.5 and CE marked; A warning related to NPSA alert – re risk of harm</li> <li>• Red, Amber, Green stickers to prompt the clinician to make sure that vital stages in NG tube positioning are completed. The stickers could possibly be attached to the NG tube itself or alternatively be directly stuck into the patient's notes. Options are for the Red, Amber, Green messages to be implemented either as a sticker system on tube OR</li> </ul>	<ul style="list-style-type: none"> <li>• Facilitate workflow</li> <li>• Review and simplify work processes; Standardise common processes</li> <li>• Design to prevent user confusion</li> <li>• Anticipate device failures and procedures</li> <li>• Follow industry conventions and consensus standards</li> </ul>

Timeframe	Development process	Human factors <sup>1-3</sup> and medical device design <sup>4-6</sup> principles incorporated
	in patients note OR instructions in pack OR something similar printed on front of pack with a warning.	
Jun 2012	<b>Industry meeting.</b> Entered agreement with Enteral UK to work together to develop prototype	
Oct 2012	<b>Prototype review meeting.</b> Wording on prompt card reviewed and revisions made	<ul style="list-style-type: none"> <li>• Facilitate workflow</li> <li>• Review and simplify work processes</li> <li>• Standardise common processes</li> </ul>
Nov2012	<b>Product development meeting</b> <ul style="list-style-type: none"> <li>• Considered whether or not to include pH paper in the pack due to use of a range of pH paper types within different organisations.</li> <li>• Sticker on the tube was deemed to potentially be more hazardous and was progressed into a prompt card in the pack.</li> <li>• The pack was initially more geared towards specific Trust guidelines, but wording was edited to make it more applicable to Trusts nationwide.</li> </ul>	<ul style="list-style-type: none"> <li>• Consider the potential for device to be used in other environments</li> </ul>
Dec 2012	<b>Advisory board meeting.</b> Nutritional nurses who reviewed the pack in the earlier stages recommended, <i>“For the hospital due to cost and accessibility the pack should include the literature, measure tape and a dressing. No pH paper advised”</i>	<ul style="list-style-type: none"> <li>• Refine designs through formative usability testing</li> <li>• Accommodate user needs and preferences</li> <li>• Consider external factors that influence task performance</li> <li>• Consider the potential for device to be used in other environments</li> </ul>
Jan 2013	<b>Product development.</b> Prompt card heavily revised via assessment of prototypes and email communication.	<ul style="list-style-type: none"> <li>• Facilitate workflow</li> <li>• Review and simplify work processes</li> <li>• Standardise common processes</li> <li>• Consider appeal</li> </ul>
May 2013	<b>Pilot of NG Tube pack.</b> Improvement from 71-100% pH check first line in the pilot ward; consultation exercise undertaken by medical student, e.g.:	<ul style="list-style-type: none"> <li>• Refine designs through summative usability testing</li> <li>• Do not exclusively rely on ‘thought leaders’</li> </ul>

Timeframe	Development process	Human factors <sup>1-3</sup> and medical device design <sup>4-6</sup> principles incorporated
	<ul style="list-style-type: none"> <li>• <i>“They are really good; it means everyone knows the right thing to do is check pH first. Can we have some more?”</i> (Staff Nurse)</li> <li>• <i>“I really like the stickers- it prompts us to do the right checks when reviewing X-rays...There is not enough awareness among doctors of the techniques to increase the chance of getting an aspirate – the guide helps remind us”</i> (Registrar)</li> </ul> <p>As a result of user feedback the pack design was refined.</p>	
Jun 2013	<b>Advisory board meeting.</b> TB and AC presented to nutritional nurses from UK and pack was refined as a result of feedback	<ul style="list-style-type: none"> <li>• Accommodate user needs and preferences</li> <li>• Consider appeal</li> </ul>
July 2013	<b>Refinements based on new incidents:</b> notification of an NG tubes adverse incident prior to the release of the pack (wrong X-ray was used to confirm tube position) triggered another prompt card sticker amendment, which now asks if ‘the most recent x-ray is being assessed’	<ul style="list-style-type: none"> <li>• Facilitate workflow</li> <li>• Prevent latent failures</li> <li>• Design to prevent user confusion</li> </ul>
Aug 2013	<b>Launch of safety pack.</b> Hospital bought 1000 units.	<ul style="list-style-type: none"> <li>• Follow industry conventions and consensus standards</li> </ul>
Aug 2013	<b>Training.</b> NG pack introduced to Junior Doctor training	<ul style="list-style-type: none"> <li>• Take into account training, instructions for use, memory</li> </ul>
Sep 2013	<b>Filming of Enteral educational video.</b> E-learning rolled out to all medics.	
Oct 2013	<b>Recognition.</b> Medipex NHS Innovation awards finalist	<ul style="list-style-type: none"> <li>• Consider appeal</li> </ul>
Oct 2013	<b>Recognition.</b> Winner of the University of Leeds Medical School Innovation Prize	
Oct 2013 – present	<b>Evaluation.</b> The first phase is currently being led by TB as part of the 4 <sup>th</sup> year of the medicine degree.	<ul style="list-style-type: none"> <li>• Evaluate effectiveness using rigorous research methods</li> </ul>

Abbreviations: TB indicates Thomas Bamford (manuscript author); NG, nasogastric; RCA, Root Cause Analysis; AC, Alison Cracknell (manuscript author); NT, Natalie Taylor (manuscript author); UK, United Kingdom; NPSA, National Patient Safety Agency; CE European conformity.

### Reference List for Supplemental Digital Appendix 1

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3. Karsh BT, Holden RJ, Alper SJ, Or CKL. A human factors engineering paradigm for patient safety: Designing to support the performance of the healthcare professional. *Qual Saf Health Care*. 2006;15(suppl 1):i59-i65.
4. Association for the Advancement of Medical Instrumentation. ANSI/AAMI HE75: Human factors engineering: Design of medical devices. Arlington: Association for the Advancement of Medical Instrumentation; 2009.
5. Wiklund ME, Weinger MB. General principles. In: Weinger MB, Wiklund ME, Gardner-Bonneau DJ, eds. *Handbook of human factors in medical device design*. Florida, USA: CRC Press; 2011.
6. Rubin J, Chisnell D. *Handbook of usability testing: How to plan, design, and conduct effective tests*. John Wiley & Sons; 2008.

# enteral

## INITIAL PLACEMENT NG TUBE

SAFETY  
PACK

### Step 1. Placing NG tube

1. Obtain Informed Consent or best interest decision made
2. Prepare Equipment
3. Prepare Patient
4. Take NEX Measurement  
(as seen on Diagram 01)
5. Insert NGT
6. Aspirate and follow traffic light
7. Remove Guidewire (If NG tubes is Radio-opaque guidewire not needed for X-ray confirmation. Refer to local policy)

**NB: Placement and on-going checks MUST be recorded in patients notes as per local policy!**

### Rapid Response Report NPSA/2012/RRR001 states;

- **NOTHING** should be introduced down the tube before gastric placement has been confirmed
- **DO NOT FLUSH** the tube before gastric placement has been confirmed
- Internal guidewires/stylets should **NOT** be lubricated before gastric placement has been confirmed

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### Step 2. How To Check NG Tube Position At Initial Placement

Confirmation on method according to patient safety alert NPSA/2011/PSA002

✓ NEX Measurement  
Correct

As per Diagram 01

### CHECK ASPIRATE

✓ pH value obtained indicates safe  
to feed as per local policy\*

**IT IS SAFE  
TO FEED**

### NO ASPIRATE

- No coiling in mouth
  - Change patient position
  - Perform mouth care
  - Flush NGT with AIR
  - Offer drink if patient has a safe swallow
  - Wait at least 15-30 minutes
  - Advance or withdraw NGT
- Problem solving solutions as per Diagram 02

### RE-ASPIRATE AFTER EACH TECHNIQUE

### DO NOT FEED IF:

1. NO aspirate or
2. pH value GREATER than  
pH level agreed for safe  
feeding in local policy\*

### REQUEST AN X-RAY

X-ray position must be confirmed  
by someone trained and assessed  
to do so

\* NPSA Alert NPSA/2011/PSA002 States pH 5  
or less is safe to feed, between pH value 5-5.5  
a check is require by second competent person.

Diagram 01  
HOW TO TAKE NEX MEASUREMENT

- N: NOSE  
E: EARLOBE  
X: XYPHOID

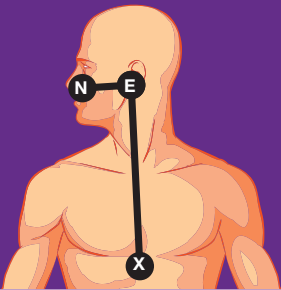
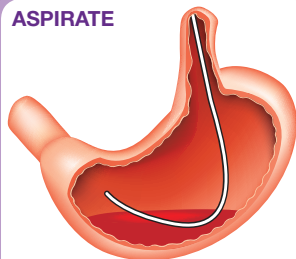


Diagram 02. TIPS if Aspirate is difficult to obtain

Tube may be above fluid level

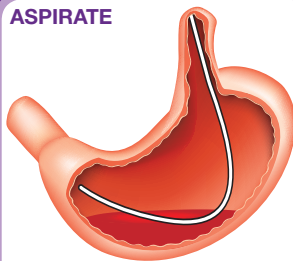
ASPIRATE



Turn patient onto their side  
This may allow the tip of the nasogastric tube to enter the gastric fluid pool.<sup>1</sup>

Tube may be in the small bowel

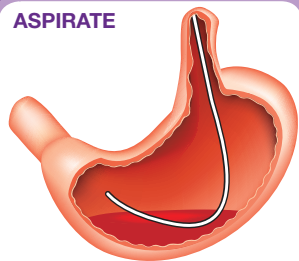
ASPIRATE



pH will normally be 6-8 and bile will usually be present. Withdraw tube in 2-3cm increments testing at each increments up to 20cm.

Tube may be occluded in Mucosa

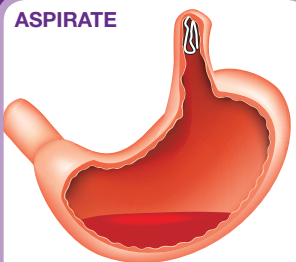
ASPIRATE



Advance or withdraw tube 5cm or aspirate with smaller syringe. Change patients position to alternative side. Refer to local policy!

Tube may be in Oesophagus

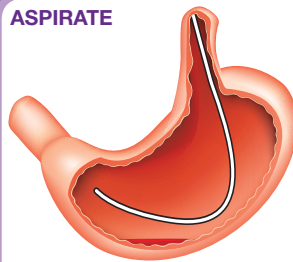
ASPIRATE



Advance the tube by 1-2cm for infants and children or 10-20cm for adults advancing the tube may allow it to pass into the stomach if it is in the oesophagus. Refer to local policy!<sup>1</sup>

There may be no fluid in the stomach

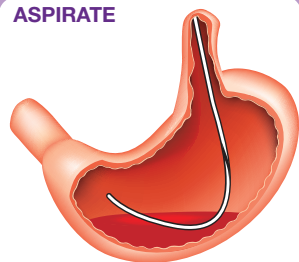
ASPIRATE



Having injected air and tried smaller syringe wait 15-30 minutes, change patients position to alternative side.

Tube may be occluded

ASPIRATE



Tube may be kinked or occluded with debris. Inject air (1-5ml for children, 10-20ml for adults) using a 20ml or 50ml syringe and try again. Refer to local policy!<sup>1</sup>

<sup>1</sup> This is NOT a testing procedure: DO NOT carry out auscultation of air ('whoosh' test) to test tube position. Advice does not replace local policy's!



- Remove Tender Grip® from liner.
- Position on patient's skin with tab



- Lift clear tab
- Peel back until resistance is felt.



- Position tube over base layer.



- Place clear fixation tab over tube and press gently



- To remove tube peel back clear fixation tab

# Tender Grip® Skin Fixation System

**Tender Grip®** is easy to apply, allows the skin to breath, holds securely and leaves the fixed tube clean and without messy residues.

- Time Saving
- Cost Effective
- Secures tubing in place
- Reduces trauma of reapplication

**Tender Grip®** consists of an adhesive “round” of microporous tape (position tube over base layer) which is applied to the patient’s skin. On top of the tape base is a fixation tab designed to position and secure tubing in place.

	Direct Code	NHS Code
Box of 25 Pairs	1005	FWM1628
Box of 100 Pairs	1006	FWM1629

**Tender Grip®...**  
Adheres and secures where other products fail!

## How to Read Enteral pH Strip

2.5 3.0 3.5 4.0 4.5

7.5

Place sample of aspirate on all three test pads

Wait 10-60 seconds until colour no longer changes

Match strip to scale on Enteral pH® container



# Initial Placement NG Tube Safety Pack

QTY	Wrapper	CE
1	Tendergrip Plaster	•
1	Measure Tape	
1	Record of Insertion Sticker	
1	NG Initial Insertion Process Literature	



## Additional Products Available

Product Description	Direct Code	NHS Code	CE
NG Tube Insertion Safety Pack	NGSP		
Enteral PH	ENT-PH	FWM1667	
Tender Grip Box of 25 Pairs	1005	FWM1628	•
Tender Grip Box of 100 Pairs	1006	FWM1629	•
NEX Measuring Tape	ENT-NEXTAPE		



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# NG TUBE INSERTION RECORD

FOR USE IN PATIENTS BEDSIDE CARE PLAN OR MEDICAL NOTES

USE ONLY IF REQUIRED

## Placement

Patients Name:

Patients ID:

Ward:

Lot Number:

NG Manufacturer

The Tube Size Is:

FR

CM

NG Tube Insertion Date:

Time:

D D M M Y Y Y Y H H : M M

Nostril Used:

Right

Left

Length of NG tube at nose:

CM

At nostril  
once  
secured

Inserters Signature:

Designation:

ID:

## Aspiration

Aspirate Obtained:

Yes

No

pH Value:

Designation:

Signature:

ID:

Second signature if required by local policy for pH 5 or 5.5

2nd Signature:

Designation:

ID:

SAFE TO FEED

Yes

No

Signature:

Designation:

ID:

## X-Ray

As per Trust guidelines if no aspirate obtained, or if pH is 5.5 or above.

X-ray Required?:

Yes

No

Most recent X-ray reviewed?

Yes

No

Date of X-ray:

Time of X-ray:

D D M M Y Y Y Y H H : M M

Confirm path of the tube:

Y N

Following the oesophagus

Y N

AND bisects the carina

Y N

AND crosses diaphragm in the midline

Y N

AND the tube is clearly visible below diaphragm

SAFE TO FEED

Yes

No

Clinician Signature:

Date:

Time:

Designation:

ID:

Insert sticker in to bedside care plan or medical notes. Ensure patient specific details are clearly documented, including consent details and any difficulties encountered when inserting the NG Tube. ENT-0003-V3-0713