Digitail[™] Injector User Documentation Standard Operating Procedure - Sample Template

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	STANDARD OPERAT	ING PROCEDURE	
SOP No: <mark>[n]</mark>	Effective Date: [Insert date]	Rev. No: <mark>[Insert</mark> revision #]	Supercedes: [Insert previous version #]
	Title: Subcutaneous Implantati using the Digitail Injector hand	-	l Identification tags

AUTHOR: [Eric Arlund]		[June 14 th , 2021]
	Signature	Date
APPROVED BY:		
	Signature	Date

1 PURPOSE

1.1 This SOP describes implanting the Somark[®] Digitail[™] tag into laboratory rodents using the Digitail Inject^{or} handheld injector.

2 SCOPE

- 2.1 This SOP can be enacted on all rats and mice of appropriate size, approximately 14 days of age to adult, without anesthesia.
- 2.2 The required placement of the Digitail[™] tag is subcutaneous in the tail. Optimum location is longitudinally at the proximal end near the hairline and rotationally midway between the dorsal midline and either lateral tail vein.

3 RESPONSIBILITY

3.1 [Please define the roles and responsibility of your staff, such as your animal technicians].

4 **DEFINITIONS**

- 4.1 **Digitail[™] tag.** An Ultra High Frequency RFID tag for the identification of laboratory mice and rats by subcutaneous placement in the tail.
- 4.2 **Digitail Inject**^{or}. The device that holds and then activates the Digitail needle cartridge to deposit the Digitail tag.
- 4.3 **Digitail cartridge**. A 21 gauge needle with internal trochar rod and Digitail tag loaded in the bevel.
- 4.4 **Depth indicator**. A mark on the needle 9 mm from the bevel tip that indicates how far the needle should be inserted under the skin for proper deposition. Indicator may be a red dot or other appearance.
- 4.5 **Digitail Reader**. The Somark Digitail tag reader which must be connected to your computer running LinkTo[™] in order to scan and record your animal's tag ID code.
- 4.6 **LinkTo[™]**. The Somark application which runs on your Windows computer (desktop PC, laptop or tablet) connected to your Digitail Reader and inserts the Digitail[™] tag ID code into the required fields on your internal colony or research / LIMS / ELN systems or Excel sheets.



5 PROCEDURE

Loading Digitail cartridges onto the Digitail Injector

5.1 Remove a cartridge from the outer packaging. Note that the base of the cartridge has two locking tabs, referred to as "pegs" later in the document. The top peg in this image is referred to as the alignment peg.



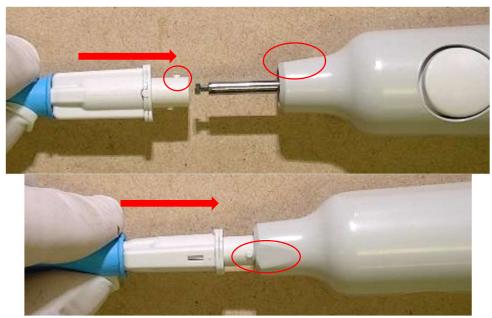
5.2 Prime the Digitail Injector by depressing the end cap. A metal rod will protrude 2cm.



- 5.3 First, identify the alignment flat on the Digitail Injector unit, circled below. Align the cartridge alignment peg (the lower of the two pegs) nearest to the open end of the cartridge with this alignment flat on the Digitail Injector. Insert the cartridge fully onto the Digitail Injector rod so the base of the cartridge is flush with the Digitail Injector.
- 5.4 Please note: The cartridge should slide over the rod and onto the injector, with the pegs sliding into the slots with no resistance. You may need a slight wiggle to complete the alignment of the cartridge pegs to the injector slots, but you should not require any pressure or force to complete the attachment.







- 5.5 Observe that when the cartridge slides onto the injector, it is linear with the Digitail Injector and **mounted flush** with Digitail Injector connector, as shown below.
- 5.6 Please note: If the cartridge is not flush with the injector, do not attempt to rotate the cartridge as instructed below, but please remove it and repeat the earlier steps. If there is any resistance, please discard the cartridge and return it to Somark.



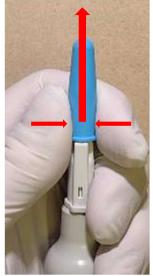
- 5.7 Gripping the light coloured body of the cartridge, rotate the Digitail Injector ¼ turn clockwise to lock the cartridge in place, you will feel an engagement click or physical step as it fully engages.
- 5.8 Please note: There should be little or no resistance when rotating the cartridge if it is correctly connected. If there is any noticeable resistance, or pressure / force is required to either slide the cartridge onto the injector or rotate the cartridge, this indicators either that the cartridge has not been correctly connected, such as the pegs have been aligned the wrong way around, or that the cartridge has a potential manufacturing fault.

Restraint of Mouse and Injection of Tag

5.9 Restrain the animal in a suitable restrainer to gain maximum access to the tail. The Somark Digitail Restraint (with the red dome) works well for mice.

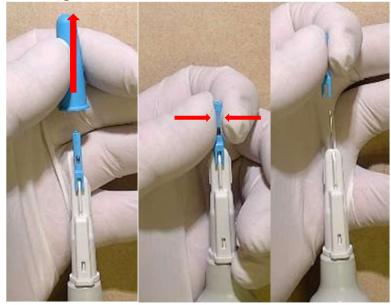


- 5.10 Restraints designed for tail vein injection may be used as well.
- 5.11 Remove the blue Digitail cartridge safety cap as shown below.

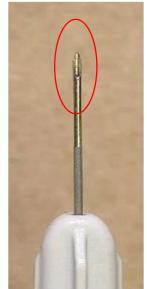


5.12 With the safety cap removed you will see the bevel cap covering the needle.

5.13 Gently grip the bevel cap at each side and unclip it from the needle, away from yourself and the needle tip. This will reveal the needle ready for tag insertion. Note: Do not slide the bevel cap off the needle as this may dislodge or remove the tag in the needle.



- 5.14 Do not hold the Digitail Injector with the attached Digitail cartridge at less than a horizontal position to ensure the Digitail tag in the needle remains in its proper insertion position. Do not shake or flick the needle as this may dislodge the position of the Digitail tag in the needle.
- 5.15 Ensure the Digitail tag is positioned fully in the needle bevel and has not advanced and is not visible in the bevel, as shown below.



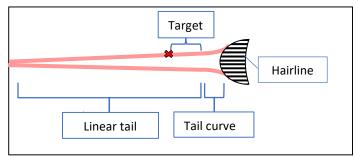
5.16 Target placement of the tag is within 1cm of the base of the tail (hairline.) The needle has a depth indicator 9mm from the tip, indicated by the colour change on the needle as shown and circled below.



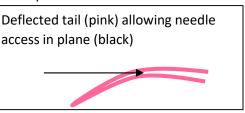


5.17 This can be used to locate the entry point to the tail. Align the needle tip 2-3 mm distal to the hairline. The depth indicator now shows where the tip should be inserted.

See Tail Diagram. For placement in the proximal end of the linear tail, align the needle tip at the far end of the target area, the depth indicator on the needle will show where to insert (red X)

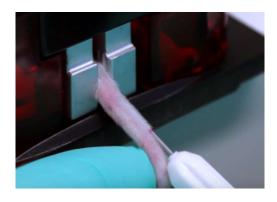


- 5.18 Ensure there is no debris, scarring or wound in the target area.
- 5.19 Optionally, prep the skin with an alcohol wipe.
- 5.20 Grasp the exposed tail distal of the target site, extend it, and deflect it downward such that the tail extends straight back from the body 2-4cm, then bends downward, as illustrated in the image below.



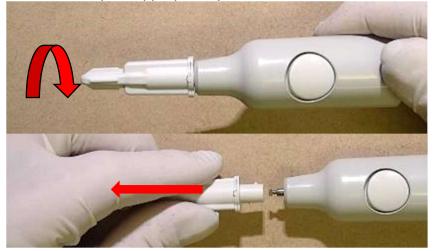
- 5.21 Optimal placement is between the dorsal midline and the lateral tail vein on either side of the tail. The blood vessels can be visualized (easier in albino animals) and the collagen fibers between these vessels may appear as a white stripe. This is the target for injection.
- 5.22 Please note, the location can be on the left or right side of the tail without any issue, in order to suit the handedness of the technician.
- 5.23 Advance the needle towards the body, bevel facing up, to make a shallow subcutaneous entry. Ensure the angle of the needle is parallel to the angle of the tail. Insert the needle to the mark (approx. 9mm inserted) as shown below.





Please note, the needle should slide smoothly towards the tail grip of the restrainer. If you experience resistance this indicates that the angle of the needle is not parallel with the tail and is penetrating too deeply or that the entry point for the needle was too close to the hairline and the needle point is no longer injecting subcutaneously in the tail.

- 5.24 Activate the button on the Digitail Injector. This will retract the needle leaving the tag behind under the skin. (Tag may be visible through the skin of lightly or non-pigmented mouse tails). A small, bright LED light shone upwards from the underside of the tail can be used to see the tag in position within the tail even in dark pigmented mice.
- 5.25 Observe the tag is fully under the skin (not protruding).
- 5.26 There should be no bleeding from the insertion site. Blot with sterile cotton to control any bleeding. Anything more than one to two drops of blood may be indicative of damage to the tail vein.
- 5.27 Remove the cartridge from the Digitail Injector by rotating it ¼ turn counter clockwise and dispose appropriately.





5.28 Follow disposal guidelines for needles as per your facility.



5.29 Scan the animal using a Somark[®] Digitail or other compatible UHF tag reader to confirm readability. This step can be done while the mouse is still in the red dome restrainer by holding the restraint near the reader such that the tail sticks out over the reader. Tagged animals may also be associated to your mice records at this time. This step automatically inserts the unique Digitail[™] tag ID code into your animal ID record if you are using LinkTo applications or your hand held reader supports Bluetooth in HID mode. (See your Digitail LinkTo User Guide, depending on which solution you use, for a detailed explanation of this step).

6 HISTORICAL REVISION

- 6.1 Revised to include steps on loading a cartridge onto the Digitail Injector, and with added descriptions to aid proper tag placement.
- 6.2 Document and title updated with current product terms and minor edits. April 30, 2019.
- 6.3 Updates and illustration of injection mark provided to aid understanding. June 14, 2019.
- 6.4 Updates and illustrations of Digitail Injector and Digitail Restraint included. July 22, 2019.
- 6.5 Updated product names. July 15 2020.
- 6.6 Updated to describe the expected cartridge connection to the injector process, identifying non-compliant connection issues which should indicate an SOP deviation or part fault. June 16 2021.
- 6.7 Updated to advise that the bevel cap should be unclipped from the needle and not slid off the needle. June 21 2021.