TIMERTAG PRO INSTRUCTIONS FOR USE

English (EN) · IFU-TTP-003 · Issued 15AUG26

Read this document before first use. Retain for reference. Non-sterile · Single use

SUPERSESSION NOTICE

This document supersedes IFU-TTP-002 (issued 14AUG26) and all earlier revisions in full. Superseded revisions describe fixed time intervals and status colours that are not features of this product. Do not rely on, distribute, or reproduce superseded revisions.

1 PRODUCT DESCRIPTION AND INTENDED PURPOSE

Timertag Pro is a passive, install-free visual communication and workflow aid that supports institutional protocol compliance by making time visible at the point of care. Each single-use adhesive label carries a printed QR code and a passive NFC (HF RFID) inlay. Scanning the label with any internet-enabled smartphone opens a web page showing either the time elapsed since the user activated the label, or the time remaining of a duration the user selected at activation.

The label itself carries a reference number only. It contains no clock, no stored time, no configuration, and no patient data. All timing is performed by the Timertag web service.

Timertag Pro requires no app installation, no user account, no login, and no authentication.

2 CLASSIFICATION NOTICE

Timertag Pro operates as a visual, educational, and administrative protocol compliance aid. It performs arithmetic on a start time and, where applicable, a duration supplied by the user.

Timertag Pro applies no clinical thresholds, sets no time limits, and makes no recommendation about when any item should be assessed, changed, or removed. It does not interface with clinical hardware, does not assess the patient or the medical consumable, does not process patient-identifiable data, and provides no diagnostic interpretation or therapeutic intervention. All clinical decisions rest with the treating clinician (Section 8).

Timertag Pro is not the medical record. It is not intended to replace existing record keeping, observation schedules, alerts, or patient safety systems, which remain unchanged.

3 INTENDED USERS AND USE ENVIRONMENT

For application and activation by clinical staff in hospitals and other professional care settings. Once activated, the status page may be viewed by clinicians, patients, and family members using a standard smartphone camera or NFC reader. Not intended for application or activation by patients.

The deploying organisation is responsible for determining which medical consumables Timertag Pro is used with, and for any time limits applied to them.

4 SYSTEM COMPONENTS

- **Timertag Pro label.** Single-use adhesive label carrying a printed 2D QR code and a passive NFC (HF RFID) inlay. Battery-free, with no internal processing, no stored time, and no stored patient data. Supplied non-sterile in rolls on a release liner perforated between labels.
- **Release liner.** Forms the flag on which the label is mounted in use (Section 7.1). Siliconised on one face only; the plain paper face is the bonding face.
- **Timertag web interface.** A web application that opens in the standard browser of any internet-enabled smartphone (iOS or Android). No installation, account, or login is required, and none exists.

5 MATERIALS AND SPECIFICATIONS

Label dimensions	20 mm × 40 mm (0.79 in × 1.57 in).
Applied format	Flag, formed with the release liner and wrapped around tubing. See Section 7.1.
Substrate	Polypropylene.
Adhesive	Acrylic adhesive.
Release liner	Paper, siliconised on one face only. Perforated between labels.
Data carrier	Printed QR code and passive NFC (HF RFID) inlay.
Data held on label	Reference number only. No timestamp, no configuration, no patient data.

Power	None. Battery-free passive label.
Connectivity	An internet connection is required both to activate a label and to display a timer.
Sterility	Supplied non-sterile.
Latex	Not made with natural rubber latex.
Session life	30 days from activation.
Inlay construction	Antenna on a carrier with an integrated passive chip.
Ferromagnetic content	None. Contains no iron, nickel, or cobalt. Contains aluminium. Electrically conductive.
Inlay risks	Contains a conductive loop; may heat if exposed to MRI. May create a local signal void in MRI.
Additional risks	Inlay may be inactivated by exposure to MRI.

1 APPLY → 2 SCAN → 3 CONFIGURE → 4 ACTIVATE → 5 MONITOR

6 CONFIGURATIONS

One label type serves all applications. The configuration is selected by the user at activation. A configuration name is a descriptor: it identifies what the user has chosen to time. It carries no clinical meaning and no time limit. Timertag applies no intervals to any configuration.

6.1 Count-up configurations

These configurations display the time elapsed since activation. They apply no thresholds, no status colours, and no prompts. All count-up configurations behave identically; the names differ only so that the display identifies what is being timed.

- Emergency peripheral IV
- Routine peripheral IV
- Urinary catheter
- Dressing

The dressing configuration times the dressing only. It does not time the central venous catheter, PICC, or peripheral IV catheter that the dressing secures.

6.2 Countdown timer

The countdown timer displays the time remaining of a duration selected by the user at activation, from: 1, 2, 4, 6, 12, 24, 48, 72, or 96 hours, or 7 days.

The duration selected must be the interval specified by facility policy for the item being timed. Timertag does not recommend, verify, or validate the duration selected, and publishes no intervals for any item.

The countdown timer is generic and is not limited to any particular item. The deploying organisation determines which items it is used with and the duration applied to each.

Final two hours. For every duration, the display changes colour for the final two hours of the countdown. The two-hour period is fixed and is identical for all ten durations. It is a workflow lead time, intended to give notice ahead of a routine bedside check. It is not derived from any protocol, standard, guideline, or replacement interval for any item, it applies no clinical meaning, and it does not indicate that any action is due or that any item requires attention. The change in colour is arithmetic on the duration the user selected.

Because the two-hour period is fixed, where a duration of 1 hour or 2 hours is selected the display will be in the changed colour for the whole or almost the whole of the countdown.

7 DIRECTIONS FOR USE

7.1 Form the flag and apply

Timertag Pro is applied as a flag wrapped around tubing. It is not applied to the patient's skin, to dressings, to securement devices, or to fluid containers.

Complete insertion, dressing, and securement of the medical consumable in accordance with hospital protocol before applying a label.

1. Tear one liner section from the roll at the perforations.
2. Peel the label from the liner.

3. Turn the liner over so that the plain paper face — not the shiny siliconised face — is uppermost.
4. Lay the tubing across the paper face of the liner.
5. Press the label down over the tubing and onto the paper face, so that the adhesive bonds to the liner on either side of the tubing and to the tubing between them.
6. Press firmly along both sides of the tubing. Confirm that the printed face lies flat and that the flag is secure.

Apply the flag at the following points:

- **Peripheral IV catheter —** the extension set or connector tubing, clear of the dressing. See 7.1.1.
- **Urinary catheter —** the drainage tubing, above the sampling port. Not the drainage bag.
- **Dressing (central venous catheter or PICC) —** the catheter limb or extension leg, distal to the securement device. Never between the securement device and the insertion site.
- **Countdown timer —** the tubing or roller clamp of the item being timed, or another clean, dry, accessible tubing surface associated with it.

Do not apply the label:

- to the patient's skin, or over broken skin;
- to a dressing, a dressing edge, a dressing inspection window, or a securement device;
- to a urinary drainage bag, an infusion bag, or any other fluid-filled container;
- over an insertion site;
- where it obstructs a clamp, roller, injection port, connector, or printed graduation;
- to silicone tubing or any other surface to which the adhesive does not bond. Confirm adhesion before relying on the label.

Position the flag so that it hangs free without pulling on the catheter, the securement device, or a connector, and so that it does not snag on bed rails or bedding. Do not apply a label in a way that transmits traction to an insertion site.

7.1.1 Peripheral IV limitations

Timertag Pro is applied to tubing. A peripheral IV catheter dressed with a needle-free connector or bung only, with no extension set or accessible tubing, provides no suitable application point. In that configuration Timertag Pro cannot be used. Do not apply the label to the dressing, to the cannula hub, or to the skin as an alternative.

Where an extension set or connector tubing is present, apply the flag to that tubing. The extension set must be replaced whenever the cannula is resited, and the label discarded with it. A label left in place across a resite will continue to time a catheter that has been replaced.

The dressing configuration requires an accessible catheter limb or extension leg and is intended for central venous catheters and PICCs. It cannot be used on a peripheral IV dressing.

7.2 Scan

Hold a smartphone camera over the QR code, or hold the phone flat against the label to read the NFC inlay. Tap the browser link that appears on screen. An internet connection is required.

7.3 Select and activate

On the configuration menu, select the option matching what is being timed. For the countdown timer, also select the duration specified by facility policy. Review the selection, then tap Activate. The server records the timestamp and the timing function begins. The browser may then be closed; the session continues on the server.

Apply and activate in a single bedside action, and confirm on screen that activation has succeeded.

If activation cannot be completed — for example where there is no internet connection — remove the label and discard it. Do not leave an unactivated label in place on a medical consumable. A label that has not been activated displays as not activated when scanned.

Activation is permanent. A session cannot be stopped, paused, edited, or reset. If a label is activated in error, or with the wrong configuration or duration, discard it, then apply and activate a new label. A replacement label runs from its own activation, so rely on facility records for the original insertion or placement time.

7.4 Monitor

Scan the label at any time to view the elapsed or remaining time. An internet connection is required to display a timer. Assess the medical consumable in accordance with institutional protocol and clinical judgment. The display does not indicate that assessment is due.

7.5 Disconnection, interruption, and change of limit

Timertag Pro sessions cannot be stopped, paused, edited, or reset. If a line is disconnected, or if facility policy assigns a different time limit following an interruption, discard the label and apply and activate a new label for the applicable duration.

7.6 Patient scanning and Timertag Go

When scanned, the page also displays a language-agnostic, graphic-supported checklist of signs that require escalation to nursing staff, including looseness, leakage, swelling, redness, pain, and fever. An information button below the guidance images opens the Timertag Go guidance page in a new browser window, where the reader may select their preferred language. No session data is passed to that page. See IFU-TTG-001.

7.7 Temporary removal for MRI or other procedures

Because timing is performed by the Timertag web service and the label carries no stored time, a label may be removed and re-applied to the same medical consumable on the same patient without affecting the session. No data is lost and no re-entry is required.

To remove, peel the label away from the liner flag and retain both. To re-apply, lay the tubing across the paper face of the liner and press the label down as described in 7.1. If the liner is damaged or unavailable, re-secure the label using appropriate adhesive tape.

Re-applying a label to the same medical consumable on the same patient is not reuse. Do not transfer a label to a different medical consumable or to a different patient in any circumstances.

7.8 Removal and replacement

Discard the label when the medical consumable it is timing is removed or replaced. Apply and activate a new label on any replacement medical consumable. Labels must also be removed before MRI — see Section 9.

8 WARNINGS AND PRECAUTIONS

! READ BEFORE USE

- Timertag Pro measures time only. It does not assess clinical symptoms, patient observations, vital signs, or indications of infection, and it does not observe the medical consumable.
- Timertag Pro applies no time limits. The duration entered for a countdown timer, and the decision to retain, adjust, or remove any medical consumable, rest solely with the treating clinician and facility policy.
- Verify that the configuration and, where applicable, the duration selected at activation match the item being timed and facility policy.
- The colour change in the final two hours of a countdown is a fixed workflow lead time on the duration the user selected. It is not an alarm or an alert, it is not derived from any protocol or replacement interval, and it does not indicate that any action is due. Do not rely on it as a prompt to act.
- Do not write on a Timertag Pro label. No patient name, identifier, room number, or other patient information may be recorded on a label or entered into the system.
- Do not apply the label to skin, dressings, securement devices, or fluid containers. Apply only as directed in Section 7.1.
- Apply the flag so that it cannot transmit traction to a catheter, a securement device, or an insertion site, and so that it cannot obstruct a clamp, port, or connector.
- An internet connection is required both to activate a label and to display a timer. Timertag Pro will not function where no internet-enabled device or no internet connection is available.
- Do not leave an unactivated label in place on a medical consumable.
- By design, the system uses no authentication. Anyone who scans a label can view its status page, and any non-activated label can be activated by anyone who scans it.
- Single use. Do not transfer a label to another medical consumable or another patient. Once activated, a session runs for 30 days and cannot be stopped or restarted. Temporary removal and re-application to the same medical consumable is permitted under 7.7.
- Timertag Pro is not the medical record and does not replace facility documentation. Record insertion, placement, and change times in the health record in accordance with facility policy.
- Timertag Pro has not been evaluated for use in the magnetic resonance (MR) environment. Remove any label that will enter the scanner bore before MRI. See Section 9.
- Where the countdown timer is used for applications other than those named in Section 7.1, the deploying organisation is responsible for determining that the label can be applied safely and read reliably on the item concerned.

9 MRI INFORMATION

Timertag Pro has not undergone magnetic resonance safety testing and carries no MR safety classification under ASTM F2503. It is neither MR Safe, MR Conditional, nor MR Unsafe, because no such determination has been made.

Before MRI. Remove any Timertag Pro label that will enter the scanner bore before the patient enters the scanner. Because Timertag Pro is applied to tubing attached to the patient, labels applied to peripheral IV extension sets, urinary drainage tubing, and central venous catheter or PICC limbs must be assumed to enter the bore unless local MR safety assessment establishes otherwise. Labels on administration sets that remain outside the bore, and outside Zone IV where local MR safety policy so requires, do not require removal.

Preserving the record. No action is required to preserve the timing. Timing is performed by the Timertag web service; removing a label does not affect the session, and re-applying the same label to the same medical consumable resumes display of the same session. See 7.7.

Projectile risk. The inlay contains no ferromagnetic material and presents no projectile hazard in the MR environment.

If a label is found in the bore during scanning. Stop the scan, remove the label, and check the underlying tubing and skin. Report any patient concern to the manufacturer at www.timertag.com/contact.

Facilities requiring an MR safety classification for this product should contact the manufacturer.

10 STORAGE, HANDLING, AND DISPOSAL

Store rolls in a dry location away from direct sunlight, at 10 °C to 30 °C. Do not use labels that are damaged, soiled, or illegible. Dispose of used labels as general waste, or in accordance with facility clinical waste procedures where contaminated with blood or body fluids.

11 DATA AND PRIVACY

Timertag Pro uses no accounts, logins, authentication, or patient identifiers, and is not connected to any medical record. There is no facility for entering free text, and no patient information can be recorded on a label or in the system.

Timing is performed on Timertag servers. Each session stores the activation timestamp, the configuration selected and, for a countdown timer, the duration selected, against the label's reference number. Session data is retained for the session life stated in Section 5. As with any web page, standard technical information such as IP address and browser type is processed to deliver the page.

Timertag Pro is not the medical record. Facility documentation requirements are unchanged.

12 SYMBOLS USED ON PACKAGING

Timertag Pro labels carry no symbols themselves. The following symbols appear on Timertag Pro packaging.

- Manufacturer
- Consult instructions for use
- Do not re-use. Single use only
- Non-sterile
- Keep dry
- Temperature limit 10–30 °C
- Catalog number
- Batch code
- Country of manufacture

13 MANUFACTURER

Senver Group Pty Ltd (ABN 90 622 761 380), trading as Timertag

53/61–65 Glencoe Street, Sutherland NSW 2232, Australia

www.timertag.com

Report product concerns or feedback to the manufacturer at www.timertag.com/contact.