Instructions for Use

BLOODLOCTM SAFETY SYSTEM

Physical barrier between wrong unit of blood and patient stops accidents

PROCEDURES FOR PHLEBOTOMISTS

Please note that patients are wearing a wristband with a three-letter Bloodloc TM code. This code is unique to each patient for the length of the hospital stay. Should the patient be readmitted, a new wristband with a new Bloodloc CM code will be issued.

There are over 12,000 codes, and wrist TABS will be color-coded in batches to ensure that there are never any duplications in the hospital at any time.

After drawing a specimen for type and cross, the three-letter Bloodloc™ code is transcribed from wristband to specimen tube. Care should be taken to print the code in capital letters and circle it so that there is no confusion with the phlebotomist's personal initials.

The Blood Bank will accept only specimens so coded. In the event a specimen is received by the Blood Bank without an identifying three-letter Bloodloc™ code, the specimen will be rendered invalid and will be discarded. A fresh sample will be requested.

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PROCEDURES FOR BLOOD BANK PERSONNEL

When specimens are received by the Blood Bank they will have, in addition to the phlebotomist's initials, an identifying three-letter Bloodloc™ code, printed in capital letters and circled. Specimens without this code will be rendered invalid and discarded. A request would then be made for a fresh sample to be drawn and identified correctly.

The Bloodloc[™] code is to be entered into the patient's current Blood Bank records where it should be readily accessible to a technician locking up blood. The following steps are then taken when the blood is ready for dispensing.

- Three-letter Bloodloc™ code is obtained from patients Blood Bank records for current admission.
- Bloodloc[™] is set by lining up three-letter Bloodloc[™] code from left to right, turning each dial CLOCKWISE, aligning with arrow marked CODE.
- •Lock is placed on level surface and all three dials are engaged by pressing down firmly with palm of hand on center. A plastic ring will separate from the bottom and is discarded. Bloodloc[™] is not set permanently at this code.
- Matched and typed packed red cells are placed into the provided outer plastic bag.
- Back of lock is inserted through hole in bag and front section is pressed firmly together. Dials are scrambled by turning in either direction. Blood is now ready for dispensing.

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PROCEDURES FOR NURSES

Please note that patient's now wear the customary hospital wristband to which has been added a three-letter code. This code is unique to each patient for the length of the hospital stay. Should the patient be readmitted, a new wristband with a new code will be issued. There are over 12,000 codes, which will be color coded in batches to ensure that there are never any duplications in the hospital at any time.

When packed red cells are delivered to the floor, the usual checks are performed to correctly identify the patient.

The RBC units will be issued locked up in an outer plastic bag. In order to unlock the blood the following steps must be taken:

- Three-letter Bloodloc[™] code is read from patient's wristband.
- Bloodloc[™] dials are turned in either direction to align the patient's Bloodloc[™] code letters from left to right with the arrow marked CODE.
- Pull Bloodloc[™] apart. If the lock does not open easily, recheck the code. If lock remains closed, assume there is an error and call the Blood Bank.
- On removal of the unit of blood, discard the lock and bag.

We suggest eliminating the second person needed to check the wristband, blood unit and accompanying compatibility documents since the BloodlocTM system is a secure system - if the BloodlocTM will not open, it's a case of wrong blood or wrong patient.

Bloodloc Medical Inc. supplies all of the components to implement the Bloodloc™ Safety System.

- Lock fronts with 3-lettered dial and lock back
- Outer plastic bags with hole cut out
- Pre-coded wrist TABS.

Autologous Program

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AUTOLOGOUS PROGRAM

Bloodloc™ addresses problems and provides answers

- In transfusion of homologous blood, there is a concern to transfuse ABO compatible blood. When transfusing autologous blood, there is the added concern to transfuse a specific unit donated by a specific patient.
- There are legal, ethical, and medical risks involved in transfusing a patient with homologous blood when autologous blood is available.
- There is a risk that an autologous donation may be transfused to a patient other than the donor.

How Bloodloc™ Works

- At the first donation, the patient is given a green wristband, bearing a unique three-letter code. One character of the code will always be #. This will be a special indicator that a particular patient has pre-donated and will act as a flag in the Blood Bank to prevent homologous blood being released ahead of autologous. To ensure effectiveness of the system, the wristband should be worn up to and through the patient's stay in hospital.
- At the time of donation, the blood is tagged with the unique code. After labeling, separating, and testing, the unit is placed in an outer plastic bag colored green and Bloodloc is set to that patient's code. The tag is then removed and the lock scrambled.
- When blood is delivered to the Operating Room, Recovery Rood, or Nursing Unit, the staff is alerted to use the green bag before the clear plastic, avoiding use of the homologous ahead of autologous blood.
- At each subsequent donation, the code is read off the patient's wristband and the same procedure followed.
- When the patient requires a transfusion, he/she is assured of receiving his/her own blood. Access to the blood can only be gained by dialing the correct unique code.

Originally, Novatek sold wrist tabs in sets of 1,500 Green (each code has a #) because the volume autologous transfusions has increased in the hospitals, the product is expanded to rotation of three colors in the same method that homologous wrist tabs are used.



BLOODLOCTM SAFETY SYSTEM

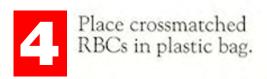
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In addition to standard identification, specimens received MUST have both a 3-letter code and drawer's initials. Enter the 3-letter code in patient's current blood bank records.

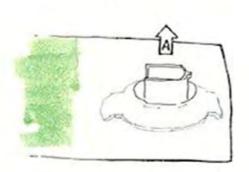


point of arrow.





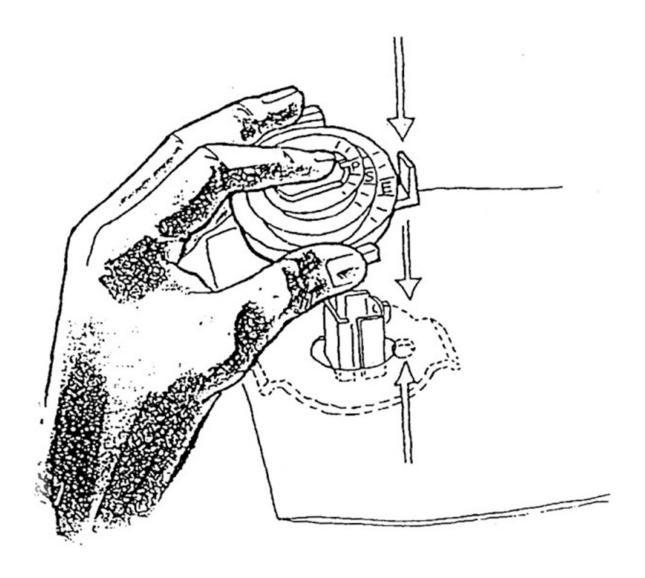
Insert back of lock (A) through hole of plastic bag and press on front(B). Then scramble all three dials before dispensing from blood bank.



Securing the Code

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To secure the code, insert back of lock through hole in plastic bag.

Holding index finger on code arrow, press front and back together.

Scramble all three dials to lock.