F604

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§483.10(e) Respect and Dignity.

The resident has a right to be treated with respect and dignity, including:

\$483.10(e)(1) The right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms, consistent with \$483.12(a)(2).

§483.12

The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms.

§483.12(a) The facility must—

§483.12(a)(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.

INTENT

The intent of this requirement is for each resident to attain and maintain his/her highest practicable well-being in an environment that:

- Prohibits the use of physical restraints for discipline or convenience;
- Prohibits the use of physical restraints to unnecessarily inhibit a resident's freedom of movement or activity; and
- Limits physical restraint use to circumstances in which the resident has medical symptoms that may warrant the use of restraints.

When a physical restraint is used, the facility must:

- •Use the least restrictive restraint for the least amount of time; and
- Provide ongoing re-evaluation of the need for the physical restraint.

DEFINITIONS

"Convenience" is defined as the result of any action that has the effect of altering a resident's behavior such that the resident requires a lesser amount of effort or care, and is not in the resident's best interest.

"**Discipline**" is defined as any action taken by the facility for the purpose of punishing or penalizing residents.

- "Freedom of movement" means any change in place or position for the body or any part of the body that the person is physically able to control.
- "Manual method" means to hold or limit a resident's voluntary movement by using body contact as a method of physical restraint.
- "Medical symptom" is defined as an indication or characteristic of a physical or psychological condition.
- "**Position change alarms**" are alerting devices intended to monitor a resident's movement. The devices emit an audible signal when the resident moves in certain ways.
- "Physical restraint" is defined as any manual method, physical or mechanical device, equipment, or material that meets all of the following criteria:
 - Is attached or adjacent to the resident's body;
 - Cannot be removed easily by the resident; and
 - Restricts the resident's freedom of movement or normal access to his/her body¹.

"Removes easily" means that the manual method, physical or mechanical device, equipment, or material, can be removed intentionally by the resident in the same manner as it was applied by the staff.

GUIDANCE

As described under Definitions, a physical restraint is any manual method, physical or mechanical device/equipment or material that limits a resident's freedom of movement and cannot be removed by the resident in the same manner as it was applied by staff. The resident's physical condition and his/her cognitive status may be contributing factors in determining whether the resident has the ability to remove it. For example, a bed rail is considered to be a restraint if the bed rail keeps a resident from voluntarily getting out of bed in a safe manner due to his/her physical or cognitive inability to lower the bed rail independently. Similarly, a lap belt is considered to be a restraint if the resident cannot intentionally release the belt buckle.

Examples of facility practices that meet the definition of a physical restraint include, but are not limited to:

- Placing a chair or bed close enough to a wall that the resident is prevented from rising out of the chair or voluntarily getting out of bed;
- Placing a resident on a concave mattress so that the resident cannot independently get out of bed;
- Tucking in a sheet tightly so that the resident cannot get out of bed, or fastening fabric or clothing so that a resident's freedom of movement is restricted;
- Placing a resident in a chair, such as a beanbag or recliner, that prevents a resident from rising independently;
- Using devices in conjunction with a chair, such as trays, tables, cushions, bars or belts, that the resident cannot remove and prevents the resident from rising;

- Applying leg or arm restraints, hand mitts, soft ties or vests that the resident cannot remove;
- Holding down a resident in response to a behavioral symptom or during the provision of care if the resident is resistive or refusing the care;
- Placing a resident in an enclosed framed wheeled walker, in which the resident cannot open the front gate or if the device has been altered to prevent the resident from exiting the device; and
- Using a position change alarm to monitor resident movement, and the resident is afraid to move to avoid setting off the alarm.

Physical Risks and Psychosocial Impacts Related to Use of Restraints

Research and standards of practice show that physical restraints have many negative side effects and risks that far outweigh any benefit from their use. Physical restraints may increase the risk of one or more of the following:

- Decline in physical functioning including an increased dependence in activities of daily living (e.g., ability to walk), impaired muscle strength and balance, decline in range of motion, and risk for development of contractures;
- Respiratory complications;
- •Skin breakdown around the area where the restraint was applied or skin integrity issues related to the use of the restraint (i.e., pressure ulcers/injuries);
- Urinary/bowel incontinence or constipation;
- •Injury from attempts to free him/herself from the restraint; and
- Accidents such as falls, strangulation, or entrapment.

Psychosocial impact related to the use of physical restraints may include one or more of the following:

- Agitation, aggression, anxiety, or development of delirium;
- Social withdrawal, depression, or reduced social contact due to the loss of autonomy;
- •Feelings of shame;
- •Loss of dignity, self -respect, and identity;
- Dehumanization;
- •Panic, feeling threatened or fearful; and
- Feelings of imprisonment or restriction of freedom of movement.

Assessment, Care Planning, and Documentation for the Use of a Physical Restraint

The regulation limits the use of any physical restraint to circumstances in which the resident has medical symptoms that warrant the use of restraints. There must be documentation identifying the medical symptom being treated and an order for the use of the specific type of restraint [See §483.12(a)(2)].

However, the practitioner's order alone (without supporting clinical documentation) is not sufficient to warrant the use of the restraint. The facility is accountable for the process to meet the minimum requirements of the regulation including appropriate assessment (see § 483.20 – Resident Assessment), care planning by the interdisciplinary team (see § 483.21-Comprehensive Person-Centered Care Planning), and documentation of the medical symptoms and use of the physical restraint for the least amount of time possible and provide ongoing re-evaluation [see §483.12(a)(2)].

The resident or resident representative may request the use of a physical restraint; however, the nursing home is responsible for evaluating the appropriateness of the request, and must determine if the resident has a medical symptom that must be treated and must include the practitioner in the review and discussion. If there are no medical symptoms identified that require treatment, the use of the restraint is prohibited. Also, a resident, or the resident representative, has the right to refuse treatment; however, he/she does not have the right to demand a restraint be used when it is not necessary to treat a medical symptom.

Facilities are responsible for knowing the effects devices have on its residents. If a device has a restraining effect on a resident, and is not administered to treat a medical symptom, the device is acting as a physical restraint. The restraining effects to the resident may have been caused intentionally or unintentionally by staff, and would indicate an action of discipline or convenience. In the case of an unintentional physical restraint, the facility did not intend to restrain a resident, but a device is being used that has that same effect, and is not being used to treat a medical symptom. These effects may result in convenience for the staff, as the resident may require less effort than previously required.

The use of a restraint must be individualized and be based upon the resident's condition and medical symptoms that must be treated. While a physical restraint may be used to treat an identified medical symptom for one resident, the use of the same type of restraint may not be appropriate to treat other residents with the same medical symptom. If a resident is identified with a physical restraint, the facility must be able to provide evidence that ensures:

- The resident's medical symptom that requires the use of a physical restraint has been identified:
- A practitioner's order is in place for the use of the specific physical restraint based upon the identified medical symptom;

NOTE: If a resident is recently admitted to the facility and a restraint was used in a previous health care setting, the facility must still conduct an assessment to determine the existence of medical symptoms that warrant the continued use of the restraint.

- Interventions, including less restrictive alternatives were attempted to treat the medical symptom but were ineffective;
- The resident/representative was informed of potential risks and benefits of all options under consideration including using a restraint, not using a restraint, and alternatives to restraint use;

NOTE: The resident, or resident representative (if applicable), has the right to refuse the use of a restraint and may withdraw consent to use of the restraint at any time. If so, the refusal must be documented in the resident's record. The facility is expected to assess the resident and determine how resident's needs will be met if the resident refuses/declines treatment.

- •The length of time the restraint is anticipated to be used to treat the medical symptom, the identification of who may apply the restraint, where and how the restraint is to be applied and used, the time and frequency the restraint should be released, and who may determine when the medical symptom has resolved in order to discontinue use of the restraint;
- The type of specific direct monitoring and supervision provided during the use of the restraint, including documentation of the monitoring;
- The identification of how the resident may request staff assistance and how needs will be met during use of the restraint, such as for re-positioning, hydration, meals, using the bathroom and hygiene;
- The resident's record includes ongoing re-evaluation for the need for a restraint and is effective in treating the medical symptom; and
- •The development and implementation of interventions to prevent and address any risks related to the use of the restraint (See also the Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 3.0, Chapter 3, Section P-Restraints for further guidance and 42 CFR §483.25(d) [F689] for concerns related to ensuring the resident receives adequate supervision to prevent accidents).

NOTE: Falls *generally* do not constitute self-injurious behavior or a medical symptom that warrants the use of a physical restraint. Although restraints have been traditionally used as a falls prevention approach, they have major, serious drawbacks and can contribute to serious injuries. There is no evidence that the use of physical restraints, including, but not limited to, bed rails and position change alarms, will prevent or reduce falls. Additionally, falls that occur while a person is physically restrained often result in more severe injuries (e.g., strangulation, entrapment).

The use of handcuffs, manacles, shackles, other chain-type restraint devices, or other restrictive devices are not considered safe, appropriate health care restraint interventions for use by a nursing home. This would not include arrests made onsite if a resident is taken into custody and is removed from the premises by law enforcement.

NOTE: For more information regarding requirements for providing services to justice-involved individuals in facilities, see also F550-Resident's Rights and S&C-16-21-https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-21.pdf).

Convenience and/or Discipline

A facility must not impose physical restraints for purposes of discipline or convenience [§§ 483.10(e)(1) and 483.12(a)(2)]. The facility is prohibited from obtaining permission from the

resident, or resident representative, for the use of restraints when the restraint is not necessary to treat the resident's medical symptoms. Anecdotally, it has been reported that staff will inform a resident, or the resident representative, that a restraint will be beneficial to the resident to prevent a fall or to safeguard the resident who may be wandering into other resident's rooms. However, in these instances, the surveyor should consider whether the restraint was used for the sake of staff convenience.

Reasons for using restraints for staff convenience or discipline may include:

- Staff state that a resident was placed in a restraint because staff are too busy to monitor the resident, and their workload includes too many residents to provide monitoring;
- •Staff believe that the resident does not exercise good judgment, including that he/she forgets about his/her physical limitations in standing, walking, or using the bathroom alone and will not wait for staff assistance;
- •Staff state that family have requested that the resident be restrained, as they are concerned about the resident falling especially during high activity times, such as during meals, when the staff are busy with other residents;
- Staff have identified to management that there is not enough staff on a particular shift or during the weekend and staffing levels were not changed;
- Staff state that new staff and/or temporary staff do not know the resident, how to approach, and/or how to address behavioral symptoms or care needs so they apply physical restraints;
- Lack of staff education regarding the alternatives to the use of restraints as a method for preventing falls and accidents;
- Staff have negative feelings or a lack of respect towards the resident, and restrain the resident to teach him/her a lesson;
- In response to a resident's wandering behavior, staff become frustrated and restrain a resident to a wheelchair; and
- When a resident is confused and becomes combative when care is provided and staff hold the resident's arms and legs down to complete the care (**NOTE**: This example differs from an emergency situation where staff briefly hold a resident for the sole purpose of providing necessary immediate medical care ordered by a practitioner).

Situations where a facility uses a physical restraint, or device acting as a physical restraint, that is not for treating a medical symptom, whether intentionally or unintentionally by staff, would indicate an action of discipline or convenience. An example that illustrates unintentional use of a physical restraint for staff convenience is when a staff member places a resident with limited mobility in a beanbag chair while other residents receive assistance during high activity times.

Determination of Use of Restraints for a Period of Imminent Danger to the Safety and Well-Being of the Resident

Some facilities have identified that a situation occurred in which the resident(s) is in "imminent danger" and there was fear for the safety and well-being of the resident(s) due to violent behavior, such as physically attacking others. In these situations, the order from the

practitioner and supporting documentation for the use of a restraint must be obtained either during the application of the restraint, or immediately after the restraint has been applied. The failure to immediately obtain an order is viewed as the application of restraint without an order and supporting documentation. Facilities may have a policy specifying who can initiate the application of restraint prior to obtaining an order from the practitioner.

If application of a restraint occurs, the facility must:

- Determine that a physical restraint is a measure of last resort to protect the safety of the resident or others:
- Provide ongoing direct monitoring and assessment of the resident's condition during use of the restraint;
- Provide assessment by the staff and practitioner to address other interventions that may address the symptoms or cause of the situation (e.g., identification of an infection process or delirium, presence of pain);
- Ensure that the resident and other residents are protected until the resident's behavioral symptoms have subsided, or until the resident is transferred to another setting;
- Discontinue the use of the restraint as soon as the imminent danger ends; and
- Immediately notify the resident representative of the symptoms and temporary intervention implemented.

Documentation must reflect what the resident was doing and what happened that presented the imminent danger, interventions that were attempted, response to those interventions, whether the resident was transferred to another setting for evaluation, whether the use of a physical restraint was ordered by the practitioner, and the medical symptom(s) and cause(s) that were identified.

Determination of Use of Bed Rails as a Restraint

Facilities must use a person-centered approach when determining the use of bed rails, which would include conducting a comprehensive assessment, and identifying the medical symptom being treated by using bed rails. Bed rails may have the effect of restraining one individual but not another, depending on the individual resident's conditions and circumstances. (See §483.25(n) - Bed Rails).

Residents who are cognitively impaired are at a higher risk of entrapment and injury or death caused by restraints. Residents in a bed with bed rails have attempted to exit through, between, under, over, or around bed rails or have attempted to crawl over the foot board, which places them at risk of serious injury or death. Serious injury from a fall is more likely from a bed with raised bed rails than from a bed where bed rails are not used. In many cases, the risk of using the bed rails may be greater than the risk of not using them as the risk of restraint-related injury and death is significant. For example, a resident who has no voluntary movement may still exhibit involuntary movements. Involuntary movements, resident weight, and gravity's effects may lead to the resident's body shifting toward the edge of the bed, increasing the risk for entrapment, when bed rails are used. Also refer to 42 CFR §483.25(n) – Bed Rails (tag F700).

The use of partial bed rails may assist an independent resident to enter and exit the bed independently and would not be considered a physical restraint. To determine if a bed rail is being used as a restraint, the resident must be able to easily and voluntarily get in and out of bed when the equipment is in use. If the resident cannot easily and voluntarily release the bed rails, the use of the bed rails may be considered a restraint.

Determination of the Use of Position Change Alarms as Restraints

Position change alarms are any physical or electronic device that monitors resident movement and alerts the staff when movement is detected. Types of position change alarms include chair and bed sensor pads, bedside alarmed mats, alarms clipped to a resident's clothing, seatbelt alarms, and infrared beam motion detectors. Position change alarms do not include alarms intended to monitor for unsafe wandering such as door or elevator alarms.

While position change alarms may be implemented to monitor a resident's movements, for some residents, the use of position change alarms that are audible to the resident(s) may have the unintended consequence of inhibiting freedom of movement. For example, a resident may be afraid to move to avoid setting off the alarm and creating noise that is a nuisance to the resident(s) and staff, or is embarrassing to the resident. For this resident, a position change alarm may have the potential effect of a physical restraint.

Examples of negative potential or actual outcomes which may result from the use of position change alarms as a physical restraint, include:

- •Loss of dignity;
- Decreased mobility;
- Bowel and bladder incontinence;
- Sleep disturbances due to the sound of the alarm or because the resident is afraid to move in bed thereby setting off the alarm; and
- •Confusion, fear, agitation, anxiety, or irritation in response to the sound of the alarm as residents may mistake the alarm as a warning or as something they need to get away from.

PROCEDURES §483.12 and (a)(2)-Physical Restraints

The process to review concerns are outlined in the Physical Restraints Critical Element Pathway (Form CMS-20077).

NOTE: A resident may have a device in place that the facility has stated can be removed by the resident. For safety reasons, do not request that the resident remove the restraint, but rather, request that staff ask the resident to demonstrate how he/she releases the device without staff providing specific instructions for the removal.

Use observations, interviews, and record review to gather and corroborate information related to:

• The use of the physical restraint, including whether the facility identified a device as a restraint, why it is used, how long it has been used, duration of use, alternatives attempted;

- What information was provided to the resident regarding the use of the restraint and whether the use of the restraint reflects the resident's preferences and choices;
- Whether the physical restraint is used for, or has the effect of, staff convenience or discipline; or
- Physical and psychosocial outcomes from the use of the restraint.

Use the Physical Restraints Critical Element (CE) Pathway, along with the above Guidance:

- When a resident's clinical record reflects the use of a physical restraint;
- If the survey team observes a position change alarm, or other device or practice that restricts or potentially restricts a resident's freedom of movement (physically or psychologically);
- If the resident or other individuals report that a restraint is being used on the resident; or
- If an allegation of inappropriate use of a physical restraint is received.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F604, the surveyor's investigation will generally show that the facility has failed, in one or more areas, to doanv one or more of the following:

- •Ensure that the resident is free from physical restraints imposed for discipline or staff convenience:
- Identify the medical symptom being treated when using a device or a facility practice that meets the definition of physical restraint;
- Define and implement interventions according to standards of practice during the use of a physical restraint that is used for treatment of a medical symptom;
- Provide the least restrictive restraint for the least time possible;
- Providing ongoing monitoring and evaluation for the continued use of a physical restraint to treat a medical symptom; or
- Develop and implement interventions for reducing or eventually discontinuing the use of the restraint when no longer required to treat a resident's medical symptoms.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

During the investigation, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include the following:

- •42 CFR §483.10, §483.10(a)(1)-(2), §483.10(b)(1)-(2), F550- Resident Rights and Dignity
- •42 CFR §483.10(c)(2)-(3), F553- Right to Participate Planning Care
- •42 CFR §483.21(b)(1), F656- Develop/Implement Comprehensive Care Plan
- •42 CFR §483.24, F675 Quality of Life
- •42 CFR §483.25(d), F689 Accidents
- •42 CFR §483.25(n)(1)-(4), F700- Special Care: Bedrails

- •42 CFR §483.35, 483.35(a), and §483.35(c)- F725 and F726 Sufficient and Competent Staff
- •42 CFR §483.40(b)-(b)(1), F742- Treatment/Svc for Mental/Psychosocial Concerns
- •42 CFR §483.70(h), F841-Responsibilities of Medical Director
- •42 CFR §483.75 (g)(2)(ii)- F867- QAA Activities

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include, but are not limited to:

- •The facility failed to identify the resident's medical symptom that warranted the use of a restraint. It was identified that a resident had repeated falls in his room usually after meals, when he attempted to transfer from his wheelchair to the bed. The clinical record documented that the resident repeatedly requested to be assisted to lie down after eating. Staff recorded that the belt restraint was being applied to prevent falls as he had fallen several times when attempting to stand up from the wheelchair after meals and lie down. Although the resident verbalized distress at being tied down in the wheelchair, staff stated they had informed the resident that they would put the resident in bed as soon as they finished taking care of the other residents in the dining room. It was documented that after staff left the room, the resident had attempted to stand up with the lap belt in place in the wheelchair, and as a result, the wheelchair tipped over and he sustained a fracture of his hand and had hit his head, resulting in hospitalization and treatment for multiple head and face lacerations and a subdural hematoma.
- •The facility failed to identify bed rails as a physical restraint, failed to assess the resident for use of a bed rail, and failed to ensure that the bed rails did not pose a risk of injury from falls. A moderately cognitively impaired resident was admitted to the facility who required extensive assistance with bed mobility and transfer, and was not ambulatory. The staff recorded on admission that the resident was at high risk for falls and as a result, placed full bed rails on all open sides of the bed. No assessment was conducted related to the use of bed rails, or the use of restraints. Documentation in the record revealed that the resident crawled to the foot of her bed while the full bed rails were in a raised position, attempted to stand and walk, and fell off the right side of the bed. The resident was hospitalized for surgical repair of a femoral neck fracture.

Examples of Severity Level 3 Noncompliance Actual Harm that is not Immediate Jeopardy include, but are not limited to:

•The facility failed to assure that a restraint was an intervention to treat a medical symptom and was not being used for staff convenience. Facility staff had placed a resident in a bean bag chair from which he could not rise. Based on staff interview, the resident was ambulatory, but had fallen in the past when attempting to stand up. The facility staff did not recognize that the bean bag was a physical restraint; thus, the staff

did not conduct any assessment to identify any medical symptoms that would necessitate a restraint. Staff stated that they placed the resident in the bean bag chair while caring for other residents. The resident reported being placed and left in the bean bag chair every day in the afternoon and was not able to stand to walk to his room orto activities. The resident said that he felt humiliated that he is not able to get out of the chair himself, when he wants to, especially since he enjoys talking with the other residents. The surveyor observed the resident struggling to get up, but was not able.

• The facility failed to assure that the use of a physical restraint was used to treat a resident's medical symptoms, and was not being used for staff convenience. A resident was admitted with a diagnosis of dementia, and had been hospitalized due to a head injury related to a fall at her home. The physician admission orders included an order for a lap belt to be used when the resident was up in the wheel chair; however, there was no identification of the medical symptom that necessitated the use of the lap belt. In a phone interview with the physician, he indicated that staff had requested the lap belt order due to the resident's falls. Based on observation, the resident sat in the day room in a wheel chair with the lap belt in place through the morning, from the breakfast service through the end of the noon meal. Staff did not provide repositioning, assistance with using the bathroom, or release of the lap belt for mobility. After lunch, the resident was transported to her room in the wheelchair with the lap belt in place; however, the lap belt was not removed and the resident remained in the same position through the afternoon without opportunities for repositioning, assistance with using the bathroom, or release of the lap belt for mobility. The resident was observed to be moving about restlessly, pulling at the lap belt, and calling out for help without staff response or intervention.

When staff prompted the resident to release the belt, the resident was not able. Observation of the resident's skin when put to bed after the PM shift arrived, revealed reddened areas on the coccyx, urine soaked incontinence product with visible skin maceration. Staff interviewed stated that the lap belt was being used as a falls prevention intervention. They stated, and the record corroborated that there had been a decline in the resident's mobility, and continence since admission.

Examples of Severity Level 2 Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to:

• The facility failed to assure that a physical restraint used for one resident was for the treatment of medical symptoms. Record review and observation revealed that the resident was alert and responded to her name, but was identified as mildly cognitively impaired and had fallen at home prior to her admission several weeks before. Observations revealed that a seat belt was used intermittently when the resident was in the wheelchair, but the resident had not attempted to rise, nor had attempted to remove the seatbelt. Staff stated that they thought the resident could release the seatbelt, although an assessment had not been completed regarding the use of the seatbelt. There was no documentation of an assessment for the use of the seat belt, whether the resident could release the seat belt

or of identification of medical symptoms that would require the use of the seat belt while in the wheelchair. The resident's record reflected no decline in functional status.

• The facility failed to ensure that the use of a concave mattress was being used in the treatment of medical symptoms and not for staff convenience. A resident, who could independently transfer self from bed to wheelchair and to bathroom, was observed to have a concave mattress. During resident interview, the resident stated that it was hard to get out of bed. The resident's record indicated no history of falls or injuries. During interview, the nurse assigned to the resident verified that the concave mattress was used to prevent the resident from exiting the bed independently. The resident's record did not include any information in the assessment, physician's orders, or care plan related to the concave mattress.

Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to assure residents are free from physical restraints not required to treat the resident's symptoms is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

¹ See CMS Minimum Data Set Resident Assessment Instrument Manual.