1 PRODUCT DESCRIPTION AND INTENDED PURPOSE

Timertag Pro is a passive, app-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 organization 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 backing of the mounted label (Section 7.1). Siliconized 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	Mounted label, formed with the release liner, with the tubing captured between the label and the liner. See Section 7.1.
Substrate	Polypropylene.
Adhesive	Acrylic adhesive.
Release liner	Paper, siliconized 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 aluminum. 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 SELECT → 4 ACTIVATE → 5 MONITOR

6 CONFIGURATIONS

One label type serves all applications. The selection is made by the user at activation, from a first screen of four options: three dwell timers and the countdown timer. 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 Dwell timers

A dwell timer displays the time elapsed since activation. Dwell timers apply no thresholds, no status colors, and no prompts. All three dwell timers behave identically; the names differ only so that the display identifies what is being timed.

- Emergency peripheral IV
- Routine peripheral IV
- Urinary catheter

6.2 Countdown timer

The countdown timer displays the time remaining of a duration selected by the user at activation, from twelve options: 1, 2, 4, 6, 8, 10, 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. It does not name the item being timed. The deploying organization determines which items it is used with and the duration applied to each.

Final two hours. For every duration, the display changes color for the final two hours of the countdown. The two-hour period is fixed and is identical for all twelve durations. It is a workflow lead time indicator, 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.

Where a 1-hour or 2-hour duration is selected, the whole of the countdown falls within the final two hours, so the display is in the changed color throughout.

End of countdown. When the selected duration has elapsed, the display shows 00h 00m. It does not display a status, and it does not quantify time elapsed beyond that point.

7 DIRECTIONS FOR USE

7.1 Application guidance

Timertag Pro is applied to tubing as a mounted label: the label is mounted on its release liner so that the tubing is captured between the label and the liner. It is not applied to the patient's skin, to dressings, to securement devices, or to fluid containers.

Timertag Pro is applied to tubing, and to nothing else. This requirement applies to every use of the product, whatever item is being timed. Where the item to be timed is held in a bag, bottle, syringe, reservoir, or any other container, the label is applied to the tubing of the associated administration or transfer set, never to the container. Where no suitable tubing is available, Timertag Pro cannot be used.

Timertag Pro identifies nothing. It carries no patient identifier, no product identifier, no donor identifier, and no lot, batch, or expiry information. It must not be used as, or in place of, any identification, matching, verification, or release step required by facility policy or by law, and a label must never obscure, replace, or be capable of being mistaken for labeling required for those purposes.

Apply the label at whatever point in the workflow suits local practice, provided it does not interfere with insertion, dressing, or securement of the medical consumable.

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 siliconized 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 mounted label is secure.

Apply the label at the following points. Each application point requires approximately 20 mm (0.8 in) of straight, accessible tubing:

- **Peripheral IV catheter —** the extension set or connector tubing, on a straight section between the cannula hub and the clamp or needle-free connector, clear of the dressing. See 7.1.1.
- **Urinary catheter —** the drainage tubing, on a straight section at least 10 cm (4 in) below the point where the catheter joins the drainage tubing, and above the drainage bag or urine meter. Not the drainage bag and not the urine meter.
- **Countdown timer —** the tubing 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, sampling port, or connector;
- to a central venous catheter or PICC catheter limb or extension leg;
- over any printed or molded text, graduation, scale, size marking, or measurement on a device or its labeling, including lumen labels and catheter length markings;
- where it interferes with the use, handling, inspection, or routine care of the device or the patient;
- to silicone tubing or any other surface to which the adhesive does not bond. Confirm adhesion before relying on the label.

This list gives examples and is not exhaustive. In every case the requirement is that the label is mounted on tubing. Any other placement is outside the application of this product.

Position the mounted label so that it hangs free without pulling on the catheter, the securement device, or a connector, so that it does not rest against the patient's skin, 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 injection cap 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 label to that tubing. The extension set must be replaced whenever the cannula is replaced, and the label discarded with it. A label left in place across a cannula change will continue to time a catheter that is no longer present.

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

Scanning an un-activated label opens the selection screen. It offers four options: Emergency peripheral IV, Routine peripheral IV, Urinary catheter, and Countdown timer. Select the option matching what is being timed. Selecting Countdown timer opens a second screen of twelve durations; 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 un-activated label in place on a medical consumable.

Activation is permanent. A session cannot be stopped, paused, edited, or reset. If a label is activated in error, or with the wrong selection, 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

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 Rev B.

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 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 selection made at activation matches the item being timed and facility policy.
- The color 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.
- Timertag Pro identifies nothing. It carries no patient, product, donor, lot, batch, or expiry information, and must not be used as, or in place of, any identification, matching, verification, or release step required by facility policy or by law.
- Timertag Pro is applied to tubing, and to nothing else. Where the item being timed is held in a container, apply the label to the tubing of the associated administration or transfer set. Where no suitable tubing is available, do not use Timertag Pro.
- Do not apply the label to skin, dressings, securement devices, fluid containers, or central venous catheter or PICC catheter limbs or extension legs. Apply only as directed in Section 7.1.
- Position the mounted label 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.
- Do not place a label where it interferes with the use, handling, inspection, or routine care of a device or the patient, or where it obscures printed or molded text, graduations, scales, size markings, or measurements.
- 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 un-activated 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.

- Timertag does not specify the items with which Timertag Pro is used. The deploying organization is responsible for determining which items it is used with, the durations applied, and whether the label can be applied safely on tubing as directed in Section 7.1 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 and to urinary drainage tubing 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.