# Literature Review for SA201 Adjusting Instrument

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# Description of Medical Device

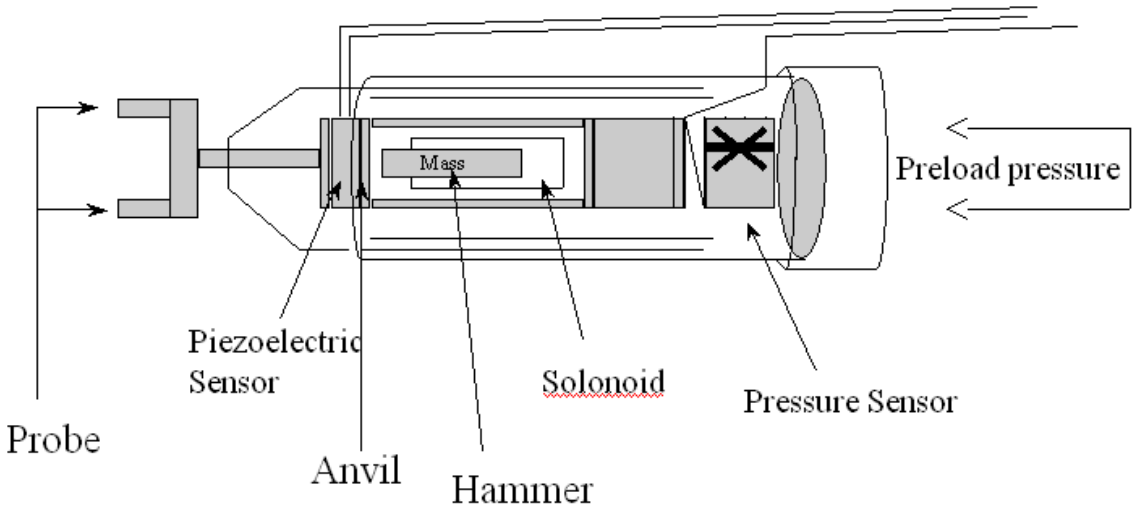
The SA201 is designed to measure joint mobility of the human vertebra and also simulate a chiropractic adjustment and/or joint mobilization through the use of a percussive force according to standard chiropractic techniques. It is intended for measurement and treatment of the human spine and extremities. The purpose in treatment is to deliver a controlled force to the treatment areas. The measurement function is designed to quantify the joint mobility commonly assessed by motion palpation. As of this writing the SA201 has been in service in the U.S. and Asia for 8 years with over 3000 doctors.

The above is accomplished via an electro-mechanical device connected to a data acquisition system with the results of both measurement and treatment displayed through a computer program.

In this literature review, we rely heavily on a product called the Activator. The design of the Activator as a treatment device is generally identical to the SA201 adjusting head listed below. Two significant differences are apparent:

1. The Activator is a manually driven device while the SA201 is electrically controlled.
2. The Activator device does not take into account any preload pressure so there is variability in how the force is transmitted to the patient.

These two major differences are seen as significant enhancements in reproducibility of treatment aspect of the instrument.



Activator Reference:

The reference below was taken from the activator website to provide historical background into the device.

"Evolved from 35 years of empirical study and 15 years of clinical research, the Activator Methods Chiropractic Technique (AMCT) uses the latest advances in orthopedic, neurological and chiropractic examinations to seek joint dysfunction in the spinal column and extremities for improved patient care. AMCT uses the Activator Adjusting Instrument to give consistent low-force, high-speed chiropractic adjustments. Over 35,000 doctors have been trained in AMCT and 2,100 doctors are Proficiency Rated, making AMCT the most widely used technique worldwide; a testament to low force patient satisfaction."

## Equivalency Statement:

The standard use of SOP 91-01 was used as a reference to establish equivalency of the literature. The description above shows that all of the relevant characteristics are the same. The differences are clearly noted and shown to be logical enhancements to the device that serve to remove more of the subjective variables inherent in the application of this type of measurement and treatment. The addition of the measurement portion while not a standard part of the activator has been used in several of the studies in a modified form of the activator that makes it identical in how it captures measurement information.

## Analysis of the data

Research in the area of physical medicine is difficult due to the nature of the application of various analysis and treatment methods. Chiropractic, Physical Therapy, and Osteopathic medicine have over 200 techniques designed to either reduce pain or create structural changes to the spine. These techniques are rooted in historical philosophies base on a trial and error method of typical "hands on" procedures. A common thread throughout these disciplines is the use of feeling or motion palpation as a means of identifying problem areas. Additionally, the use of a doctor or therapist's hands is also involved in types of treatment to induce joint mobility and/or facilitate structural changes to the body. It is these two areas that we are most interested. The review of the literature will be categorized as follows:

**Motion Palpation:**

The current state of the art and its shortcomings concluded with information on equivalent methods of the SA201 as a significant enhancement in providing a scientific basis for problem area in this area of medical practice.

**Treatment Effectiveness of SA201 type of Treatment including safety**

The literature is reviewed to the effective treatment and clinical studies and a review of the forces that are now used by hands on therapy and how this relates to the use of less force to achieve the same results thereby reducing the risk of current techniques.

**Measurement Validity**

A literature review of the state of the art methods of measuring forces and resultant outcomes.

**Motion Palpation Review**

The goal the SA201 system is to provide a means by which to assess joint mobility through the use a hand held device connected to a computer. The goal of this device is to reduce the number of subjective variable commonly used in the assessment of the human spine through the traditional use of motion palpation. These variables are the preload force, the force used to assess the mobility of the vertebral segment and the measurement itself. It is common knowledge that motion palpation is not a reliable method for assessing joint function. However, it is the current state of the art method used by doctors in the area of physical medicine.

In this section we reviewed the current body of literature associated with the motion palpation and listed the many shortcomings in this method of analysis as well as the notations of areas for improvement. Simmons noted that:

Inter-therapist variability was high, and there was a systematic bias in underestimating the magnitude of applied force and in overestimating motion. The variability in force application and the general overestimation of motion detection may explain the poor reliability of measurements obtained with clinical tests based on motion palpation. 1

Indicating that both motion palpation and force of mobilization forces are not known. The SA201 device removes the variability of the unknown force from the measurement.

Hawk et. Al. also indicates the need to devise a standard approach to this issue in his study on the reliability assessment of the human spine.

The results of this study, similar to those of other studies, indicate that even chiropractors trained in the same technique seem to show little consensus on the indications for the necessity to adjust specific segments of the spine. A more standardized assessment approach might be helpful in improving the reliability of diagnostic assessments. 2

The SA201 by removing subjective variables is designed to do exactly that.

To fully understand the issue facing the current state of the art, we have listed several more citations below that point to this existing problem within the area of physical medicine:

Schops stated that:

Chiropractic techniques are an essential part of every examination of the cervical spine. The clinical impact has not been scientifically established until up to now. Based on our findings and literature, we conclude that interexaminer reliability of manual diagnosis in the examination of the cervical spine should be improved by standardizing the examination process and setting guidelines for documentation and evaluation criteria. 3

While Hestbaek reiterated the need to develop reliable test procedures:

Palpation for muscle tension, palpation for misalignment, and visual inspection were either undocumented, unreliable, or not valid. The detection of the manipulative lesion in the lumbo-pelvic spine depends on valid and reliable tests. Because such tests have not been established, the presence of the manipulative lesion remains hypothetical. Great effort is needed to develop, establish, and enforce valid and reliable test procedures.4

And French Stated the problem of using motion palpation alone as a means of determining lesions:

This study of commonly used chiropractic diagnostic methods in patients with chronic mechanical low-back pain to detect manipulable lesions in the lower thoracic spine, lumbar spine, and the sacroiliac joints has revealed that the measures are not reproducible. The implementation of these examination techniques alone should not be seen by practitioners to provide reliable information concerning where to direct a manipulative procedure in patients with chronic mechanical low-back pain.5

Leboeuf goes further and states that:

Motion palpation does not appear to be a good method to differentiate persons with or without low back pain. It is possible to dissociate the findings of fixations and those of pain reactions.6

Again Marcotte describes the need to have a more reproducible system:

A greater reliability, arising from a high level of reproducibility, enables us to document the advantages of the standardization of motion palpation in chiropractic.7

Russell as far back as 1983 also indices that there should be a better method:

Spinal palpation as employed by practitioners of manipulative therapy is a common diagnostic tool used to identify manipulable lesions. Three methods of diagnostic palpation are static palpation, active motion palpation and passive motion palpation. As a diagnostic technique, spinal palpation suffers from a lack of research on its statistical reliability. Assessment of the clinical efficacy of manipulative therapy would be better addressed if a statistically reliable method of palpatory diagnosis were developed.8

Mootz also states that this is further complicated by increasing the inaccuracy between examiners:

Moderate test-retest agreement beyond chance was noted at L1/2, minimal reliability at L4/5, and no significant agreement within examiners was detected for mid-lumbar segments. Interexaminer agreement beyond chance was poor for all segments assessed. When segments were grouped regionally and re-evaluated, some increase in intrarater agreement was evident, especially at L4/5/S, but interrater agreement was still absent.9

The review of the above literature suggests the need for a standard technique that removes the human subjective variables inherent to motion palpation. Further in this review we will explore how the current state of the art by the most knowledgeable people in this area point to exactly the type of device we have developed.

## Measurement Validity

As stated above the problems associated with motion palpation are very pervasive. Additionally, manual treatment has the same problems. The following study used a mirror image of the SA201 to measure and determine forces and found that the forces used during a mobilization treatment are extremely variable. This is an important study because the construction of the study measures the forces of used by the doctor in the exact same way the SA201 measures the resultant force. Also it shows that the force is variable. The SA201 provides the same force controlled by a computer well below the maximum listed in this study in a controlled manner.

BACKGROUND AND PURPOSE. Despite the widespread use of spinal mobilization, little is known about the forces used or the accuracy of therapists in estimating the forces they use in administering the technique. The purposes of this study were to quantify the forces used and to determine the accuracy of therapists in applying forces on a mechanical model. SUBJECTS. Ten physical therapists participated. METHODS. A spinal model was used to measure applied force and displacement under different conditions of stiffness. The therapists applied oscillatory posteroanterior mobilizations to the model under three different conditions of stiffness. RESULTS. Mean peak forces across grades and stiffness levels ranged between 57.59 and 178.27 N. The forces were generally lower in the least stiff condition. Displacement varied with stiffness and mobilization grade. In the least stiff condition, the mean displacement varied between 2.25 and 3.45 mm for grades 1 to 4, respectively. CONCLUSION AND DISCUSSION. Inter-therapist variability was high, and there was a systematic bias in underestimating the magnitude of applied force and in overestimating motion. The variability in force application and the general overestimation of motion detection may explain the poor reliability of measurements obtained with clinical tests based on motion palpation.10

Following the above article this article explains the construction of the SA201 as well as it's inherent accuracy and application in a scientific testing environment.

OBJECTIVE: To determine the dynamic force-time and force-frequency characteristics of the Activator Adjusting Instrument and to validate its effectiveness as a mechanical impedance measurement device; in addition, to refine or optimize the force-frequency characteristics of the Activator Adjusting Instrument to provide enhanced dynamic structural measurement reliability and accuracy. METHODS: An idealized test structure consisting of a rectangular steel beam with a static stiffness similar to that of the human thoracolumbar spine was used for validation of a method to determine the dynamic mechanical response of the spine. The Activator Adjusting Instrument equipped with a load cell and accelerometer was used to measure forces and accelerations during mechanical excitation of the steel beam. Driving point and transfer mechanical impedance and resonant frequency of the beam were determined by use of a frequency spectrum analysis for different force settings, stylus masses, and stylus tips. Results were compared with beam theory and transfer impedance measurements obtained by use of a commercial electronic PCB impact hammer. RESULTS: The Activator Adjusting Instrument imparted a very complex dynamic impact comprising an initial high force (116 to 140 N), short duration pulse (<0.1 ms) followed by several lower force (30 to 100 N), longer duration impulses (1 to 5 ms). The force profile was highly reproducible in terms of the peak impulse forces delivered to the beam structure (<8% variance). Spectrum analysis of the Activator Adjusting Instrument impulse indicated that the Activator Adjusting Instrument has a variable force spectrum and delivers its peak energy at a frequency of 20 Hz. Added masses and different durometer stylus tips had very little influence on the Activator Adjusting Instrument force spectrum. The resonant frequency of the beam was accurately predicted by both the Activator Adjusting Instrument and electronic PCB impact hammer, but variations in the magnitude of the driving point impedance at the resonant frequency were high (67%) compared with the transfer impedance measurements obtained with the electronic PCB impact hammer, which had a more uniform force spectrum and was more repeatable (<10% variation). The addition of a preload-control frame to the Activator Adjusting Instrument improved the characteristics of the force frequency spectrum and repeatability of the driving point impedance measurements. CONCLUSION: These findings indicate that the Activator Adjusting Instrument combined with an integral load cell and accelerometer was able to obtain an accurate description of a steel beam with readily identifiable geometric and dynamic mechanical properties. These findings support the rationale for using the device to assess the dynamic mechanical behavior of the vertebral column. Such information would be useful for SMT and may ultimately be used to evaluate the [corrected] biomechanical effectiveness of various manipulative, surgical, and rehabilitative spinal procedures.11

Smith then reaffirms this notion in his interpretation of piezoelectric accelerometers:

The results suggest the possibility that, with further development, piezoelectric accelerometers can be a noninvasive tool to study dynamic, relative, bone movement.12

Keller then asserts that this construction works for measurements of the body essentially describing the SA201:

Calculations of the peak dynamic stiffness derived from impedance vs. frequency measurements indicate that the dynamic stiffness of the thoracolumbar spine is considerably greater than previously reported stiffness values obtained using static and quasistatic manipulation and mobilization procedures. Computations of spinal input impedance are relatively simple to perform, can provide a noninvasive measure of the dynamic mechanical behavior of the spine, appear to have potential to discriminate pathologic changes to the spine, and warrant further study on a larger sample of normals and patients. Ultimately, chiropractic clinicians may be able to use low force, impact type spinal manipulation, together with dynamic impedance analysis procedures, to quantify the mechanical response of the normal and abnormal spine, to perform spinal diagnosis and subsequently to prescribe therapeutic treatment to patients.13

From the above research Solinger reasons why based on this objective research why there are so many different subjective techniques:

This study indicates how both force (determining amplitude) and thrust speed or duration (determining frequencies excited) may enter in terms of optimizing the efficacy of chiropractic adjustments. If stimulation of specific spinal frequencies, say as central nervous input, were most essential, then many chiropractic thrusts could be clinically similar. This may explain how over 90 chiropractic techniques can co-exist.14

**Treatment Effectiveness of SA201 type of Treatment including safety**

The SA201 is used as treatment device as well. A review of the literature was done to as to the effectiveness of the treatment including the safety and effectiveness.

Does the percussion of instrument do anything? The following studies demonstrate the effectiveness in treatment:

Fuhr measured bone movement and an EMG response.

The impedance-head-equipped spring-loaded Activator chiropractic adjusting instrument had a low velocity when used on the patient and appeared to cause bone movement and a measurable EMG response.15

Kirstukas measured the amount of force during a normal manipulation showing that it exceeds that of the instrument. This indicates an inherent increased safety factor using the instrument.

In the application of the reinforced unilateral manipulative treatment, the physician establishes contact and applies a near-static preload force of 250 to 350 N. The dynamic portion of the typical thrust is preceded by a 22% decrease in force magnitude, and the peak thrust magnitude is linearly related to the preload force magnitude. We estimate that the peak contact pressure beneath the chiropractor's pisiform can exceed 1000 kPa, with the highest pressures transmitted over areas as small as 3.6 cm2, depending on manipulative style. CONCLUSIONS: This work represents the first attempt at performing simultaneous measurements of the physician-applied loading and table force response and measuring the contact pressure distribution at the physician-patient contact region during chiropractic manipulation. This type of work will lead to a better understanding of the relationship between the dynamic physician-applied normal forces and the resulting load response at the table and gives us additional outcome parameters to quantify manipulative technique.16

Kawchuk also lists the forces used in various techniques.

RESULTS: Outcome measures for each manipulative technique were as follows: LAT = normalized mean peak force of 102.2 N at 86.7 msec, GON = 109.8 N at 91.9 msec, ACT = 40.9 N at 31.8 msec, TOG = 117.6 N at 47.5 msec, ROT = 40.5 N at 79.1 msec. CONCLUSION: The observed differences and similarities in force profiles between the five techniques studied here may partly be the manifestation of how a particular technique delivers force to the cervical spine. The clinical significance of force profile characterization is not yet known.17

These conclusions are also supported by his previous study.

SMT to the cervical spine (toggle method) on three separate occasions over a 2-wk period. The clinical relevancy of the treatment was assessed via before and after measures of tissue compliance. MAIN OUTCOME MEASURE: a) Forces during manipulation: preload and peak forces. b) Duration of applied forces. RESULTS: a) Mean peak force = 117.7 N (+/- 15.6 N). b) Mean duration of force = 101.7 msec (+/- 14.7 msec).18

Keller researched the effectiveness of the activator instrument and found that while the force was lower than that of manual manipulations they were just as relevant:

CONCLUSIONS: In vivo kinematic measurements of the normal and pathologic human lumbar spine indicate that low force, PA impulses produce measurable segmental motions and reinforce the notion that mechanical processes play an important role in spinal manipulation and mobilization.19

Polkinghorn reported that using an instrument to adjust could benefit people who because of existing problems could not be treated with traditional manual treatment.

Conservative chiropractic treatment may provide an effective therapeutic intervention in selected cases of cervical disc protrusion. Instrument-delivered adjustments may provide benefit in cases in which manual manipulation causes an exacerbation of the symptoms or is contraindicated altogether.20

Polkinghorn again reported in 1999 that instrument adjusting being a more gentle method was comfortable tolerated by the patient.

Chiropractic coccygeal manipulation may be effectively delivered via instrumental adjustment in certain cases of coccygodynia. The use of an AAI II in administering the coccygeal adjustment has the benefit of being a gentle, noninvasive procedure, as well as being comfortably tolerated by the patient. This method of coccygeal adjustment may bear consideration in certain cases of coccygodynia.21

Polinghorn and Colloca also sited the added advantage of the reduction of torsional stress using an instrument to deliver the mobilization.

This report suggests that chiropractic treatment of lumbar disc disorders may be effectively implemented, in certain cases, via mechanical-force, manually assisted adjusting procedures using an AAI. We speculate that the use of an AAI, combined with Activator methods, may provide definitive benefits over side-posture manipulation of the lumbar spine in treatment of resistive disc lesions, because of the lack of torsional stress imposed upon the disc during instrumental spinal adjustment. Further study should be made in this regard to determine the safest and most effective method to treat lumbar disc lesions in a chiropractic setting.22

Wood found that cervical range of motion and pain reduction can be achieved by using either manual or instrument manipulation.

CONCLUSIONS: The results of this clinical trial indicate that both instrumental (MFMA) manipulation and manual (HVLA) manipulation have beneficial effects associated with reducing pain and disability and improving cervical range of motion in this patient population. A randomized, controlled clinical trial in a similar patient base with a larger sample size is necessary to verify the clinical relevance of these findings.23

Polkinghorn and Colloca found that instrument manipulation may be used in situations were manual manipulation are containdiacated:

Chiropractic treatment of postsurgical neck syndrome may be effectively treated, in certain cases, by mechanical force, manually assisted adjusting procedures with an AAI. The use of instrumental adjustment methodology may provide chiropractic physicians with an effective alternative to manual manipulation in those cases in which the patient's surgical history or presenting symptoms make forceful manipulation of the spine, particularly performed at end range, inappropriate. This approach may be contemplated by physicians faced with managing this type of condition.24

Keller found an increase in sEMG response to be significant indicating that altered muscle function may be an additional therapeutic effect of treatment with the instrument.

CONCLUSIONS: The results of this preliminary clinical trial demonstrated that MFMA SMT results in a significant increase in sEMG erector spinae isometric MVC muscle output. These findings indicate that altered muscle function may be a potential short-term therapeutic effect of MFMA SMT, and they form a basis for a randomized, controlled clinical trial to further investigate acute and long-term changes in low back function.25

Polkinghorn reported that low force mechanical manipulations may contain certain benefits that manipulations do not.

CONCLUSION: Chiropractic care may be able to provide an effective mode of therapeutic treatment for certain types of these difficult cases. Low force instrumental adjustments, in particular, may present certain benefits in these cases that the more forceful manipulations and/or mobilizations cannot.26

**Conclusion:**

The SA201 analysis and treatment instrument provides enhanced analysis over motion palpation, which the literature states is unreliable due to human errors. As a treatment protocol it is as effective as standard treatments and in many cases more safe due to the use of less force than other modalities. The volume of research in this area is relatively scant and more studies need to be done. However, based on the standard analysis and treatment approaches currently in use the SA201 provides a more reliable measurement and safer treatment than more common techniques on the market today.

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